UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended: December 31, 2024

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

Commission file number 001-35092

EXACT SCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**02-0478229**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
5505 Endeavor Lane, Madison, Wisconsin	**53719**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(608) 284-5700**

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

Common Stock, $0.01 Par Value	**EXAS**	**The Nasdaq Stock Market LLC**

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 report(s), 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post 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. (Check one):

Large accelerated filer ☒	Accelerated filer ☐	Non-accelerated filer ☐	Smaller reporting compan ☐	Emerging growth ☐
		(Do not check if a smaller reporting 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 the voting and non-voting common equity held by non-affiliates of the Registrant, as of the last business day of the Registrant's most recently completed second fiscal quarter was approximately $7,726,320,579 (based on the closing price of the Registrant's Common Stock on June 28, 2024 of $42.25 per share).

The number of shares outstanding of the Registrant's $0.01 par value Common Stock as of February 18, 2025 was 185,755,406.

DOCUMENT INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days after the end of the fiscal year ended December 31, 2024. Portions of such proxy statement are incorporated by reference into Part III of this Form 10-K.

EXACT SCIENCES CORPORATION
ANNUAL REPORT ON FORM 10-K
YEAR ENDED DECEMBER 31, 2024

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PART I

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are intended to be covered by the "safe harbor" created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies, and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "would," "could," "seek," "intend," "plan," "goal," "project," "estimate," "anticipate" or other comparable terms. All statements other than statements of historical facts included in this Annual Report on Form 10-K regarding our strategies, prospects, expectations, financial condition, operations, costs, plans, and objectives are forward-looking statements. Examples of forward-looking statements include, among others, statements we make regarding expected future operating results; expectations for development or launching of new or improved products, and services and their impact on patients; insurance reimbursement potential; our strategies, commercialization efforts, positioning, competition, resources, capabilities, and expectations for future events or performance; and the anticipated benefits of our acquisitions, including estimated synergies and other financial impacts. Forward-looking statements are neither historical facts nor assurances of future performance or events. Instead, they are based only on current beliefs, expectations, and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy, and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Actual results, conditions, and events may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause actual results, conditions, and events to differ materially from those indicated in the forward-looking statements include, among others, the following: our ability to successfully develop and commercialize new products and services and assess potential market opportunities; our ability to successfully and profitably market our products and services; the acceptance of our products and services by patients and healthcare providers; our reliance upon certain suppliers; our ability to retain and hire key personnel; approval and maintenance of adequate reimbursement rates for our products and services within and outside of the U.S.; the amount and nature of competition for our products and services; the effects of any judicial, executive or legislative action affecting us or the healthcare system; changes in government policies, laws, regulations, and staffing; recommendations, guidelines and quality metrics issued by various organizations regarding cancer screening or our products and services; our ability to obtain and maintain regulatory approvals and comply with applicable regulations; our ability to protect and enforce our intellectual property; our success establishing and maintaining collaborative, licensing and supplier arrangements; the results of our validation studies and clinical trials, including the risks that the results of future studies and trials may differ materially from the results of previously completed studies and trials; our ability to manage an international business and our expectations regarding our international expansion and opportunities; the potential effects of changing macroeconomic conditions and geopolitical conflict; the possibility that the anticipated benefits from our business acquisitions will not be realized in full or at all or may take longer to realize than expected; the outcome of any potential litigation or legal proceeding; and our ability to raise the capital necessary to support our operations or meet our payment obligations under our indebtedness. The risks included above are not exhaustive. Other important risks and uncertainties are described in the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections in this Annual Report on Form 10-K and our subsequently filed Quarterly Reports on Form 10-Q. You are further cautioned not to place undue reliance upon any such forward-looking statements, which speak only as of the date made. Except as otherwise required by the federal securities laws, we undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Item 1. Business

Overview

A leading provider of cancer screening and diagnostic tests, Exact Sciences Corporation (together with its subsidiaries, "Exact," "we," "us," "our" or the "Company") gives patients and health care professionals the clarity needed to take life-changing action earlier. Building on the success of the Cologuard® and Oncotype DX® tests, we are investing in our pipeline to develop innovative solutions for use before, during, and after a cancer diagnosis.

During 2024, we achieved many milestones, including:

- delivering more than 4.6 million results to patients with our portfolio of cancer tests,
- being recognized as a Great Place to Work for the sixth consecutive year,
- growing revenue 10% while controllable operating expenses grew just 3%,
- generating cash provided by operating activities of $210.5 million for the year ended December 31, 2024, an improvement of $54.4 million, respectively, compared to the year ended December 31, 2023,
- securing United States ("U.S.") Food and Drug Administration ("FDA") approval and Medicare pricing for Cologuard Plus™, our next-generation colon cancer screening test,
- completing two studies for Oncodetect™, our molecular residual disease test ("MRD"), and
- generating evidence for our liquid biopsy colon cancer screening test as well as our multi-cancer screening test ("MCED"), Cancerguard™.

Our Products and Services

With a leading portfolio of products for earlier cancer detection and treatment guidance, we provide patients with earlier, smarter answers. Our current products and services focus on screening and precision oncology tests.

Our Screening Tests

Cologuard Test

Our flagship screening product, the Cologuard test, is a patient-friendly, non-invasive, stool-based DNA ("sDNA") screening test that utilizes a multi-target approach to detect DNA and hemoglobin biomarkers associated with colorectal cancer and pre-cancer. Eleven biomarkers are targeted that have been shown to be strongly associated with colorectal cancer and pre-cancer. Methylation, mutation, and hemoglobin results are combined in the laboratory analysis through a proprietary algorithm to provide a single positive or negative reportable result.

We believe the large, underserved population of unscreened and inadequately screened patients represents a significant opportunity for our Cologuard test. It is widely accepted that colorectal cancer is among the most preventable, yet least prevented cancers. Colorectal cancer can take up to 10-15 years to progress from a pre-cancerous lesion to metastatic cancer and death. Patients who are diagnosed early in the progression of the disease — with pre-cancerous lesions or early-stage cancer — are more likely to have a complete recovery and to be treated less expensively. Colorectal cancer is the second leading cause of cancer deaths in the U.S. and the leading cause of cancer deaths in the U.S. among non-smokers. Each year in the U.S. there are approximately 154,000 new cases of colorectal cancer and approximately 53,000 deaths.

Upon approval by the FDA in August 2014, our Cologuard test became the first and only FDA-approved sDNA non-invasive colorectal cancer screening test. Our Cologuard test is now indicated for average risk adults 45 years of age and older.

Our peer-reviewed study, "Multitarget Stool DNA Testing for Colorectal-Cancer Screening," published in the New England Journal of Medicine in April 2014, highlighted the performance of the Cologuard test in its 10,000 patient Deep-C clinical trial:

- Cancer Sensitivity: 92%
- Stage I and II Cancer Sensitivity: 94%

- High-Grade Dysplasia Sensitivity: 69%
- Specificity: 87%

We believe the competitive advantages of sDNA screening provide a significant market opportunity. There are nearly 110 million Americans between the ages of 45 and 85 who are at average risk for colorectal cancer. At a three-year screening interval and an average revenue per test of approximately $500, this represents a potential $18 billion market for our Cologuard test.

More than 40% of Americans between the ages of 45 and 85 who are at average risk for colorectal cancer are not up-to-date with screening according to the American Cancer Society's ("ACS") colorectal cancer screening guidelines. We believe our Cologuard test helps more people get screened for colorectal cancer. Internal studies have shown that approximately 40% of surveyed Cologuard users were previously unscreened for colorectal cancer.

Our Cologuard test is included in key guidelines and quality measures that many healthcare providers rely on when making screening recommendations.

- In its updated guidelines released in May 2021, the U.S. Preventive Services Task Force ("USPSTF") gave an "A" grade to colorectal cancer screening starting at age 50 and continuing until age 75 and a "B" grade to colorectal cancer screening for ages 45 to 49. The updated guidelines include our Cologuard test (referred to in their statement as sDNA-FIT) as a recommended screening method for all average-risk patients in the 45-75 age group.
- The ACS has specifically included our Cologuard test as a recommended colorectal cancer screening test in average-risk, asymptomatic individuals. The ACS recommends colorectal cancer screening beginning at age 45 for people at average risk of colorectal cancer.
- The National Comprehensive Cancer Network ("NCCN") includes sDNA screening at a once-every-three-years interval in its Colorectal Cancer Screening Guidelines.
- The National Committee for Quality Assurance ("NCQA") includes sDNA testing on a three-year interval as one of the methods permitted for colorectal cancer screening in its most recent Healthcare Effectiveness Data and Information Set ("HEDIS") quality measures.
- The Centers for Medicare & Medicaid Services ("CMS") includes our Cologuard test in its most recent Medicare Advantage Star Ratings program.

Genetic Testing

We have an extensive menu of predefined genetic tests for nearly all clinically relevant genes, additional custom panels, and comprehensive germline, whole exome ("PGxome®"), and whole genome ("PGnome®") sequencing tests.

Our Precision Oncology Tests

Our precision oncology portfolio delivers actionable genomic insights to inform prognosis and cancer treatment after a diagnosis. We enable patients to take a more active role in their cancer care and make it easy for providers to order tests, interpret results, and personalize medicine by applying real-world evidence and guideline recommendations.

Oncotype DX Breast Recurrence Score® Test

Our Oncotype DX Breast Recurrence Score test has been demonstrated to identify patients who are most likely to benefit from chemotherapy as well as those who may receive no clinical benefit from chemotherapy.

Among women, breast cancer is the most commonly diagnosed cancer and the leading cause of cancer death. In 2025, nearly 317,000 women are expected to be diagnosed with invasive breast cancer in the U.S. according to ACS, and nearly 59,000 women are expected to be diagnosed with non-invasive (in situ) breast cancer. Worldwide, it is estimated that there are approximately 2.3 million newly diagnosed cases of breast cancer each year.

The Oncotype DX Breast Recurrence Score test examines the activity of 21 genes in a patient's breast tumor tissue to provide personalized information for tailoring treatment based on the biology of the patient's individual disease. The test is supported by multiple rigorous clinical validation studies, including the landmark TAILORx and RxPONDER studies, confirming the test's ability to predict the likelihood of chemotherapy benefit as well as the chance of cancer recurrence in the most common sub-type of early-stage breast cancer.

As the only test proven to predict both the likelihood of chemotherapy benefit and cancer recurrence, the Oncotype DX Breast Recurrence Score test is recognized globally as standard of care and is included in all major breast cancer treatment guidelines.

Oncotype DX Breast DCIS Score® Test

Our Oncotype DX Breast DCIS Score test provides ductal carcinoma in situ ("DCIS") patients an individualized prediction of the 10-year risk of local recurrence (DCIS or invasive carcinoma), represented by a DCIS Score® result. This test helps guide treatment decision-making in women with DCIS treated by local excision, with or without tamoxifen. Development of our Oncotype DX Breast DCIS Score test was based on published results for the Oncotype DX Breast Recurrence Score test that showed similarity in the expression profiles of genes between DCIS and invasive breast cancer when both are present within the same patient tumor.

Oncotype DX Colon Recurrence Score® Test

In patients with stage II and stage III colon cancer, the decision to treat with chemotherapy following surgery is based on an assessment of the likelihood of cancer recurrence and, as a result, it is critical for clinicians to accurately assess a patient's risk of recurrence. Our Oncotype DX Colon Recurrence Score test is a multi-gene test for predicting recurrence risk in patients with stage II and stage III A/B colon cancer to enable an individualized approach to treatment planning. By evaluating specific genes within a patient's colon tumor, the test can determine the likelihood that the cancer cells will spread and cause the disease to return after surgery. Based on this information, healthcare providers and patients can make more informed treatment decisions. The Oncotype DX Colon Recurrence Score test is supported by three rigorous clinical validation studies confirming the test's ability to provide additional and independent value beyond the currently used measures for determining colon cancer recurrence risk.

OncoExTra® Test

In April 2021, we began performing and selling the OncoExTra test, previously known as GEM ExTra, as a result of our acquisition of Ashion Analytics, LLC ("Ashion"). The OncoExTra test applies comprehensive tumor profiling, utilizing whole exome and whole transcriptome sequencing, to aid in therapy selection for patients with advanced, metastatic, refractory, relapsed, or recurrent cancer. With an extensive panel of approximately 20,000 genes and 169 introns, the OncoExTra test is one of the most comprehensive genomic (DNA) and transcriptomic (RNA) panels available today.

Riskguard® Test

Riskguard, our hereditary cancer test, helps people understand their inherited risk of cancer, arming them with critical information to make more informed treatment decisions.

COVID-19 Testing Business

We discontinued our COVID-19 testing operations in the second quarter of 2023. From March 2020 through June 2023, we partnered with various customers, including the State of Wisconsin Department of Health Services, to administer testing. Customers were responsible for employing trained personnel to collect specimens. Specimens were sent to our laboratory in Madison, Wisconsin, where we ran the assay in our laboratories and provided test results to ordering providers.

Upcoming Test Launches

We are preparing to launch three new tests in 2025 across the largest patient impact opportunities in cancer diagnostics.

- *Cologuard Plus* - The Cologuard Plus test, which features novel biomarkers, improved laboratory processes, and enhanced sample stability, detects colorectal cancers and precancerous polyps with even greater sensitivity than our Cologuard test while reducing false positives by nearly 40%. Results from the pivotal BLUE-C study published in the New England Journal of Medicine in March 2024 showed 95% overall cancer sensitivity and 43% sensitivity for advanced precancerous lesions at 94% specificity when age-weighted to the U.S. population with no findings on colonoscopy. In October 2024, the FDA approved our Cologuard Plus test for adults ages 45 and older of average risk for colorectal cancer. We expect to launch our Cologuard Plus test with Medicare coverage and guideline inclusion in the second quarter of 2025.

- *Oncodetect* - Our tumor-informed Oncodetect MRD test is designed to detect small amounts of tumor DNA that may remain in patients' blood after they have undergone initial treatment. This test is expected to help patients and oncologists understand the success of initial treatment, guide further treatment, and monitor for cancer recurrence. Results from the Alpha-CORRECT study, which primarily included patients with stage III colorectal cancer, showed our Oncodetect test achieved 78% sensitivity at the post-surgical timepoint and 91% sensitivity during the surveillance monitoring period, with specificities of 80% and 94%, respectively. In January 2025, complete findings from Alpha-CORRECT were published in the Journal of Surgical Oncology. Results from our Beta-CORRECT study, which we expect to present at an upcoming scientific conference, confirm a significant association between MRD positivity and recurrence in patients with stages II through IV colorectal cancer. Based on results from these two studies, we expect to launch the test as a laboratory developed test ("LDT") with Medicare reimbursement through the Molecular Diagnostic Services Program ("MolDX") in the second quarter of 2025.

- *Cancerguard* - Our Cancerguard test is designed to detect multiple cancers in their earliest stages from a single blood draw. Building on decades of research with Mayo Foundation for Medical Education and Research ("Mayo") and The Johns Hopkins University ("JHU"), the Cancerguard test combines multiple biomarker classes for earlier cancer detection, provides high specificity to help minimize false positives, and utilizes a streamlined imaging-based diagnostic pathway to reduce follow-up procedures. In November 2024, results from the a multi-center, prospective, case-control ASCEND-2 study showed 60% overall sensitivity at 98.5% specificity when excluding cancer organ types with average-risk standard of care screening, and 67% overall sensitivity for the six most aggressive cancer organ types with the shortest 5-year survival rate. We expect to launch the test as an LDT in the second half of 2025.

Pipeline Research and Development

We are continuing to advance our pipeline of future screening and diagnostic products, including risk assessment, screening and prevention, early disease diagnosis, adjuvant and/or neoadjuvant disease treatment, metastatic disease treatment selection, and recurrence monitoring.

Through our collaboration with Mayo, we have successfully performed feasibility studies involving multiple types of cancer using tissue, blood, and other sample types. Our research and development programs are also powered by technologies we have exclusively licensed from JHU, Broad Institute, Inc. ("Broad Institute"), Oxford University, the Ludwig Institute for Cancer Research, and TwinStrand Biosciences, Inc. ("TwinStrand").

We are focusing our research and development efforts on three main areas:

- *Colorectal Cancer Screening Test Development*. Beyond Cologuard Plus, we are working to develop a blood-based screening test for colorectal cancer. In September 2024, we presented performance data for our blood-based colorectal cancer screening test at the ESMO Congress, showing sensitivities of 88% for colorectal cancer and 31% for advanced precancerous lesions at specificity of 90% for negative samples confirmed by colonoscopy. BLUE-C pivotal study results for our blood-based colorectal cancer screening test are expected in the middle of 2025 and performance degradation is expected for advanced precancerous lesion sensitivity and overall CRC sensitivity.

- *MRD Test Development.* In addition to the evidence supporting Oncodetect in colorectal cancer, we plan to validate our Oncodetect test in breast cancer and, subsequently, in multiple other solid tumor types. We also expect to enhance our MRD test by leveraging the Broad Institute's Minor Allele Enriched Sequencing Through Recognition Oligonucleotides ("MAESTRO") diagnostic testing technology, which we secured exclusive rights to in June 2023 through a sponsored research and license agreement. We are currently developing the MAESTRO platform and expect to analytically validate this technology in 2025.

- *MCED Test Development.* In July 2024, our Cancerguard test was approved as an Investigational Device Exemption by the FDA to be used within a real-world evidence study, providing an opportunity to test 25,000 people over the next three years. The first patient was enrolled within this study at Baylor Scott & White, the primary study site, in August 2024. In the future, we plan to begin recruiting patients for the FDA registrational Study of All comeRs ("SOAR") trial, which we expect to be one of the largest prospective, interventional multi-cancer screening trial ever conducted in the U.S.

Research and development, which includes our clinical study programs, accounts for a material portion of our operating expenses. As we seek to enhance our product portfolio and advance our pipeline, we expect that our research and development expenditures will continue to be a significant portion of our operating expenditures.

Commercial Operations

Our commercial functions include specific teams focused on screening, precision oncology, and international markets.

Cologuard Test Commercial Operations

We promote our Cologuard test through a national and market-based model comprised of our health systems, payers, primary care, market development, and inside sales team members.

Our sales team actively engages with healthcare providers and payers to emphasize the need for colorectal cancer screening, educate them on the value of our Cologuard test, and facilitate their ability to order the test. We focus on specific healthcare providers and payers based on a combination of Cologuard order history and ordering potential data. We also focus on healthcare provider groups and larger regional and national health systems through large, organized screening programs.

A critical part of the value proposition of our Cologuard test is its adherence program, which involves active engagement with patients and providers by our adherence team. This customer-oriented support activity is focused on encouraging and helping patients complete Cologuard tests that have been ordered for them by their providers. We undertake a variety of health care activities to promote patient adherence including letters, text messages, online chat, emails, phone calls, and other direct-to-consumer digital efforts.

We have undertaken a significant marketing public relations effort to engage prospective patients in the U.S., including through the launch of targeted, direct-to-consumer advertising campaigns across national television, digital, social media, print, and audio channels. During 2024, we continued to deepen our investment in large, organized screening programs to further solidify our Cologuard test as a solution for patients who infrequently visit their health care provider.

Precision Oncology Commercial Operations

We promote our precision oncology tests through our precision oncology sales force. Our commercial infrastructure, including our sales force, managed care group, and patient support network, is critical to the success of our precision oncology products. In our domestic sales, marketing, and reimbursement efforts, we interact directly with medical, radiation, and surgical oncologists, pathologists, and payers. We employ a direct sales approach that targets oncologists and cancer surgeons. We also plan to continue to utilize data from our clinical studies published in peer-reviewed journals to demonstrate the clinical value of our precision oncology products. We believe the combination of these approaches is our best means to increase patient and healthcare provider awareness of our precision oncology products and services and the number of favorable reimbursement coverage decisions by third-party payers.

International Commercial Operations

We commercialize or plan to commercialize our Oncotype® tests internationally through employees in Canada, Japan, and a number of European countries, as well as through exclusive distribution agreements. We have provided our Oncotype tests in approximately 120 countries outside of the U.S. We do not offer our Cologuard test, Cancerguard test, or Oncodetect test outside of the U.S. We are exploring opportunities to make these tests and other future products available outside of the U.S.

Inclusion of our products in guidelines and quality measures will be critical to our international success. The Oncotype DX breast cancer test is recognized in international guidelines issued by the St. Gallen International Breast Cancer Expert Panel and European Society for Medical Oncology. Our Oncotype DX breast cancer test has been recommended to guide certain patients' chemotherapy treatment decisions by the National Institute for Health and Care Excellence in England, the Gynecologic Oncology Working Group in Germany, and the Japan Breast Cancer Society. Our Oncotype DX breast cancer test is reimbursed for certain patients in the public health systems in more than ten countries.

We are exploring opportunities to establish local laboratories in certain locations outside of the U.S. and established local testing capacity in Germany beginning in late 2021. Certain countries have severe restrictions on reimbursing tests performed abroad or exporting tissue samples or patient health data. These restrictions limit our ability to offer our tests in those countries without local laboratories or a method of test delivery that does not require samples to be transported to our U.S. laboratory.

Reimbursement for our Tests

Reimbursement for our Cologuard Test

Our Cologuard test has broad reimbursement coverage from Medicare and commercial payers. Updated USPSTF colorectal cancer screening guidelines mandate coverage of our Cologuard test beginning at age 45 for ACA covered health plans. Medicare Part B covers our Cologuard test once every three years for beneficiaries who are age 45 to 85, asymptomatic and at average risk for developing colorectal cancer.

The following laws and regulations establish coverage requirements relevant to our Cologuard test.

- Section 2713 of the Patient Protection and Affordable Care Act ("ACA") mandates that certain health insurers cover, without imposing any patient cost-sharing, evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of USPSTF ("ACA Mandate"), which includes follow-up colonoscopy after a positive non-invasive stool-based screening test be covered without cost sharing.
- Federal regulations require that Medicare Advantage plans cover "A" or "B" rated preventive services without patient cost-sharing, and CMS has issued a notice affirming that Medicare Advantage plans must include coverage of our Cologuard test every three years without patient cost-sharing including coverage of a follow-up colonoscopy after a positive non-invasive stool-based screening test effective January 1, 2023. Additional Part B cost sharing for procedures performed in addition to follow-on colonoscopy (e.g. polyp removal or pathology) will be phased out by 2030.
- We believe that most states' laws mandate coverage of our Cologuard test by certain health insurance plans.

Most commercial payers have issued positive coverage decisions for our Cologuard test, and we have negotiated contracts with most payers to include our Cologuard test as an in-network service. In-network agreements with payers have varying terms and conditions, including reimbursement rate, term, and termination. Other payers may perform post-payment reviews or audits, which may lead to payment recoupments.

State Medicaid agencies generally assign a reimbursement rate for our Cologuard test equal to or less than the prevailing Medicare rate, often determined by state law as a percentage of the Medicare reimbursement rate.

In November 2024 our Cologuard Plus test, which we expect to launch in 2025, received a payment rate on the Clinical Lab Fee Schedule, which applies to Medicare Part B claims, that was effective January 1, 2025. This rate is higher than the Medicare rate for the Cologuard test. Commercial payers will need to issue positive coverage decisions for the Cologuard Plus test and we will negotiate amendments to our existing network agreements with those payers to add the Cologuard Plus test.

Reimbursement for our Precision Oncology Tests

We depend on government insurance plans, managed care organizations, and commercial insurance plans for reimbursement of our precision oncology tests.

Medicare coverage for our precision oncology tests is currently subject to the discretion of the local Medicare Administrative Contractors ("MAC"). Palmetto, the MAC that establishes the coverage and coding policies for most of our tests under Medicare, developed the MolDX, to identify and establish Medicare coverage for molecular diagnostic tests that fall within the scope of its Molecular Diagnostic Test local coverage decision ("LCD"). To obtain coverage under the MolDX program, developers of molecular diagnostic tests must submit a detailed dossier of analytical and clinical data to substantiate that a test meets Medicare's requirements for coverage. We have received positive coverage decisions under the MolDX program for our breast, colon, Riskguard, and OncoExTra tests.

Reimbursement of our precision oncology tests by third-party payers is essential to our commercial success. Where there is a payer policy, contract or agreement in place, we bill the third-party payer, the hospital or referring laboratory and/or the patient (for deductibles and coinsurance or co-payments, where applicable) in accordance with established policy, contract or

agreement terms. Some payers may apply various medical management requirements, including a requirement that they give prior authorization for a precision oncology test before they are willing to pay for it. Where there is no payer policy in place, we pursue third-party reimbursement on behalf of each patient on a case-by-case basis. Our efforts on behalf of these patients involve a substantial amount of time and expense, and bills may not be paid for many months, if at all. Furthermore, if a third-party payer denies coverage after final appeal, it may take a substantial amount of time to collect from the patient, if we are able to collect at all.

State Medicaid agencies generally assign a reimbursement rate for our precision oncology tests equal to or less than the prevailing Medicare rate, often determined by state law as a percentage of the Medicare reimbursement rate.

International Reimbursement

In many countries, public healthcare systems are primarily responsible for financing and establishing reimbursement for diagnostic tests. The majority of our international precision oncology revenues come from reimbursement (directly or indirectly), payments from our distributors, and patient self-pay. We have obtained coverage or other public financing for our Oncotype DX breast cancer test outside of the U.S., including coverage for certain patients in more than ten countries.

We expect that our international sales will be heavily dependent on the availability of reimbursement, and broadening coverage and reimbursement for our precision oncology tests and other tests outside of the United States will take years.

Reimbursement for Future Products

Successful commercialization of our newly developed products, including our Oncodetect and our Cancerguard tests, will also depend on our ability to obtain and maintain reimbursement at adequate reimbursement rates from government insurance plans, managed care organizations, commercial insurance plans, and public healthcare systems outside the U.S. for such products.

Our Clinical Laboratory and Manufacturing Facilities

We process our Cologuard test at two state-of-the-art, high-throughput clinical laboratories in Madison, Wisconsin that are certified pursuant to federal Clinical Laboratory Improvement Amendments ("CLIA") and accredited by College of American Pathologist ("CAP"). Our total lab capacity at both facilities is approximately seven million Cologuard tests per year, with the opportunity to add additional capacity, if needed.

We currently manufacture our Cologuard and Cologuard Plus tests at our facilities in Madison, Wisconsin. We are committed to manufacturing and providing medical devices and related products that meet customer expectations and applicable regulatory requirements. We adhere to manufacturing and safety standards required by federal, state, and local laws and regulations and operate our manufacturing facilities under a quality management system. We purchase certain components for our Cologuard and Cologuard Plus tests from third-party suppliers and manufacturers.

A majority of our internally developed Oncotype tests for domestic and international patients are currently processed in our CLIA-certified and CAP-accredited clinical reference laboratory facilities in Redwood City, California. Beginning in 2022, Oncotype DX breast cancer tests for German patients have been processed in our newly constructed facility in Trier, Germany, a portion of which is operated by a third-party partner. Our OncoExTra tests, along with tests completed under certain of our reference lab agreements, are processed in our CLIA-certified and CAP-accredited clinical reference laboratory facilities in Phoenix, Arizona.

We process our predefined genetic tests for nearly all clinically relevant genes, additional custom panels, and comprehensive germline whole exome and whole genome sequencing tests in addition to our hereditary cancer test, Riskguard at our CLIA-certified and CAP-accredited DNA testing laboratory in Marshfield, Wisconsin.

We believe that we currently have sufficient capacity to process all of our tests for at least the next 12 months. We are in the process of expanding our existing facilities to prepare for the expected future growth in our operations.

Competition

We operate in a rapidly evolving and highly competitive industry. There are a number of private and public companies that offer products or have announced that they are developing products that compete with ours. We expect additional competition as other established and emerging companies introduce new tests and technologies. Certain of these companies have or may be acquired by, or enter into commercial partnerships with, larger companies with greater expertise, resources or brand recognition, which may increase their ability to offer or develop products that compete with ours.

We believe the principal competitive factors for our current and in-development products include the following:

- test performance, as demonstrated in clinical and analytical studies as well as in commercial and real-world experience;
- scope and extent of reimbursement and payer coverage;
- ease of use, including user experience for both patients and providers;
- value of product offerings, including pricing and impact on other healthcare spending;
- effectiveness of sales and marketing efforts and brand awareness;
- breadth of distribution of products and partnership base;
- reputation among patients and providers for development and introduction of new, innovative products;
- operational execution, including test turn-around time and test failures; and
- key opinion leader support, including endorsement in influential clinical guidelines.

We believe that the success of our products depends on our ability to differentiate ourselves, including through continued investment in product enhancements and new technologies, and to demonstrate that our products deliver the clinical and operational attributes that are most important to hospitals, clinics, group purchasing organizations, physicians, and patients.

Screening Competition

The U.S. opportunity for colorectal cancer screening is large, consisting of nearly 110 million eligible individuals between the ages of 45 and 85, and has attracted numerous competitors. Our Cologuard and Cologuard Plus tests face competition from procedure-based detection technologies such as colonoscopy, flexible sigmoidoscopy, "virtual" colonoscopy—a radiological imaging approach that visualizes the inside of the bowel by CT scan (spiral computerized axial tomography)—as well as other stool-based colorectal cancer tests (including the fecal occult blood test, the fecal immunochemical test ("FIT")), capsule endoscopy, and liquid biopsy tests.

In the past year, Geneoscopy, Inc. ("Geneoscopy") received FDA approval for its ColoSense stool-based test which will compete directly with our Cologuard tests in the United States. We are aware of at least two other companies (Mainz Biomed and Prescient Metabiomics) who are developing stool-based colorectal cancer screening tests.

We are also aware of many companies including Guardant Health, Inc. ("Guardant"), Freenome, Inc., GRAIL, Inc., and Natera Inc. ("Natera"), that have developed or are developing blood-based colorectal cancer screening tests. Guardant Health recently received FDA approval and Medicare coverage of its blood-based test (Shield). Collectively, these tests could represent significant competition for our current tests, our own in-development blood-based colorectal cancer screening test, and other tests we may develop in the future. Our competitors may also be developing additional methods of detecting colorectal cancer and pre-cancer that have not yet been announced.

We are also entering the MCED market with our Cancerguard test. We are aware of other companies with MCED products either commercially available or in development that will compete directly with our Cancerguard test. These companies include GRAIL, Inc., Guardant Health, Inc., and Freenome, Inc.

The genetic testing market is highly competitive, and we expect this competition to intensify in the future as our competitors consolidate and new competitors emerge. We face competition from a variety of sources, including Ambry Genetics (now owned by Tempus AI); Myriad Genetics, Inc.; Natera; Color Health, Inc.; GeneDx; Illumina; Variantyx; 3billion; a few large, established general testing companies such as Laboratory Corporation of America Holdings (LabCorp) and Quest Diagnostics Incorporated; and clinical laboratories in an academic or healthcare provider setting that perform clinical genetic testing on behalf of their affiliated institutions.

Precision Oncology Competition

Our precision oncology products compete against a number of companies that are developing or commercializing products to profile genes and gene expression in breast and colon cancer. These companies include Agendia Inc., Veracyte, Inc., Myriad Genetics, Inc., and Hologic, Inc.

There are multiple companies who have therapy selection products (either tissue-based or blood-based) which compete with the OncoExTra test and our in-development Oncoliquid™ test including Tempus AI, Caris Life Sciences, NeoGenomics, Myriad Genetics, Inc., and Delfi. With respect to our MRD test in development, each of Natera, Tempus AI, Guardant, NeoGenomics, Myriad Genetics, Inc., Quest Diagnostics, and Personalis have commercially available competitive MRD tests or have such tests in development. Historically, our principal competition for our precision oncology tests has also come from existing diagnostic methods used by pathologists and oncologists. Advances in digital pathology and artificial intelligence have the potential to replace or complement these entrenched methods and may offer value comparable to our molecular tests. Other potential competitors include companies that develop diagnostic tests such as Roche Holding, Ltd, and Siemens AG, as well as other companies and academic and research institutions.

Seasonality

We are continuing to learn how seasonal factors may affect our business. Based on our experience to date, we expect some seasonal variations in our financial results due to a variety of factors, such as the year-end holiday period and other major holidays, vacation patterns of both patients and healthcare providers, climate and weather conditions in our markets, seasonal conditions that may affect medical practices and patient, payer, and provider activity, including influenza outbreaks that may reduce the percentage of patients that can be seen or decrease patient's willingness to visit medical practices, and other factors relating to the timing of patient deductibles and co-insurance limits.

Regulation

Certain of our activities are subject to regulatory oversight by the FDA under provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA") and regulations thereunder, including regulations governing the development, marketing, labeling, promotion, manufacturing, distribution, and export of diagnostic products. Our clinical laboratory facilities are subject to oversight by CMS pursuant to CLIA, as well as agencies in various states, including New York. We are subject to many other federal, state, and foreign laws, including anti-fraud and abuse, anti-kickback, and patient privacy. Failure to comply with applicable requirements can lead to significant sanctions, including interruption of our operations, withdrawal of products from the market, recalls, payment denials, refunds and recoupments, refusal to authorize government contracts, product seizures, exclusion from participation in federal and state healthcare programs, civil money penalties, injunctions, and criminal prosecution. For more information, see "Item 1A. Risk Factors — Risks Relating to Governmental Regulation and Reimbursement."

U.S. Food and Drug Administration

Unless otherwise exempted or subject to enforcement discretion, medical devices, which include screening and diagnostic tests, must receive either FDA or regulatory approval or clearance before being marketed in the United States. Our Cologuard and Cologuard Plus tests are regulated by the FDA as a Class III medical devices. The FDA granted premarket approval ("PMA") for our Cologuard and Cologuard Plus tests in August 2014 and October 2024, respectively. The regulations governing our PMA-approved tests' approval place substantial restrictions on how our tests may be marketed and sold, specifically, by prescription only.

Additionally, manufacturers of medical devices must comply with various regulatory requirements under the FDCA and regulations thereunder, including, but not limited to, quality system regulations, unless they are exempt, facility registration, product listing, labeling requirements, and certain post-market surveillance requirements. Entities that fail to comply with FDA requirements can be liable for criminal or civil penalties, such as recalls, detentions, orders to cease manufacturing, and restrictions on labeling and promotion, among other potential sanctions.

Certain of our products in development or additional diagnostic products and services that we seek to develop may be regulated by the FDA as medical devices and require FDA approval or clearance. The regulatory review and approval process for medical devices can be costly, timely, and uncertain. This process may involve, among other things, successfully completing clinical trials and submitting a premarket clearance notice or filing a premarket approval application with the FDA.

Laboratory Developed Tests

Our Oncotype® tests, OncoExTra test, and certain other tests we offer are regulated as LDTs, and we may seek to commercialize certain of our products in development as LDTs. LDTs are clinical laboratory tests that are developed and validated by a laboratory for its own use. The FDA historically has taken the position that it has the authority to regulate such tests as medical devices under the FDCA and until recently has for the most part exercised enforcement discretion and not required clearance or approval of LDTs prior to marketing.

In May 2024, the FDA issued a final rule (the "LDT Rule") that amended the FDA's regulations to make explicit that LDTs are devices under the FD&C Act. Along with the final rule, the FDA finalized a policy under which the FDA's historical LDT enforcement discretion will be phased out over the course of three years, as well as targeted enforcement discretion policies for certain categories of LDTs. Under the LDT Rule and this policy, (1) from May 2025 to May 2028 various requirements will be phased in including medical device reporting ("MDR") requirements, correction and removal reporting requirements, registration and listing requirements, labeling requirements, investigational use requirements and quality system requirements, (2) beginning in November 2027, premarket review requirements will become applicable to high risk (e.g., Class III) LDTs and (3) beginning in May 2028, premarket review requirements will become applicable to moderate and low risk LDTs. LDTs that were first marketed prior to May 6, 2024 (and have not been significantly modified) ("Grandfathered LDTs") and LDTs for unmet medical needs manufactured and performed by labs integrated in a healthcare system, will not be subject to premarket review and most of the quality system requirements. Implementation and enforcement of the LDT Rule by the FDA may materially impact our development and commercialization of LDTs, including our Oncotype tests.

The LDT Rule has been challenged in the federal courts and that case is ongoing. It is possible that courts could strike down portions or all of the LDT Rule. It is unclear how the new Trump Administration may implement or enforce the LDT Rule. Additionally, the U.S. Congress may enact statutory changes that could alter or eliminate the LDT Rule. Even if the LDT Rule remains in its current form, the FDA will likely develop new policies to implement the rule that may materially impact our development and commercialization of LDTs, including our Oncotype tests.

Laboratory Certification, Accreditation, and Licensing

We are also subject to U.S. and state laws and regulations regarding the operation of clinical laboratories. CLIA requirements and laws of certain states impose certification requirements for clinical laboratories, and establish standards for quality assurance and quality control, among other things. CLIA provides that a state may adopt different or more stringent regulations than federal law and permits states to apply for exemption from CLIA if the state's laboratory laws are equivalent to or more stringent than CLIA. For example, the State of New York's clinical laboratory regulations, which have received an exemption from CLIA, contain provisions that are in certain respects more stringent than federal law. Therefore, as long as New York maintains a licensure program that is CLIA-exempt, we will need to comply with New York's clinical laboratory regulations in order to offer our clinical laboratory products and services in New York.

We have current certificates to perform clinical laboratory testing. Clinical laboratories are subject to inspection by regulators and to sanctions for failing to comply with applicable requirements. Sanctions available under CLIA and certain state laws include prohibiting a laboratory from running tests, requiring a laboratory to implement a corrective plan, and imposing civil monetary penalties.

HIPAA and Other Privacy Laws

The Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act ("HIPAA") established comprehensive protection for the privacy and security of health information. The HIPAA standards apply to three types of organizations, or "Covered Entities": health plans, healthcare clearinghouses, and healthcare providers that conduct certain healthcare transactions electronically. Covered Entities and their business associates must have in place administrative, physical, and technical standards to guard against the misuse of individually identifiable health information. We perform activities that may implicate HIPAA, such as providing clinical laboratory testing services and entering into specific kinds of relationships with Covered Entities and business associates of Covered Entities. Penalties for violations of HIPAA include civil money and criminal penalties.

Our activities must also comply with other applicable privacy laws, which impose restrictions on the access, use and disclosure of personal information. More state and international privacy laws are being adopted. Many state laws are not preempted by HIPAA because they are more stringent or are broader in scope than HIPAA, including the California Consumer

Privacy Act of 2018 (“CCPA”), including expansions and amendments to CCPA pursuant to the California Privacy Rights Act which became operative on January 1, 2023. CCPA protects personal information other than health information covered by HIPAA and allows certain data access and erasure rights to California consumers as well as rights to limit use and disclosure of sensitive personal information. Other similar state laws have been enacted. Further, we are required to comply with international, national, and provincial personal data protection laws and regulations, including the European Union's (“E.U.”) General Data Protection Regulation (“GDPR”) and Japan's Act on the Protection of Personal Information (“APPI”). The GDPR and other national or provincial laws provide a prescriptive, detailed regulation that provides extensive powers to public authorities to sanction and stop use of personal data. The GDPR and national or provincial laws outside of Europe such as APPI have and will continue to require significant effort and expense to ensure compliance. All of these laws may impact our business and may change periodically, which could adversely affect our business operations.

Federal and State Billing and Fraud and Abuse Laws

Anti-fraud Laws/Overpayments. We are subject to numerous federal and state anti-fraud and abuse laws, including the Federal False Claims Act. Many of these anti-fraud laws are broad in scope, and neither the courts nor government agencies have extensively interpreted these laws. Prohibitions under some of these laws include:

- the submission of false claims or false information to government programs,
- the retention of any overpayments by governmental payers,
- deceptive or fraudulent conduct,
- excessive or unnecessary services or services at excessive prices, and
- defrauding private sector health insurers.

Numerous federal and state agencies enforce the anti-fraud and abuse laws. In addition, private insurers may also bring private actions. In some circumstances, private whistleblowers are authorized to bring fraud suits on behalf of the government against providers and are entitled to receive a portion of any final recovery.

In addition, amendments to the False Claims Act impose severe penalties for the knowing and improper retention of overpayments collected from governmental payers. Within 60 days of identifying and quantifying an overpayment, a provider is required to notify CMS or the Medicare contractor of the overpayment and the reason for it and return the overpayment. These amendments could subject our procedures for identifying and processing payments to greater scrutiny. Overpayments may occur from time to time in the healthcare industry without any fraudulent intent. For example, overpayments may result from mistakes in reimbursement claim forms or from improper processing by governmental payers. We maintain protocols intended to identify any overpayments. From time to time we have identified overpayments and made refunds to government payers.

To avoid liability, we must carefully and accurately code claims for reimbursement, proactively monitor the accuracy and appropriateness of Medicare claims and payments received, diligently investigate any credible information indicating that we may have received an overpayment, and promptly return any overpayments.

Federal and State “Anti-Kickback” and “Self-Referral” Restrictions

Anti-Kickback Statute. The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs, unless an exception applies. The term “remuneration” is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value. Sanctions for violations of the federal Anti-Kickback Statute may include imprisonment and other criminal penalties, civil monetary penalties, and exclusion from participation in federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs, and do not contain identical safe harbors.

In addition, the Eliminating Kickbacks in Recovery Act of 2018 ("EKRA") imposes criminal penalties for knowing or willful payment or offer, or solicitation or receipt, of any remuneration, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for the referral or inducement of laboratory testing (among other healthcare services) unless a specific exception applies. Although it appears that EKRA was intended to reach patient brokering and similar arrangements to induce patronage of substance use recovery and treatment, the language in EKRA is broadly written and could apply to laboratory services covered under public or private payer arrangements.

Self-Referral Law. The federal "self-referral" law, commonly referred to as the "Stark" law, provides that healthcare providers who, personally or through a family member, have ownership interests in or compensation arrangements with a laboratory are prohibited from making a referral to that laboratory for laboratory tests reimbursable by Medicare, and also prohibits laboratories from submitting a claim for Medicare payments for laboratory tests referred by healthcare providers who, personally or through a family member, have ownership interests in or compensation arrangements with the testing laboratory. The Stark law contains a number of specific exceptions which, if met, permit healthcare providers who have ownership or compensation arrangements with a testing laboratory to make referrals to that laboratory and permit the laboratory to submit claims for Medicare payments for laboratory tests performed pursuant to such referrals. We are subject to comparable state laws, some of which apply to all payers regardless of source of payment, and do not contain identical exceptions to the Stark law.

Sunshine Act

In 2010, Congress enacted a statute commonly known as the Sunshine Act, which aims to promote transparency. The Sunshine Act requires manufacturers of drugs, devices, biologicals, and medical supplies covered by Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS any payments or other transfers of value made to healthcare providers and teaching hospitals, unless an exception applies. Manufacturers must also disclose to CMS any healthcare provider ownership or investment interests. Some states have similar transparency laws.

International

When marketing our tests outside of the U.S., we are subject to other countries' regulatory requirements governing human clinical testing, export of tissue, marketing approval for our products, and performance and reporting of tests in each market. These requirements vary by jurisdiction, differ from those in the U.S., and may require us to perform additional pre-clinical or clinical testing. For example, the E.U. has amended its existing regulatory framework for in vitro diagnostics by introducing the Regulation 2017/746 (EU) ("EU IVDR"), which amends the existing framework and imposes stricter requirements for the development, marketing, and sale of in vitro diagnostics such as our Oncotype DX Breast Recurrence Score test in the E.U. These new regulations are more stringent in a variety of areas, including clinical requirements, traceability, quality systems, and post-market surveillance activities. The EU IVDR became effective starting in May 2022. As our Oncotype DX Breast Recurrence Score test has a pre-existing certification from our notified body, we had until May 2026 to meet certain of the new, more stringent regulatory requirements of EU IVDR with respect to our Oncotype DX Breast Recurrence Score test, including obtaining a new positive conformity assessment from our notified body. We received a CE marking on our Oncotype DX Breast Recurrence Score test in December 2023, certifying that we are in compliance with the new EU IVDR regulatory requirements. Complying with the requirements of these regulations has required us to, and may continue to require us to, incur significant expenditures. Failure to meet these requirements could adversely impact our business in the E.U. and other regions that tie their product registrations to the E.U. requirements. Additionally, in many countries outside of the U.S., coverage, pricing, and reimbursement approvals are also required in order for our tests to be made available to patients in substantial volume.

Many countries in which we offer our tests have anti-inducement laws or regulations prohibiting providers, as well as medical and in vitro diagnostic device manufacturers, from offering, paying, soliciting, or receiving remuneration, directly or indirectly, or providing a benefit to a healthcare professional in order to induce business, or may require declaration of any benefits provided to healthcare professionals. In situations involving healthcare providers employed by public or state-funded institutions or national healthcare services, violation of the local anti-corruption or anti-gift laws 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 from offering or providing, directly or through a third party, including the distributors we 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 ("SEC") to have false or inaccurate books or records or to fail to maintain a system of internal accounting controls. We are also 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.

Other Laws

Occupational Safety and Health. In addition to its comprehensive regulation of health and safety in the workplace in general, the Occupational Safety and Health Administration has established extensive requirements aimed specifically at laboratories and other healthcare-related facilities. In addition, because our operations require employees to use certain hazardous chemicals, we also must comply with regulations on hazard communication and hazardous chemicals in laboratories. These regulations require us, among other things, to develop written programs and plans, which must address methods for preventing and mitigating employee exposure, the use of personal protective equipment, and training.

Specimen Transportation. Our commercialization activities subject us to regulations of the Department of Transportation, the U.S. Postal Service, and the Centers for Disease Control and Prevention that apply to the surface and air transportation, as well as importation, of clinical laboratory specimens.

Environmental. The cost of compliance with federal, state, and local provisions related to the protection of the environment has had no material effect on our business. There were no material capital expenditures for environmental control facilities in the year ended December 31, 2024 and there are no material expenditures planned for such purposes for the year ended December 31, 2025.

Intellectual Property

We rely on a combination of patents, patent applications, copyrights, and trademarks, as well as contracts, such as confidentiality, material data transfer, and license and invention assignment agreements to protect our intellectual property rights. We also rely upon trade secret laws to protect unpatented know-how and continuing technological innovation.

We have intellectual property rights to a wide variety of technologies including sample preparation, sample preservation, biomarkers, gene expression and sequencing technology, and related methods and formulations.

Our success depends upon our ability to protect our technologies through patent coverage and, where necessary, defend and enforce our patents in administrative proceedings and litigation. As of December 31, 2024, we had 257 issued patents in the U.S. and 930 issued patents outside of the U.S., which includes validated patents issued by the European Patent Office in key E.U. countries, covering genes and methods that are components of the Cologuard test, Oncoguard® Liver test, Oncotype DX tests, pipeline technologies or research methods, and platform technologies. Our issued U.S. patents expire at various times between 2025 and 2044. In addition, we have pending patent applications in the U.S. and in other countries, including provisional and non-provisional filings. Some of these U.S. patent applications also have corresponding pending or granted applications under the Patent Cooperation Treaty in Canada, Europe, Japan, Australia, and other jurisdictions. We solely own, jointly own, or exclusively license these patents and patent applications. In certain cases where joint ownership positions were created, we have negotiated contractual provisions providing us with the opportunity to acquire exclusive rights under the patents and patent applications. Under some patents and patent applications, we have elected to allow exclusive options to lapse without exercising the option. The joint ownership agreements generally are in the form of agreements that were executed at the onset of our collaborations with third parties.

License Agreements

We license certain technologies that are, or may be, incorporated into our technology under several license agreements, as well as the rights to commercialize certain diagnostic tests through collaboration agreements. Generally, the license agreements require us to pay single-digit royalties based on net revenues received using the technologies and may require minimum royalty amounts, milestone payments, or maintenance fees.

Mayo Foundation for Medical Education and Research

In June 2009, we entered into an exclusive, worldwide license agreement with Mayo Foundation for Medical Education and Research, under which Mayo granted us an exclusive, worldwide license to certain Mayo patents and patent applications, as well as a non-exclusive, worldwide license with regard to certain Mayo know-how. The scope of the license covers any screening, surveillance, or diagnostic test or tool for use in connection with any type of cancer, pre-cancer, disease, or condition. Our license agreement with Mayo was most recently amended and restated in September 2020.

The licensed Mayo patents and patent applications contain both method and composition claims that relate to sample processing, analytical testing, and data analysis associated with nucleic acid screening for cancers and other diseases. The jurisdictions covered by these patents and patent applications include the U.S., Australia, Canada, the E.U., China, Japan, and Korea. Under the license agreement, we assumed the obligation and expense of prosecuting and maintaining the licensed Mayo patents and are obligated to make commercially reasonable efforts to bring to market products using the licensed Mayo intellectual property.

Pursuant to our license agreement with Mayo, we are required to pay Mayo a low-single-digit royalty on net sales of current and future products using the licensed Mayo intellectual property each year during the term of the Mayo agreement.

We are also required to pay Mayo up to $3.0 million in sales-based milestone payments upon cumulative net sales of each product using the licensed Mayo intellectual property reaching specified levels.

The license agreement will remain in effect, unless earlier terminated by the parties in accordance with the agreement, until the last of the licensed patents expires in 2043 (or later, if certain licensed patent applications are issued). However, if we are still using the licensed Mayo know-how or certain Mayo-provided biological specimens or their derivatives on such expiration date, the term shall continue until the earlier of the date we stop using such know-how and materials and the date that is five years after the last licensed patent expires. The license agreement contains customary termination provisions and permits Mayo to terminate the license agreement if we sue Mayo or its affiliates, other than any such suit claiming an uncured material breach by Mayo of the license agreement.

In addition to granting us a license to the covered Mayo intellectual property, Mayo provides us with product development research and development assistance pursuant to the license agreement and other collaborative arrangements. In September 2020, Mayo also agreed to make available certain personnel to provide such assistance through January 2025.

Johns Hopkins University

Through the acquisition of Thrive Earlier Detection Corporation ("Thrive"), we acquired a worldwide exclusive license agreement with The Johns Hopkins University for use of several JHU patents and licensed know-how. We are seeking to utilize the JHU licensed technology to develop and commercialize a blood-based MCED test. The agreement terms would require us to pay single-digit sales-based royalties and up to $45.0 million in sales-based milestone payments for each JHU licensed product that reaches specified net sales levels.

In addition to granting us a license to the covered JHU intellectual property, JHU provides us with research and development assistance pursuant to other collaboration arrangements.

Human Capital

Our vision to provide the clarity to take life-changing action earlier drives us to find ambitious, dynamic individuals who thrive in a team-based environment. To facilitate talent attraction and retention, we strive to make Exact Sciences a diverse and inclusive workplace, with opportunities for our employees to grow and develop in their careers, supported by strong compensation, benefits, and health and wellness programs.

At December 31, 2024, we had approximately 7,000 full-time, part-time and temporary employees, 6,900 of which were full-time employees. More than 95% of our employees are located in the United States and none of our employees are represented by a labor union. During fiscal year 2024, our voluntary turnover rate was approximately 8%, below the healthcare industry benchmark, which is comprised of certain of our key competitors (Aon, 2024 Salary Increase and Turnover Study — Second Edition, June 2024).

Diversity and Inclusion

We believe diversity in thought, experience, perspective, and background within our team is necessary to support our core value of innovation. We are firmly committed to providing equitable opportunity in all aspects of employment and will not discriminate in any employment decision because of a person's race, color, sex, religion, national origin, age, disability, sexual orientation, marital status, gender identity, genetic information, veteran status, or any other basis prohibited by applicable law. In order to increase the pool of diverse candidates for open positions, we partner with community resource groups and participate in diversity-focused career recruiting efforts.

Our talent strategy and inclusion team, led by our Executive Vice President, Human Resources and Service, is responsible for developing and implementing our inclusion and diversity programs. The Human Capital Committee of our Board of Directors oversees and monitors our policies and strategies relating to culture, talent, and human capital management, including diversity, equity, and inclusion. We track and monitor workforce diversity data to ensure we are fulfilling our diversity and inclusion aspiration – to be known as a great place to work for all. Thanks, in part, to our compelling mission, competitive benefits and the positive results of our diversity and inclusion program, women make up approximately 53% of total employees (full-time and part-time), and 47% of management positions. Our ten-member Board of Directors includes four female members to support diversity of opinion and perspective at the board level. In addition, we have been awarded with a Great Place to Work Certification®, Gallup Exceptional Workplace Award, and Wisconsin State Journal Top Workplaces in 2024.

Compensation and Benefits

Attracting the best talent starts with offering industry-leading compensation and benefits. We want our compensation and benefits to give our employees a sense of ownership in our company, and pride and determination to achieve our mission. To help our eligible employees achieve financial well-being and share in the success they create, we offer competitive base pay, a company-sponsored 401(k) plan with employer matching, retirement planning resources, employee stock purchase plan opportunities, stock awards, and annual cash bonus programs. To help our eligible employees get and stay healthy, we offer our employees generous health benefits, including among others, medical, dental, and vision care coverage for employees and their dependents; family formation benefits (such as adoption assistance, (in)fertility treatments, etc.), life, disability, and accident insurance and critical illness benefits; health care and dependent care flexible spending account programs and employer contributions to health savings accounts (for specific medical plans). To enable our eligible employees to take the time they need to re-energize and focus on what matters most, we offer a parental leave program and ample time away benefits (vacation, sick, holidays, volunteer time, voting time, other leaves). To foster a culture of care and compassion, we offer eligible employees an employee assistance program with employer-paid counseling coverage for employee and household members, charitable donation matches, commuter benefits, wellness programs, including fitness and mental health/well-being, and more.

Training and Development

We invest significant resources to develop the talent needed to achieve long-term success. We have implemented a comprehensive employee training program that applies to all employees, including full-time, part-time, and temporary employees. Senior leadership, in conjunction with Human Resources, is responsible for ensuring that all staff, including contractors and consultants, have the appropriate education, training, competency, and credentials.

We create opportunities for personal growth, professional growth, and career mobility for all employees. From facilitated workshops to eLearning modules, individual development plans, mentoring, and coaching, we have invested in developmental capabilities to meet our employees at any stage of their career and help them grow. We have a variety of tools to facilitate developmental feedback. We maintain a mentoring program aimed to support the growth and development journey of employees, increase talent retention, enhance our inclusive culture, and increase partnership and collaboration across the business. We also host an annual leadership summit, bringing leaders across the Company together for two and a half days of dedicated development and enrichment activities. Thanks, in large part, to our training and development investments, in 2024 we were able to fill 35% of our open positions with internal candidates.

Financial Information

See our consolidated financial statements included elsewhere in this Form 10-K and accompanying notes to the consolidated financial statements.

Available Information

We were incorporated in the State of Delaware on February 10, 1995. Our corporate headquarters are located at 5505 Endeavor Lane, Madison, Wisconsin 53719. Our telephone number is 608-284-5700. Our Internet website address is *www.exactsciences.com*. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge through the investor relations page of our Internet website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Our Internet website and the information contained therein or connected thereto are not intended to be incorporated into this Annual Report on Form 10-K.

Item 1A. Risk Factors

We operate in a rapidly changing environment that involves a number of risks that could materially affect our business, financial condition or future results, some of which are beyond our control. This discussion highlights some of the risks that may affect future operating results. These are the risks and uncertainties we believe are most important for you to consider. We cannot be certain that we will successfully address these risks. If we are unable to address these risks, our business may not grow, our stock price may suffer, and we may be unable to stay in business. Additional risks and uncertainties not presently known to us, which we currently deem immaterial or which are similar to those faced by other companies in our industry or business in general, may also impair our business operations.

Risk Factors Summary

The following is a summary of the principal risks that could adversely affect our business, operations, and financial results.

Risks Related to our Business and Business Strategy

- We may never become profitable or sustain profitability.
- We may need additional capital to execute our strategic plan.
- Our success depends heavily on our Screening and Precision Oncology tests and the successful commercialization of our tests in development.
- Our operating results could be subject to significant fluctuation, which could increase the volatility of our stock price and cause losses to our shareholders.
- We face intense competition from other companies and may not be able to compete successfully.
- If any of our facilities or our laboratory equipment were damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business could be materially harmed.
- We heavily rely upon certain suppliers, including suppliers that are the sole source of certain supplies and products used in our tests and business operations. The loss or interruption of supply from our suppliers could have a disruptive effect on our business.
- Cyberattacks, security breaches, loss of data, and other disruptions in relation to our information technology systems, as well as those of our third-parties with whom we have business relationships, could compromise sensitive information related to our business, prevent us from accessing it and expose us to substantial liability, which could adversely affect our business and reputation.
- We rely on courier delivery services to transport Cologuard collection kits to patients and samples for all of our tests back to laboratory facilities for analysis. If these delivery services are disrupted or become significantly more expensive, customer satisfaction and our business could be negatively impacted.
- The success of our business substantially depends on the efforts of our senior management team and qualified personnel.
- Our business and reputation will suffer if we are unable to establish and comply with stringent quality standards to assure that the highest level of quality is observed in the performance of our tests.
- Our inability to manage growth could harm our business.
- We may engage in acquisitions or divestitures that are not successful and which could disrupt our business and reduce our financial resources and shareholder value.
- International expansion of our business exposes us to business, regulatory, labor, political, operational, financial, liability, compliance, payment collection, and economic risks associated with doing business outside of the U.S.
- Our business may be adversely affected by global macroeconomic conditions and volatility in the capital markets.
- Public health crises, such as the COVID-19 pandemic, have had, and could in the future have, adverse effects on our business and financial results.
- Ethical, legal, and social concerns related to the use of genetic information could reduce demand for our genetic tests.
- Climate change, or legal or regulatory measures to address climate change or other corporate social responsibility and sustainability matters, could adversely affect our business, financial condition, and results of operations.
- The use of Artificial Intelligence presents new risks and challenges to our business.
- We may be a party to litigation in the normal course of business or otherwise, which could affect our business and financial position.

Risks Relating to Governmental Regulation and Reimbursement

- We face uncertainty related to healthcare reform, pricing, coverage, and reimbursement.
- If payers, including managed care organizations, do not approve and maintain reimbursement for our tests at adequate reimbursement rates, our commercial success could be compromised.
- If we are unable to obtain or maintain reimbursement at adequate reimbursement rates for our Oncotype DX tests outside of the U.S., our ability to expand internationally will be compromised.
- Failure to comply with federal, state, and foreign laboratory licensing and related requirements could cause us to lose the ability to perform our tests, experience disruptions to our business, or become subject to administrative or judicial sanctions.
- Our products could be subject to recall.
- Delays in receipt of, or failure to obtain, required FDA clearances or approvals for our products in development, or improvements to or expanded indications for our current offerings, could materially delay or prevent us from commercializing or otherwise adversely impact future product commercialization.
- The FDA's implementation of the LDT Rule may cause us to incur substantial costs and time delays associated with meeting requirements for pre-market clearance or approval or we could experience decreased demand for or reimbursement of our tests.

- We are subject to numerous U.S. and foreign laws and governmental regulations, and any governmental enforcement action may materially affect our financial condition and business operations.
- Our business is subject to various complex laws and regulations applicable to providers of clinical diagnostics and services.
- Due to billing complexities in the diagnostic and laboratory service industry, we may have difficulties receiving timely payment for the tests we perform, and may face write-offs, disputes with payers and patients, and long collection cycles.
- Some of our activities may subject us to risks under federal, state, and foreign laws prohibiting "kickbacks" and false or fraudulent claims.
- Some of our activities may subject us to risks under the Foreign Corrupt Practices Act and similar anti-bribery laws in non-U.S. jurisdictions.
- Failure to comply with privacy, security, and consumer protection laws and regulations could result in fines, penalties, and damage to our reputation and have a material adverse effect on our business.
- Our employees, independent contractors, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.
- Changes in tax laws or regulations or exposure to tax liabilities could adversely affect our financial condition and results of operations.

Risks Relating to Product Development, Commercialization and Sales of our Products

- The success of the screening and diagnostic products and services we currently offer or may offer in the future will depend on the degree of market acceptance by healthcare providers, patients, healthcare payers, and others in the medical community.
- Uncertainty in the development and commercialization of our new tests or services could materially adversely affect our business, financial condition and results of operations.
- If we do not successfully manage the launch and marketing of new products or services, our financial results could be adversely affected.
- Recommendations, guidelines, and quality metrics issued by various organizations may significantly affect payers' willingness to cover, and healthcare providers' willingness to prescribe or order, our products.
- We expect to continue to make significant investments in our research and development efforts, which may not be successful.
- Interim, topline and preliminary data from our clinical studies that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- Our industry is subject to rapid change, which could make our current products and any future products we may develop, obsolete.
- The sizes of the markets for our current and future products have not been established with precision, and may be smaller than we estimate.
- Our dependence on distributors for sales in many countries outside of the U.S. could limit or prevent us from selling our tests in those countries and impact our revenue.

Risks Relating to our Intellectual Property

- We rely on strategic collaborative and licensing arrangements with third parties to develop critical intellectual property. We may not be able to successfully establish and maintain such intellectual property.
- We may be subject to substantial costs and liability, or be prevented from using technologies incorporated in our screening or diagnostic tests as a result of litigation or other proceedings relating to patent or other intellectual property rights.
- If we are unable to protect or enforce our intellectual property effectively, we may be unable to prevent third parties from using our intellectual property, which would impair any competitive advantage we may otherwise have.
- If patent regulations or standards are modified, such changes could have a negative impact on our business.

Risks Relating to our Securities

- If we fail to maintain an effective system of internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our reported financial information and our stock price may be adversely impacted.
- Our stock price has fluctuated widely and is likely to continue to be volatile.
- We have recorded significant impairment charges and could do so again in the future
- Our balance sheet includes significant amounts of goodwill and intangible assets. The impairment of a significant portion of these assets would negatively affect our results of operations.
- Our significant indebtedness could adversely affect our business, financial condition, and results of operations and our ability to meet our payment obligations under such indebtedness and limit our ability to raise additional capital to fund our operations.

Risks Related to our Business and Business Strategy

We may never become profitable or sustain profitability.

We have incurred losses since we were formed. From our date of inception on February 10, 1995 through December 31, 2024, we have accumulated a total deficit of approximately $4.50 billion. Our net loss was $1.03 billion, $204.1 million and $623.5 million for the years ended December 31, 2024, December 31, 2023, and December 31, 2022, respectively. We expect to continue investing significantly toward development and commercialization of our colorectal cancer screening technology, our precision oncology tests, our MCED and MRD tests, and other products and services. If our revenue does not continue to grow faster than our cost of sales and operating expenses, we will not become profitable. We cannot be certain that the revenue from the sale of any products or services based on our technologies will be sufficient to make us profitable.

We may need additional capital to execute our strategic plan.

Although we believe that we have sufficient capital to fund our operations for at least the next 12 months, we may require additional capital to fully fund our current strategic plan, which includes continuing to scale our screening and precision oncology tests and developing a pipeline of future products and services. Additional financing may not be available in amounts or on terms satisfactory to us or at all. Our success in raising additional capital may be significantly affected by general market conditions, the market price of our common stock, our financial condition and existing indebtedness, uncertainty about the future commercial success of our current products and services, the development and commercial success of future products or services, regulatory developments, the status and scope of our intellectual property, any ongoing litigation, our compliance with applicable laws and regulations, and other factors. If we raise additional funds through the sale of equity, convertible debt or other equity-linked securities, our shareholders' ownership will be diluted, and the market price of our common stock could be depressed. We may issue securities that have rights, preferences, and privileges senior to our common stock. If we raise additional funds through collaborations, licensing arrangements or other structured financing transactions, we may relinquish rights to our technologies, products or services, grant security interests in our assets or grant licenses to third parties on terms that are unfavorable to us.

Our success depends heavily on our Screening and Precision Oncology tests and the successful commercialization of our tests in development.

Our ability to generate revenues depends very substantially on the commercial success of our screening and precision oncology tests. Additionally, we are devoting significant resources to developing new tests in colorectal cancer screening, MRD, MCED, and other areas of cancer diagnostics. There can be no assurance that we will be able to continue to grow sales of our screening and precision oncology tests or that we will develop or commercialize any other products or services that will generate significant revenue. The commercial success of our tests, our successful commercialization of any new products and our ability to generate revenues will depend on a variety of factors, including the following:

- acceptance in the medical community;
- inclusion in healthcare guidelines and recommendations;
- inclusion in quality measures, including the HEDIS measures and the CMS Medicare Advantage Star Ratings;
- recommendations and studies that may be published by government agencies, professional organizations, academic or medical journals or other key opinion leaders;
- patient acceptance and demand;
- patient compliance with orders for our tests by healthcare providers, and patient adherence to recommendations regarding periodic re-testing;
- successful new screening initiatives, including gap closure programs through which we partner with health systems and payers to deliver Cologuard test kits to their patients or members who are due for colorectal cancer screening under applicable guidelines;
- effective marketing and educational programs, including successful direct-to-patient marketing such as television advertising and social media;
- sufficient coverage and reimbursement by payers;
- the existence of federal or state laws that mandate coverage for colorectal cancer and other types of screening, the extent to which those laws mandate coverage of our tests and the enforcement of those laws;
- the amount and nature of competition from other products and procedures;
- maintaining regulatory approvals to legally market our products and services; and
- the ease of use of our ordering process for healthcare providers.

If we are unable to continue growing sales of our screening and precision oncology tests, we are delayed or limited in doing so, or we are unable to successfully commercialize our tests in development or other new products, our business prospects, financial condition, and results of operations would be adversely affected.

Our operating results could be subject to significant fluctuation, which could increase the volatility of our stock price and cause losses to our shareholders.

Our revenues and results of operations have historically, and may in the future, fluctuate significantly, depending on a variety of factors, including the following:

- our success in marketing and selling, and changes in demand for, our screening and precision oncology tests, and the level of reimbursement and collection obtained for such tests;
- seasonal variations or non-seasonal events or circumstances affecting healthcare provider recommendations for our tests and patient compliance with healthcare provider recommendations, including without limitation, holidays, weather events, and circumstances such as disease outbreaks that may limit patient access to medical practices or institutions for diagnostic tests and preventive services;
- our success in collecting payments from third-party and other payers, patients and collaborative partners, variation in the timing of these payments and recognition of these payments as revenues;
- the pricing of our tests, including potential changes in CMS or other reimbursement rates;
- circumstances affecting our ability to provide our tests, including weather events, supply shortages, or regulatory or other circumstances that adversely affect our ability to manufacture our tests or process tests in our clinical laboratories;
- the results of our annual testing of intangible assets and goodwill for impairment charges when events or changes in circumstances indicate the carrying value may not be recoverable;
- fluctuations in the amount and timing of our selling and marketing costs and our ability to manage costs and expenses and effectively implement our business; and
- our research and development activities, including the timing, size, complexity, and cost of clinical studies.

If our revenues or operating results fall below the expectations of investors or public market analysts, the trading price of our common stock could decline substantially.

We face intense competition from other companies and may not be able to compete successfully.

We operate in a rapidly evolving and highly competitive industry. There are a number of private and public companies that offer products, or have announced that they are developing products that compete with ours.

Some of our current and potential competitors may have significant competitive advantages over us, which may make them more attractive to hospitals, clinics, group purchasing organizations, and physicians. See “Item 1. Business — Competition” in this Annual Report on Form 10-K for additional information regarding our competitors and the effects of competition on our business.

We may be unable to compete effectively against our competitors either because their products and services are superior or because they are more effective in developing or commercializing competing products and services. Furthermore, even if we do develop new marketable products or services, our current and future competitors may develop products and services that are more clinically or commercially attractive than ours, and they may bring those products and services to market earlier or more effectively than us. If we are unable to compete successfully against current or future competitors, we may be unable to increase market acceptance for, and sales of, our tests, which could prevent us from increasing or sustaining our revenues or achieving sustained profitability and could cause the market price of our common stock to decline.

If any of our facilities or our laboratory equipment were damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business could be materially harmed.

Our manufacturing, testing and laboratory facilities are located in Madison and Marshfield, Wisconsin, Redwood City, California, Phoenix, Arizona, and Trier, Germany, and our headquarters are also located in Madison, Wisconsin. If our present, or any future facilities, were to be damaged, destroyed or otherwise unable to operate, whether due to fire, floods, storms, tornadoes, earthquakes, other inclement weather events or natural disasters, employee malfeasance, terrorist acts, power outages, or otherwise, it may render it difficult or impossible for us to perform our tests for some period of time, and our

business could be severely disrupted. Our facilities and the equipment we use to perform our tests would be costly to replace and could require substantial lead time to repair or replace. The inability to perform our tests or the backlog of tests that could develop if any of our facilities become inoperable for even a short period of time may result in the loss of customers or harm our reputation, and we may be unable to regain those customers or rebuild our reputation in the future. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

If our testing facilities become inoperable for any reason, we may not be able to transfer any or all testing to our other facilities and would need to rely on a third party to perform certain of these tests. We could use only another facility with established state licensure and CLIA accreditation, and for tests provided internationally, ISO 15189 accreditation. We cannot assure you that we would be able to find an appropriately certified facility willing to comply with the required procedures, that this laboratory would be willing to perform the tests for us on commercially reasonable terms, or that it would be able to meet our quality or regulatory standards. Alternatively, establishing a redundant facility for certain of our testing would require considerable time and money to secure adequate space, construct the facility, recruit and train employees, and establish the additional operational and administrative infrastructure necessary to support this facility. We also may not be able, or it may take considerable time, to replicate our testing processes or results in a new facility. Additionally, any such new facility would be subject to certification under CLIA and licensing by several states, including California and New York, which could take a significant amount of time and result in delays in our ability to resume operations.

We heavily rely upon certain suppliers and other vendors, and any disruptions or failures with respect to our relationships with these counterparties could have a disruptive effect on our business.

We purchase certain supplies and products from third-party suppliers. In some cases, due to the unique attributes of certain products that are incorporated into our tests or otherwise used in our operations, we maintain either a single-source supplier relationship or a very limited set of supplier relationships. Certain of our third-party suppliers possess exclusive intellectual property or otherwise may be the only party with the rights or expertise to provide us critical supplies and/or products. These third parties are independent entities subject to their own unique operational, regulatory compliance, and financial risks that are outside our control. These third parties may not be willing to enter or renew long-term supply arrangements with us or continue to supply us at all. Additionally, they may not perform their obligations in a timely and cost-effective manner, and they may be unwilling or unable to increase production capacity commensurate with demand for our tests or future products or services.

We may become dependent on additional single- or limited-source suppliers, or become increasingly dependent on existing suppliers, as we expand and develop our product and service pipeline. For example, our OncoExTra test is currently only validated to be performed on Illumina's sequencing platform, and the MRD and MCED tests we expect to launch in 2025 will similarly utilize this platform. We also rely on Hamilton Company ("Hamilton") to provide us laboratory equipment and related supplies (such as racking and pipette tips) necessary to perform certain critical steps in our clinical laboratory tests, including our Cologuard and precision oncology tests. Although other companies may offer viable alternative platforms, we have invested significant capital, time and expertise to procure Illumina and Hamilton machines and to optimize their use in our tests.

We rely on third parties, such as contract research organizations, medical institutions and clinical investigators to conduct studies of our technologies that may be required by the FDA or other U.S. or foreign regulatory bodies. Our reliance on these third parties will not relieve us of our requirement to prepare, and ensure our compliance with, various procedures required under good clinical practices, even though third-party contract research organizations may prepare and comply with their own, comparable procedures. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, our studies may be extended, delayed, suspended or terminated, the study data may be invalidated, and we may not be able to obtain a required regulatory approval.

We rely on certain software provided by Epic Systems Corporation ("Epic"), to manage or support a variety of critical business processes and activities (such as receiving and fulfilling orders, billing, collecting and making payments, shipping products, providing services and support to customers and fulfilling contractual obligations). Implementing new software to replace Epic would not only be costly, complex and difficult, but could negatively affect financial accounting and reporting processes, and disrupt external commercial activities such as order receipt and product delivery.

We have engaged third party vendors to provide services with respect to a variety of business processes. Failure by these third parties to meet their contractual, regulatory and other obligations to us, or our failure to adequately monitor their performance, could result in our inability to achieve the expected cost savings or efficiencies and could result in additional costs to correct errors made by such service providers. Moreover, we have diminished control over the quality and timeliness of the outsourced services, including the cybersecurity protections implemented by these third parties.

The loss of a critical supplier or other vendor, the failure to perform by any such party, the deterioration of our relationship with any such party or any unfavorable modification to the contractual terms under which we are supplied certain supplies or services could have a disruptive effect on our business, and could adversely affect our results of operations for an extended period of time, particularly if we are required to validate an alternative vendor.

Cyberattacks, security breaches, loss of data, and other disruptions in relation to our information technology systems, as well as those of our third-parties with whom we have business relationships, could compromise sensitive information related to our business, prevent us from accessing it and expose us to substantial liability, which could adversely affect our business and reputation.

In the ordinary course of our business, we collect and store sensitive data, including personal information, credit card and other financial information, intellectual property and proprietary business information owned or controlled by us or other parties such as customers and payers. We also communicate sensitive data, including patient data, through phone, Internet, facsimile, multiple third-party vendors and their subcontractors. We depend on information technology ("IT") systems for significant elements of our operations, including our laboratory information management system and our ExactNexus™ technology platform. Our IT systems support a variety of functions, including laboratory operations, test validation, sample tracking, quality control, customer service support, billing and reimbursement, research and development activities, scientific and medical curation and general administrative activities. We face a number of risks related to protecting this critical information, including loss of access, inappropriate use or disclosure, unauthorized access, inappropriate modification and our being unable to adequately monitor, audit or modify our controls over such critical information. This risk extends to the third-party vendors and subcontractors we use to manage this sensitive data or otherwise process it on our behalf as well as other third parties we share information with like hospitals and health systems.

IT systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts from criminal hackers, hacktivists, state-sponsored intrusions, industrial espionage and employee malfeasance, breaches due to employee error and natural disasters. Cyberattacks are becoming more sophisticated and frequent, and in some cases have caused significant harm at other companies. While we devote significant resources to protect the security of our IT systems, including the personal data and other information that we receive and store, there can be no assurance that any security measures will be effective against current or future security threats. We have experienced and expect to continue to experience attempted cyberattacks of our IT systems and networks. To date, none of these attempted cyberattacks has had a material effect on our operations or financial condition. However, any such breach or interruption could compromise our networks and the information stored therein could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our IT systems, unauthorized access, loss or disclosure could also disrupt our operations, including our ability to:

- process tests, provide test results, bill payers or patients;
- process claims and appeals;
- provide customer assistance services;
- conduct research and development activities;
- collect, process and prepare company financial information;
- provide information about our tests and other patient and healthcare provider education and outreach efforts through our website; and
- manage the administrative aspects of our business.

Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996, similar U.S. state data protection regulations, the GDPR, and other regulations, the breach of which could result in significant penalties and damage to our reputation. In addition, disruptions to our business occurring as a result of system updates and enhancements, such as our efforts to move our precision oncology tests to our technology and services platform, could have a material adverse effect on our financial condition and operating results. There can be no assurance that our process of improving existing systems, developing new systems to support our expanding operations, protecting confidential patient

information, and improving service levels will not be delayed or will not give rise to additional systems issues in the future. Although we carry insurance for this purpose, failure to adequately protect and maintain the integrity of our information systems and data, including as a result of a security breach, may result in significant losses that exceed our insurance coverage limits and have a material adverse effect on our financial position, results of operations, and cash flows.

We rely on courier delivery services to transport Cologuard collection kits to patients and samples for all of our tests back to laboratory facilities for analysis. If these delivery services are disrupted or become significantly more expensive, customer satisfaction and our business could be negatively impacted.

In most cases, we ship Cologuard collection kits to patients, and patients ship samples to our Madison, Wisconsin laboratory facilities for analysis by air and ground express courier delivery service. Additionally, medical providers typically ship samples for Oncotype testing to our laboratory facilities via air and ground express courier delivery service. Disruptions in delivery service, whether due to bad weather, natural disaster, labor disruptions, terrorist acts or threats, or for other reasons, can adversely affect customer satisfaction, specimen quality, and our ability to provide our services on a timely basis. If the courier delivery services that transport Cologuard collection kits or other test samples institute significant price increases, our profitability would be negatively affected and we may need to identify alternative delivery methods, if possible, modify our service model, or attempt to raise our pricing, which may not be possible with regard to tests covered by Medicare or commercially practicable with regard to tests covered by commercial payers.

The success of our business substantially depends on the efforts of our senior management team and our qualified personnel.

Our success depends largely on the skills, experience, and performance of our senior management team, and of the highly skilled personnel supporting our research and development programs, commercial laboratory operations, sales efforts, and information technology infrastructure. The loss of the service of any member of our senior management could significantly delay or prevent the achievement of our corporate strategies and initiatives, or adversely impact our ability to develop key relationships and commercialize our products and services. Also, facilitating seamless leadership transitions for key positions is a critical factor in sustaining the success of our organization. If our succession planning efforts are not effective, it could adversely impact our business. We face intense competition with other life science and technology businesses for certain highly technical or scientific personnel and experienced salespeople. We also compete with universities and public and private research institutions for highly qualified scientific personnel. In addition, as our sales efforts grow in size and complexity, we may not be able to successfully manage our dispersed or inside sales forces or our sales force may not be effective. Market competition for commercial, marketing, and medical affairs talent is significant, and we may not be able to hire or retain such talent, or acquire it through independent sales or other third-party organizations, on commercially reasonable terms, if at all.

Our business and reputation will suffer if we are unable to establish and comply with stringent quality standards to assure that the highest level of quality is observed in the performance of our tests.

Inherent risks are involved in providing and marketing our tests, including our Cologuard and Cologuard Plus tests and our precision oncology tests, and related services. Patients and healthcare providers rely on us to provide accurate clinical and diagnostic information that may be used to make critical healthcare decisions. As such, users of our tests may have a greater sensitivity to errors than users of some other types of products and services.

We must maintain top service standards and FDA-mandated and other quality controls. Past or future performance or accuracy defects, incomplete or improper process controls, excessively slow turnaround times, unanticipated uses of our tests or mishandling of samples or test results (whether by us, patients, healthcare providers, courier delivery services, or others) can lead to adverse outcomes for patients and interruptions to our services. These events could lead to voluntary or legally mandated safety alerts relating to our tests or our laboratory facilities and could result in the removal of our products and services from the market or the suspension of our laboratories' operations. Insufficient quality controls and any resulting negative outcomes could result in significant costs and litigation, as well as negative publicity that could reduce demand for our tests and payers’ willingness to cover our tests. Even if we maintain adequate controls and procedures, damaging and costly errors may occur.

Our inability to manage growth could harm our business.

In connection with the commercialization of our tests, we have added, and expect to continue adding, personnel to certain areas of our business, including laboratory operations, quality assurance, and compliance. Our number of full-time employees has increased from 4,800 as of December 31, 2020 to 7,000 as of December 31, 2024. As we continue to build our commercialization, marketing, and sales efforts and expand research and development activities for current and new products and services, the scope and complexity of our operations is increasing significantly. In addition, our acquisitions have contributed to the increasing complexity of operations, requiring significant changes to our corporate operations as we integrate other companies and their personnel to our systems. This growth has also increased our operating expenses and capital requirements, and we expect that they will continue to increase. Our ability to manage our growth effectively requires us to expend funds to improve our operational, financial and management controls, reporting systems, and procedures. As we expand the commercialization of our current tests and move towards commercializing new tests, we will also need to effectively manage our growing manufacturing, laboratory operations, and sales and marketing needs. We are continuing to explore the need to add new facilities to support anticipated demand for our current and future tests. We face various risks in managing these expansion efforts, including financing, construction delays, budget management, quality control, design efficiency, and transition execution. If we are unable to manage our anticipated growth effectively, our business could be harmed.

We may engage in acquisitions or divestitures that are not successful and which could disrupt our business and reduce our financial resources and shareholder value.

We undertake acquisition activities from time to time. Certain risks may exist as a result of these and other acquisition activities, including, among others:

- potential unknown liabilities and unforeseen increased expenses, delays, or unfavorable conditions in connection with the integration of the acquired businesses into our business;
- diversion of management's attention and company resources from our existing operations of our business;
- the issuance of dilutive securities, assumption or incurrence of additional debt obligations or expenses, or use of substantial portions of our cash in acquisitions;
- difficulties in successful integration of the operations and information technology systems of acquired businesses into our business;
- the potential loss of key employees, customers, and strategic partners of ours and of acquired businesses;
- the inability to realize the anticipated benefits of the acquisitions or do so within the anticipated timeframe;
- negative impacts on our near-term financial results after an acquisition or on our future financial results if we do not effectively manage our expanded operations; and
- the market price of our common stock may decline as a result of the acquisitions.

In the future, we may enter into transactions to acquire other businesses, products, services, or technologies, which may ultimately be unsuccessful. If we do identify suitable acquisition targets, we may not be able to make such acquisitions on favorable terms or at all. Any acquisitions we make may not strengthen our competitive position, and these transactions may be viewed negatively by investors, healthcare providers, patients, and others. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results.

We may also pursue strategic divestitures that may prove distracting, unprofitable, or otherwise unsuccessful. A successful divestiture depends on various factors, including our ability to effectively transfer liabilities, contracts, facilities, and employees to the buyer, identify and separate the personnel, contracts, and assets, including intellectual property, to be divested from the portion of the business and assets that we wish to keep, and reduce fixed costs previously associated with the divested assets or business. In exiting a business, we may still retain liabilities associated with that business and other indemnification obligations. We may also need to provide transition services to the buyer for an extended period of time following the closing, which may cause us to incur unanticipated costs and distraction. With respect to any divestiture, we may encounter difficulty finding potential buyers or other divestiture options on favorable terms. We may agree to milestone or earnout-based consideration, the achievement of which will be outside our control, and which we may ultimately never receive. Any divestiture could affect our profitability as a result of the gains or losses on such sale of a business or service, the loss of the operating income resulting from such sale or the costs or liabilities that are not assumed by the acquirer (i.e., stranded costs) that may negatively impact profitability subsequent to any divestiture. We may also be required to recognize impairment charges as a result of a divestiture.

International expansion of our business exposes us to business, regulatory, labor, political, operational, financial, liability, compliance, payment collection, and economic risks associated with doing business outside of the U.S.

While we do not offer our Cologuard and Cologuard Plus tests outside of the U.S., we currently commercialize or plan to commercialize our precision oncology tests through employees in Canada, Japan, and a number of European countries, as well as through exclusive distribution agreements. We have provided our Oncotype tests in approximately 120 countries. Our business strategy incorporates continued international expansion, which includes growing our direct sales and healthcare provider outreach and education capabilities outside of the U.S. and developing our relationships with payers and distributors in foreign markets. Doing business internationally involves a number of risks, including:

- difficulties in complying with multiple, conflicting, and changing laws, regulations, and policies, such as tax laws, trade policies, export and import restrictions, tariffs, employment laws, privacy and data protection laws, regulatory requirements and other governmental approvals, permits, and licenses, including the changing regulation in Europe with regard to medical device and in vitro diagnostic regulations;
- significant competition from local and regional product offerings and the fact that products designed for U.S. markets may not be preferred by foreign authorities, payers, medical providers, and patients;
- restrictions or prohibitions of transmitting personal data, including patient data, from foreign jurisdictions to our centralized laboratories in the U.S.;
- difficulties in staffing and managing foreign operations;
- difficulties in managing distributor relationships;
- complexities associated with managing multiple payer reimbursement regimes, public payers, or patient self-pay systems;
- logistics and regulations associated with shipping tissue samples, performing tests locally or complying with local regulations concerning the analysis of tissue, including infrastructure conditions and transportation delays;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, lower margins resulting from smaller scale foreign operations, and exposure to foreign currency exchange rate fluctuations;
- regulatory and compliance risks that relate to maintaining accurate information and control over the activities of our sales force and distributors that may fall within the purview of the FCPA, its books and records provisions or its anti-bribery provisions, or similar anti-bribery or anti-corruption laws or regulations, such as the United Kingdom (“U.K.”) Anti-bribery Act and the U.K. Criminal Finances Act; and
- complexity of compliance with local standard contractual requirements to access public customers and payers.

Any of these factors could significantly harm our current international operations or future international expansion and, consequently, our financial condition and results of operations.

Our business may be adversely affected by global macroeconomic conditions and volatility in the capital markets.

The growth of our business is, and will continue to be, affected by changes in the overall global economy. Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, high interest rates, foreign currency exchange rates, weakness in general economic conditions, and threatened or actual recessions, including those resulting from the current and future conditions in the global financial markets, shifting political landscapes, and budgeting constraints of governmental entities. Cost inflation, including increases in raw material prices, labor rates, transportation costs, and tariffs, may impact our profitability. Our ability to recover these cost increases through price increases is significantly limited by the process by which we are reimbursed for our products and services by government and private payers. In addition, disruptions in the U.S., Europe or other economies, including due to geopolitical conflict or uncertainty and changing international trade policies, could disrupt global markets, interrupt global supply chains, and have other potential inflationary or recessionary effects on the global economy.

The volatility of the capital markets could also affect the value of our investments and our ability to liquidate our investments in order to fund our operations. The high interest rate environment and reduced access to capital markets could also adversely affect the ability of our suppliers, distributors, licensors, collaborators, contract manufacturers, and other commercial partners to remain effective business partners or to remain in business. The loss of a critical business partner, or a failure to perform by a critical business partner, could have a disruptive effect on our business and could adversely affect our results of operations.

Public health crises, such as the COVID-19 pandemic, have had, and could in the future have, adverse effects on our business and financial results.

Pandemics or disease outbreaks, such as the COVID-19 pandemic, have created and may continue to create significant volatility, uncertainty and economic disruption in the markets in which we sell or plan to sell our current or future tests and in which we operate, and may negatively impact business and healthcare activity globally. For example, in response to the COVID-19 pandemic, governments around the world imposed measures designed to reduce the transmission of COVID-19, patients postponed visits to healthcare providers, certain healthcare providers temporarily closed their offices or restricted patient visits, healthcare provider employees became generally unavailable and there were disruptions in the operations of payers, suppliers, and other third parties that are necessary for our tests to be administered. The extent to which fear of exposure to or actual effects of COVID-19, new variants, disease outbreak, epidemic or a similar widespread health concern impacts our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the speed and extent of geographic spread of the disease, the duration of the outbreak, travel restrictions, the efficacy of vaccination, and treatment; impact on the U.S. and international healthcare systems, the U.S. economy and worldwide economy; the timing, scope, and effectiveness of U.S. and international governmental response; and the impact on the health, well-being, and productivity of our employees; and short- and long-term changes in the behaviors of medical professionals and patients resulting from any such pandemic, outbreak, epidemic, or other health concern.

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

Genetic testing has raised ethical, legal, and social issues regarding privacy rights and the appropriate uses of the resulting information. Governmental authorities could, 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. Similarly, these concerns may lead patients to refuse to use, or clinicians to be reluctant to order, genetic tests even if permissible. These and other ethical, legal, and social concerns may limit market acceptance of our genetic tests or reduce the potential markets for these tests, either of which could have an adverse effect on our business, financial condition or results of operations.

Climate change, or legal or regulatory measures to address climate change or other corporate social responsibility and sustainability matters, could adversely affect our business, financial condition, and results of operations.

The effects of global climate change present risks to our business. Natural disasters, extreme weather, and other conditions caused by or related to climate change could adversely impact our supply chain, the courier delivery services we use, the availability and cost of raw materials and components, energy supply, water, transportation, or other inputs necessary for the operation of our business. Climate change and natural disasters could also impact behaviors of medical providers or patients or result in physical damage to our facilities as well as those of our suppliers, health care providers, and other business partners, all of which could negatively impact and disrupt our business and operations. Our facilities and our laboratory equipment would be costly to replace and could require substantial lead time to repair or replace. Although we believe we possess adequate insurance for the disruption of our business from causalities, such insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

New or additional legal or regulatory requirements may be enacted to reduce greenhouse gas emissions, mitigate the effects of climate change on the environment or address other corporate social responsibility and sustainability matters. Any such new or additional legal or regulatory requirements may increase the costs associated with, or disrupt, the development, manufacturing, and distribution of our tests or the performance of related services, which may adversely affect our business and financial results. In addition, any failure to adequately address stakeholder expectations with respect to corporate social responsibility and sustainability matters, including addressing climate change, may result in the loss of business, damage to our reputation, diluted market valuations, challenges in attracting and retaining talented employees and restrictions on certain aspects of our activities. Furthermore, our adoption of certain standards for our corporate social responsibility and sustainability efforts and related matters or mandated compliance to certain requirements could necessitate additional investments that could hinder our profitability.

The use of Artificial Intelligence presents new risks and challenges to our business.

Artificial Intelligence ("AI") is increasingly being used across the global business landscape, including in the life sciences and healthcare industries. We have already employed certain AI technologies into our business to enhance our operations, products, technology, and services and expect our use of AI to increase as the technology rapidly evolves and improves.

However, AI innovation presents risks and challenges that could impact our business. AI algorithms may be flawed. Datasets may be insufficient or contain biased information. Ineffective AI development and deployment practices by us or our commercial partners could result in violations of our confidentiality and privacy obligations or applicable laws and regulations, jeopardize our intellectual property rights, cause or contribute to unlawful discrimination, result in the misuse of personally identifiable information, including PHI, or give rise to significant cyber security risks, any of which could have a material adverse effect on our business, results of operations, and financial condition.

We may also face increased competition from other companies that are employing AI and related technologies, some of whom may develop more effective methods than we and any of our commercial partners have, which could have a material adverse effect on our business, results of operations, or financial condition. In addition, uncertainties regarding developing legal and regulatory requirements and standards may require significant resources to modify and maintain business practices to comply with U.S. and foreign laws concerning the use of AI and related technologies, the nature of which cannot be determined at this time.

We may be a party to litigation in the normal course of business or otherwise, which could affect our business and financial position.

From time to time, we are a party to or otherwise involved in legal proceedings, claims and government investigations, and other legal matters, both inside and outside the U.S., arising in the ordinary course of our business or otherwise. We are currently involved in various legal proceedings and claims that have not yet been fully resolved, and additional claims may arise in the future. Legal proceedings in which we are currently involved include those proceedings described in Note 15 of the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K ("Notes to Consolidated Financial Statements".

Additionally, the distribution, sale, use, and results of our tests could lead to liability claims. Legal proceedings can be complex and take many months, or even years, to reach resolution, with the final outcome depending on a number of variables, some of which are not within our control. From time to time, we may also be compelled to protect our business interests through the initiation of litigation against others. Litigation, whether offensive or defensive, is subject to significant uncertainty and may be expensive, time-consuming, and disruptive to our operations.

Although we will vigorously defend and advocate for ourselves in such legal proceedings, their ultimate resolution and potential financial and other impacts on us are uncertain. For these and other reasons, we may choose to settle legal proceedings and claims, regardless of their actual merit. If a legal proceeding is resolved against us, it could result in significant compensatory damages, and in certain circumstances punitive or trebled damages, disgorgement of revenue or profits, remedial corporate measures or injunctive relief imposed on us. Even if litigation is resolved in our favor, costs and disruptions to the Company may have a negative impact on business. If our existing insurance does not cover the amount or types of damages awarded, or if other resolution or actions taken as a result of a legal proceeding were to restrain our ability to operate, our financial position, results of operations or cash flows could be materially adversely affected. Any claim brought against us, with or without merit, could increase our liability insurance rates or prevent us from securing insurance coverage in the future. In addition, legal proceedings, and any adverse resolution thereof, can result in adverse publicity and damage to our reputation, which could adversely impact our business.

The amounts we record for legal contingencies can result from a complex series of judgments about future events and uncertainties and can rely heavily on estimates and assumptions. While we have accrued for certain potential legal liabilities, there is no guarantee that additional costs will not be incurred beyond the amounts accrued.

Risks Relating to Governmental Regulation and Reimbursement

We face uncertainty related to healthcare reform, pricing, coverage, and reimbursement.

We must navigate complex and evolving healthcare regulations, which control how we conduct our business and how we are paid. Existing legislation, and possible future legal and regulatory changes, including potential repeal or modification of the ACA, could materially change the structure and finances of the health insurance system and the methodology for reimbursing medical services, drugs, and devices, including our current and future products and services. The ACA has also been the subject of various legal challenges and if the plaintiffs in any case challenging the ACA are ultimately successful insurance coverage for our tests could be materially and adversely affected. For example, in June 2024, the Fifth Circuit Court of Appeals in *Braidwood Management v. Becerra* affirmed a district court ruling that the ACA's requirement that insurance cover certain

preventive services without cost sharing is unconstitutional. The *Braidwood* ruling remains subject to an ongoing appeal to the U.S. Supreme Court, which has agreed to hear the lawsuit with oral arguments expected in spring 2025 and a decision expected in the summer of 2025. We cannot predict the final outcome of the *Braidwood* matter, whether there will be additional future challenges to the ACA, or what impact, if any, such challenges may have on our business. Any change in reimbursement policy could result in a change in patient cost-sharing, which could adversely affect a provider's willingness to prescribe and patient's willingness and ability to use our tests and any other product or service we may develop. Healthcare reforms, which may intend to reduce healthcare costs, may have the effect of discouraging third-party payers from covering certain kinds of medical products and services, particularly newly developed technologies, like those we have developed in the past or we may develop in the future. We cannot predict whether future healthcare reform initiatives will be implemented at the federal or state level or the effect any such future legislation or regulation will have on us. The taxes imposed by new legislation, cost reduction measures and the expansion or contraction in the government's role in the U.S. healthcare industry may result in decreased profits to us, which may adversely affect our business, financial condition, and results of operations.

The Protecting Access to Medicare Act of 2014 ("PAMA") presents significant uncertainty for future CMS reimbursement rates. Because Medicare currently covers a significant number of our patients, any reduction in the CMS reimbursement rate for our tests would negatively affect our revenues and our business prospects. Under PAMA, CMS reimbursement rates for clinical diagnostic laboratory tests are updated every three years or annually for clinical laboratory tests that are considered "advanced diagnostic laboratory tests." There can be no assurance under PAMA that adequate CMS reimbursement rates will continue to be assigned to our tests.

Coverage of our Cologuard and Cologuard Plus tests and other screening or diagnostic products that we may develop may also depend, in whole or in part, on whether payers determine, or courts and/or legislative or regulatory authorities determine, coverage is required under applicable federal or state laws mandating coverage of certain cancer screening or diagnostic services. For example, while we believe the ACA Mandate requires most health insurers to cover our Cologuard and Cologuard Plus tests for most patients between the ages of 45 and 75 without patient cost-sharing, some health insurers have disagreed and determined not to cover our Cologuard and Cologuard Plus tests and others may take that position in the future. Further, states may decide to modify their laws, which may include repeal of those coverage mandates that we believe currently apply to our Cologuard and Cologuard Plus tests.

If payers, including managed care organizations, do not approve and maintain reimbursement for our tests at adequate reimbursement rates, our commercial success could be compromised.

Our commercial success depends, in large part, on the availability of reimbursement at adequate reimbursement rates for our current tests, including our flagship Cologuard and Oncotype tests and our products in development, from government insurance plans, managed care organizations and commercial insurance plans. Although we received positive coverage decisions and what we believe are adequate reimbursement rates from CMS for our Cologuard and Cologuard Plus tests, it is also critical that other third-party payers approve and maintain reimbursement for our Cologuard test at adequate reimbursement rates. We also have received positive coverage determinations for our Oncotype DX breast cancer test for N-, ER+ patients from most third-party payers, but have less favorable coverage for our other Oncotype tests. Additionally, successful commercialization of our newly developed products, including our Cologuard Plus test, our Oncodetect MRD test, and our Cancerguard MCED test, will also depend on our ability to obtain and maintain reimbursement from government insurance plans, managed care organizations, and commercial insurance plans at adequate reimbursement rates. Healthcare providers may be reluctant to prescribe, and patients may be reluctant to complete, our tests if they are not confident that patients will be reimbursed for our tests.

Third-party payers, both in the U.S. and internationally, are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for healthcare products and services. As a result, there is uncertainty surrounding the future level of reimbursement, if any, for our current tests and any new tests we may develop. Reimbursement by a third-party payer may depend on a number of factors, including a payer's determination that tests using our technologies are sufficiently sensitive and specific; not experimental or investigational; approved or recommended by the major guideline organizations; subject to applicable federal or state coverage mandates; reliable, safe, and effective; medically necessary; appropriate for the specific patient; and cost-effective. Moreover, coverage determinations and reimbursement rates are subject to change, and we cannot guarantee that even if we initially achieve adequate coverage and reimbursement rates for our tests, they will continue to apply in the future or remain adequate as we face increases in operating costs, such as labor and supply costs that are subject to inflation, and government and commercial payers may cause us to accept lower prices.

Even where a third-party payer agrees to cover one of our tests, other factors may have a significant impact on the actual reimbursement we receive from that payer. For example, if we do not have a contract with a given payer, we may be deemed an "out-of-network" provider by that payer, which could result in the payer allocating a portion of the cost of the test to the patient, notwithstanding any applicable coverage mandate. We may be unsuccessful in our efforts to enter into, or maintain, a network contract with a given payer, and we expect that our network status with a given payer may change from time to time for a variety of reasons, many of which may be outside our control. To the extent one of our tests is out of network for a given payer, healthcare providers may be less likely to prescribe that test for their patients and their patients may be less likely to comply with those prescriptions that are written. Also, some payers may mandate prior authorization or other medical management practices that impose significant additional costs on us, may be difficult to comply with given our position as a laboratory that generally does not have direct access to patient medical records, may make healthcare providers less likely to prescribe our tests for their patients, and may make patients less likely to comply with healthcare provider orders for our tests, all or any of which may have an adverse effect on our revenues.

If we are unable to obtain or maintain reimbursement at adequate reimbursement rates for our Oncotype DX tests outside of the U.S., our ability to expand internationally will be compromised.

The majority of our international Oncotype DX breast and colon cancer test revenues come from payer reimbursement, including from public or government-controlled or regulated payers, payments from our distributors, and patient self-pay. Obtaining reimbursement from public payers outside of the U.S. generally involves complex requirements that we may be unable to satisfy.

Even if public or private reimbursement is obtained, it may be discontinued, cover competing tests, or the reimbursement may be limited to a subset of the eligible patient population or conditioned upon local performance of the tests or other requirements we may have difficulty satisfying.

Reimbursement levels outside of the U.S. may vary considerably from the domestic reimbursement amounts we receive. In addition, because we generally rely on distributors to obtain reimbursement for our tests in certain countries outside of the U.S., to the extent we do not have direct reimbursement arrangements with payers, we may not be able to retain reimbursement coverage in those countries if our agreement with a distributor is terminated or expires, if a distributor fails to pay us or if other events prevent payment.

Failure to comply with federal, state, and foreign laboratory licensing and related requirements could cause us to lose the ability to perform our tests, experience disruptions to our business, or become subject to administrative or judicial sanctions.

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 certified laboratory. CLIA certification is also required in order for us to be eligible to bill state and federal healthcare programs, as well as commercial payers, for our tests. In addition, some states, including California and New York, require that we hold licenses or permits to test samples from patients in those states, even if our laboratory facilities are not located in those states, and as a result we are also required to maintain standards related to those states' licensure requirements to conduct testing in our laboratories.

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, on-site monitoring, civil monetary penalties, criminal sanctions, inability to receive reimbursement from Medicare, Medicaid, and commercial payers, 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, a state or foreign license or accreditation, 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.

We may also be subject to laboratory regulations in foreign jurisdictions as we seek to expand international utilization of our tests or as such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations such as restrictions on the transport of specimens necessary for us to perform our tests that may limit our ability to make our tests 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.

Our products could be subject to recall.

Manufacturers of medical devices must comply with various regulatory requirements under the FDCA and regulations thereunder, including, but not limited to, quality system regulations, unless they are exempt, facility registration, product listing, labeling requirements, and certain post-market surveillance requirements. If we do not meet applicable regulatory or quality standards, our products may be subject to recall, and, under certain circumstances, we may be required to notify applicable regulatory authorities about a recall. Any such recalls could have an adverse effect on our ability to provide our tests, which in turn would adversely affect our financial condition.

Delays in receipt of, or failure to obtain, required FDA clearances or approvals for our products in development, or improvements to or expanded indications for our current offerings, could materially delay or prevent us from commercializing or otherwise adversely impact future product commercialization.

Unless otherwise exempted or subject to enforcement discretion, medical devices, which include screening and diagnostic tests, must receive either FDA regulatory approval or clearance before being marketed in the U.S. Our Cologuard and Cologuard Plus tests are regulated by the FDA as medical device and we may develop new tests that are deemed medical devices and require FDA clearance or approval. Additionally, our current and future LDT products may be subject to some or all of the FDA medical device requirements under the LDT Rule. The FDA determines whether a medical device will require either regulatory approval or clearance based on statutory criteria that include the risk associated with the device and whether the device is similar to an existing, legally marketed product. The process to obtain either regulatory approval or clearance is costly, time-consuming, and uncertain. The regulatory approval process is generally more challenging than the clearance process. Even if we design a product that we expect to be eligible for the regulatory clearance process, the FDA may require that the product undergo the regulatory approval process. There can be no assurance that the FDA will ever permit us to market any new product that we develop. Even if regulatory approval or clearance is granted, such approval may include significant limitations on indicated uses, which could materially and adversely affect the prospects of any new medical device.

FDA regulatory approval or clearance is also required for certain enhancements we may make to our current tests or future FDA-approved or -cleared tests. FDA approval or clearance may also be required to make changes to the processes, equipment, reagents, and other consumables used in connection with a test. Some of our current LDTs that qualify as Grandfather LDTs under the LDT Rule may require FDA approval or clearance if they are modified beyond what FDA determines to be acceptable under the LDT Rule. The FDA's approval pathway can be time-consuming and costly and there can be no assurance that the FDA will ultimately approve any premarket approval submitted by us in a timely manner or at all.

In addition, the FDA's ability to review and clear or approve new products or changes to existing products can be affected by a variety of factors, including government budget, funding, and staffing levels, changes in Presidential administration, 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. Average review times at the agency have fluctuated in recent years as a result. In addition, prolonged government shutdowns or global health concerns may prevent or delay the FDA or other regulatory authorities from conducting, at all or in a timely manner, their regular inspections, reviews, or other regulatory activities (including pre-submission engagements). Any such delay in the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions could have a material adverse effect on our business.

Delays in receipt of, or failure to obtain, clearances or approvals could materially delay or prevent us from commercializing our products or result in substantial additional costs that could decrease our profitability. In addition, even if we receive FDA clearance or approval for a new or enhanced product, the FDA may condition, withdraw, or materially modify its clearance or approval.

The FDA's implementation of the LDT Rule may cause us to incur substantial costs and time delays associated with meeting requirements for pre-market clearance or approval or we could experience decreased demand for or reimbursement of our tests.

Our Oncotype tests, OncoExTra test, and certain other tests we offer are marketed as LDTs and we may seek to commercialize certain of our products in development as LDTs. LDTs are clinical laboratory tests that are developed and validated by a laboratory for its own use. The FDA historically has taken the position that it has the authority to regulate such tests as medical devices under the FDC Act but until recently has for the most part exercised enforcement discretion and has not required clearance, de novo classification, or approval of LDTs prior to marketing.

In May 2024, the FDA issued the LDT Rule which amended the FDA's regulations to make explicit that LDTs are devices under the FD&C Act. Along with the final rule, the FDA finalized a policy under which the FDA's historical LDT enforcement discretion will be phased out over the course of three years, as well as targeted enforcement discretion policies for certain categories of LDTs. Under the LDT Rule and this policy, (1) from May 2025 to May 2028 various requirements will be phased in including MDR requirements, correction and removal reporting requirements, registration and listing requirements, labeling requirements, investigational use requirements and quality system requirements, (2) beginning in November 2027, premarket review requirements will become applicable to high risk (e.g., Class III) LDTs and (3) beginning in May 2028, premarket review requirements will become applicable to moderate and low risk LDTs. LDTs that were first marketed prior to May 6, 2024 (and have not been significantly modified) ("Grandfathered LDTs") and LDTs for unmet medical needs manufactured and performed by laboratories integrated in a healthcare system, will not be subject to premarket review and most of the quality system requirements. Implementation and enforcement of the LDT Rule by the FDA may materially impact our development and commercialization of LDTs, including our Oncotype tests. The regulatory approval process may involve, among other things, successfully completing additional clinical studies and submitting a pre-market clearance notice or filing a pre-market approval application with the FDA. Such pre-market clinical testing could delay the commencement or completion of other clinical testing, significantly increase our test development costs, delay commercialization of any future LDTs, and interrupt sales of our current LDTs. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical studies may also ultimately lead to delay or denial of regulatory clearance or approval. If pre-market review is required by the FDA, there can be no assurance that our LDTs will be cleared or approved on a timely basis, if at all, nor can there be assurance that the labeling claims cleared or approved by the FDA will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our LDTs.

We are subject to numerous U.S. and foreign laws and governmental regulations, and any governmental enforcement action may materially affect our financial condition and business operations.

We are subject to regulation in the U.S. by both the federal government and the states in which we conduct our business, as well as in other jurisdictions outside of the U.S., including:

- Federal, state, and local laws regarding the use, storage, handling and disposal of medical and hazardous waste, as well as regulations relating to the safety and health of laboratory employees;
- the Federal Anti-Kickback Statute and state anti-kickback prohibitions and EKRA;
- the Federal Physician Self-Referral Law, commonly known as the Stark Law, and the state equivalents;
- the HIPAA, the CCPA, including expansions and amendments pursuant to the California Privacy Rights Act, and other state privacy laws;
- Federal, state, and local consumer protection laws governing communications and advertising, including the Telephone Consumer Protection Act ("TCPA"), the Controlling the Assault of Non-Solicited Pornography and Marketing Act ("CAN-SPAM Act"), and the Lanham Act;
- the Medicare civil money penalty and exclusion requirements;
- the Federal False Claims Act civil and criminal penalties and state equivalents; and
- the FCPA, the United Kingdom Anti-Bribery Act, the GDPR and other national or provincial laws protecting personal information, the E.U. Medical Device and In Vitro Diagnostic Device Regulations, and national laws restricting industry interaction with healthcare professionals, all of which may or will apply to our international activities.

We have adopted policies and procedures designed to comply with these laws. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance is also subject to governmental review. The growth of our business and sales organization and our expansion outside of the U.S. may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations.

The U.S. Attorney's Offices have increased their scrutiny over the healthcare industry in recent years. The U.S. Congress, U.S. Department of Justice ("DOJ"), Office of Inspector General of the Department of Health and Human Services, and Department of Defense have all issued subpoenas and other requests for information to conduct investigations of, and commenced, civil and criminal litigation against healthcare companies related to financial arrangements with healthcare providers, regulatory compliance, product promotional practices, and documentation, coding, and billing practices. In addition, the Federal False Claims Act and state equivalents have led to whistleblowers filing numerous qui tam civil lawsuits against healthcare companies, in part, because a whistleblower can receive a portion of any amount obtained by the government through such a lawsuit.

Governmental enforcement action or qui tam civil litigation against us may result in material costs and occupy significant management resources, even if we ultimately prevail. In addition, qui tam litigation or governmental enforcement action may result in substantial damages (including treble damages), fines, civil and criminal penalties, payment of attorney's fees, or administrative remedies, including exclusion from government reimbursement programs and entry into corporate integrity agreements with governmental agencies, which could entail significant obligations and costs. As described further in Note 15 of the Notes to Consolidated Financial Statements, in September 2023, we entered into settlement agreements with the United States, acting through the U.S. DOJ, with respect to (1) a civil investigative demand initiated by the U.S. DOJ concerning Genomic Health, Inc.'s ("Genomic Health") compliance with the Medicare Laboratory Date of Service billing regulations prior to our acquisition of Genomic Health in 2019 and (2) a qui tam lawsuit alleging violations of the Federal Anti-Kickback Statute and False Claims Act for offering gift cards to patients in exchange for returning the Cologuard screening test, for which Niles Rosen M.D., the petitioner in the qui tam lawsuit, was also a party to the settlement agreement. The settlement agreement between Genomic Health and the U.S. DOJ required us to pay $32.5 million, which was paid in September 2023 and the settlement agreement with the U.S. DOJ and Dr. Rosen required us to pay $13.8 million plus legal fees, which was paid in October 2023. Any such actions or litigation in the future could result in adverse penalties or outcomes that could materially and adversely affect our business, financial condition, and results of operations.

Our business is subject to various complex laws and regulations applicable to providers of clinical diagnostic products and services.

As a provider of clinical diagnostic products and services, we and our partners are subject to extensive and frequently changing federal, state, local, and foreign laws and regulations governing various aspects of our business. In particular, the clinical laboratory and healthcare industry is subject to significant governmental certification and licensing regulations, as well as federal, state, and foreign laws regarding:

- test ordering and billing practices;
- marketing, sales, and pricing practices;
- health information privacy and security, including HIPAA and comparable state and foreign laws;
- insurance, including foreign public reimbursement;
- anti-markup legislation; and
- consumer protection.

We are also required to comply with FDA regulations, including with respect to our labeling and promotion activities. In addition, advertising of our tests is subject to regulation by the Federal Trade Commission, or FTC, and advertising of laboratory services is regulated by certain state laws. Violation of any FDA requirement could result in enforcement actions, such as seizures, injunctions, civil penalties and criminal prosecutions, and violation of any FTC or state law requirement could result in injunctions and other associated remedies, all of which could have a material adverse effect on our business. Most states also have similar regulatory and enforcement authority for medical devices. Additionally, most foreign countries have authorities comparable to the FDA and processes for obtaining marketing approvals. In particular, the entry into application of the E.U.'s In Vitro Diagnostic Device Regulation will impose new requirements and create new compliance risks. Obtaining and maintaining these approvals, and complying with all laws and regulations, may subject us to similar risks and delays as those we could experience under FDA, FTC, and state regulation. We incur various costs in complying and overseeing compliance with these laws and regulations. The growth of our business and sales organization, the acquisition of additional businesses or products and services and our expansion outside of the U.S. may increase the potential of violating these laws, regulations or our internal policies and procedures.

Healthcare policy has been a subject of extensive discussion in the executive and legislative branches of the federal and many state governments, and healthcare laws and regulations are subject to change. Development of the existing commercialization strategy for our tests and planned development of products in our pipeline has been based on existing healthcare policies. We cannot predict what additional changes, if any, will be proposed or adopted or the effect that such proposals or adoption may have on our business, financial condition, and results of operations.

If we, or our partners, fail to comply with these laws and regulations, we could incur significant fines and penalties and our reputation and prospects could suffer. Additionally, any such partners could be forced to cease offering our products and services in certain jurisdictions, which could materially disrupt our business.

Due to billing complexities in the diagnostic and laboratory service industry, we may have difficulties receiving timely payment for the tests we perform, and may face write-offs, disputes with payers and patients, and long collection cycles.

Billing for diagnostic and laboratory services is a complex process. We bill many different payers including patients, private insurance companies, Medicare, Medicaid, and employer groups, all of which have different billing requirements.

We are continuing to work with third-party payers to cover and reimburse our tests. If we are unsuccessful, we may not receive payment for the tests we perform for patients on a timely basis, if at all, and we may not be able to provide services for patients with certain healthcare plans. We may face patient dissatisfaction, complaints or lawsuits, including to the extent our tests are not fully covered by insurers and patients become responsible for all or part of the price of the test. As a result, patient demand for our tests could be adversely affected. To the extent patients express dissatisfaction with our billing practices to their healthcare providers, those healthcare providers may be less likely to prescribe our tests for other patients, and our business would be adversely affected.

Even if payers agree to cover our tests, our billing and collections process may be complicated by the following and other factors, which may be beyond our control:

- complex and disparate reimbursement rules and requirements;
- disputes among payers as to which payer is responsible for payment;
- disparity in coverage among various payers or among various healthcare plans offered by a single payer;
- payer medical management requirements, including prior authorization requirements;
- differing information and billing requirements among payers;
- failure by patients or healthcare providers to provide complete and correct billing information; and
- limitations and requirement for patient billing, including those related to deductibles, co-payments, and co-insurance originating from contracts with commercial payers.

For example, pursuant to certain CMS rules (the "Medicare Laboratory Date of Service billing regulation"), subject to certain exceptions issued by CMS, we cannot bill Medicare directly for some tests provided for Medicare beneficiaries in some situations involving certain hospital patients and instead must bill hospitals for such tests. In these circumstances, only the hospital may bill Medicare for such tests. These billing rules may lead to confusion regarding whether Medicare provides adequate reimbursement for our tests, and could discourage providers from ordering our tests for Medicare patients or even non-Medicare patients. In addition, changes in Medicare billing rules and processes could result in delays in receiving payments or receiving payments that are less than the original invoice. When hospitals disclaim responsibility for or delay payment of our bills for tests affected by the Medicare Laboratory Date of Service billing regulation, and when our collection efforts are unsuccessful, we may be forced to accept payments from hospitals that are less than the original invoice or we may be unable to collect from hospitals at all despite diligent efforts.

Similarly, when we have a contract with a commercial payer to cover our tests, we are not permitted to bill patients insured by that payer for amounts beyond deductibles, co-payments, and co-insurance as prescribed in the coverage agreement between the payer and the patients. Therefore, when such contracted payers do not pay us our full, contracted rate for a test, for example, for failure to satisfy prior-authorization or other payer medical management requirements, we may not be permitted to collect the balance from the patient and our business is adversely impacted.

In the past, failures to submit claims to insurers timely have required us to record downward adjustments to our revenue. Despite efforts to improve our billing systems and prevent recurrences of these failures, future failures to timely submit claims could result in further downward adjustments to revenue.

As a result of the above, we may face write-offs of doubtful accounts, disputes with payers and patients, and long collection cycles.

We also may face lawsuits by government or commercial payers if they believe they have overpaid us for our test services or as a result of other circumstances. For example, as described in Note 15 of the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K, in September 2023, Genomic Health, entered into a settlement agreement with the United States, acting through the U.S. DOJ, to resolve a civil investigation concerning Genomic Health's compliance with the Medicare Date of Service billing regulation prior to our acquisition of Genomic Health in 2019. This settlement agreement required us to pay $32.5 million, which was paid in October, 2023.

Some of our activities may subject us to risks under federal and state laws prohibiting "kickbacks" and false or fraudulent claims.

In addition to FDA marketing and promotion restrictions, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the healthcare product and service industry and to regulate billing practices and financial relationships with healthcare providers, hospitals, and other healthcare providers. These laws include a federal law commonly known as the Medicare/Medicaid anti-kickback law, and several similar state laws, which prohibit payments intended to induce healthcare providers or others either to refer patients or to acquire or arrange for or recommend the acquisition of healthcare products or services. While the federal law applies only to referrals, products or services for which payment may be made by a federal healthcare program, state laws often apply regardless of whether federal funds may be involved. These laws constrain the sales, marketing, and other promotional activities of manufacturers of medical devices and providers of laboratory services by limiting the kinds of financial arrangements, including sales programs, that may be used with hospitals, healthcare providers, laboratories, and other potential purchasers or prescribers of medical devices and laboratory services. In addition, the Eliminating Kickbacks in Recovery Act of 2018

imposes criminal penalties for knowing or willful payment or offer, or solicitation or receipt, of any remuneration, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for the referral or inducement of laboratory testing (among other healthcare services) unless a specific exception applies. Although it appears that EKRA was intended to reach patient brokering and similar arrangements to induce patronage of substance use recovery and treatment, the language in EKRA is broadly written and can apply to laboratory services covered under public or private payer arrangements. EKRA permits the DOJ to issue regulations clarifying EKRA's exceptions or adding additional exceptions, but it has not done so. As a result, there is no agency guidance and limited court precedent to indicate how, and to what extent, it will be applied and enforced. We cannot assure you that our relationships with healthcare providers, sales representatives, hospitals, customers, or any other party will not be subject to scrutiny or will survive regulatory challenge under EKRA. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, or are for items or services that were not provided as claimed.

Additionally, to avoid liability under federal false claims laws, we must carefully and accurately code claims for reimbursement, proactively monitor the accuracy and appropriateness of Medicare claims and payments received, diligently investigate any credible information indicating that we may have received an overpayment, and promptly return any overpayments. Medicare payments are subject to audit, including through the Comprehensive Error Rate Testing ("CERT") program, and payments may be recouped by CMS if it is determined that they were improperly made. Currently, a significant percentage of our revenues are generated by payments from Medicare. The federal anti-kickback statute and certain false claims laws prescribe civil and criminal penalties (including fines) for noncompliance that can be substantial. While we continually strive to comply with these complex requirements, interpretations of the applicability of these laws to marketing and billing practices are constantly evolving and even an unsuccessful challenge could cause adverse publicity and be costly to respond to, and thus could harm our business and prospects. Our failure to comply with applicable laws could result in various adverse consequences that could have a material adverse effect upon our business, including the exclusion of our products and services from government programs and the imposition of civil or criminal sanctions.

Some of our activities may subject us to risks under the Foreign Corrupt Practices Act and similar anti-bribery laws in non-U.S. jurisdictions.

Many countries in which we or our distributors offer our tests have regulations prohibiting providers, as well as medical and in vitro diagnostic device manufacturers, from offering or providing a benefit to a healthcare professional in order to induce business. In situations involving healthcare providers employed by public or state-funded institutions or national healthcare services, violation of local anti-corruption or anti-gift laws may also constitute a violation of the FCPA.

The FCPA prohibits any U.S. individual, business entity or employee of a U.S. business entity from offering or providing, directly or through a third party, including the distributors we 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. We are also 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. Other countries, including the U.K. and other Organisation for Economic Co-operation and Development ("OECD") Anti-Bribery Convention members, have similar extraterritorial anti-corruption laws.

While there currently exists uncertainty regarding future enforcement of the FCPA, any violation of these laws, or allegations of such violations, by us or any of our commercial partners could disrupt our operations, involve significant management distraction, cause us to incur significant costs and expenses, including legal fees, and result in a material adverse effect on our business. We could also suffer severe penalties, including criminal and civil penalties, debarment from public procurement, disgorgement and other remedial measures.

Failure to comply with privacy, security, and consumer protection laws and regulations could result in fines, penalties, and damage to our reputation and have a material adverse effect on our business.

We are subject to a number of foreign, federal, and state laws and regulations protecting the use, disclosure, and confidentiality of certain patient health and personal information, including patient records, and restricting the use and disclosure of that protected information, including state breach notification laws, the Health Insurance Portability and Accountability Act, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, the European Union's General Data Protection Regulation, the U.K. Data Protection Act and the U.K. GDPR, and the California Consumer Privacy Act, among others.

HIPAA extensively regulates the use and disclosure of individually identifiable health information, known as "protected health information," and require covered entities, including health plans and most health care providers, to implement administrative, physical and technical safeguards to protect the security of such information. Covered entities must report breaches of unsecured protected health information to affected individuals without unreasonable delay and notification must also be made to the U.S. Department of Health & Human Services, Office for Civil Rights (the "OCR") and, in certain situations involving large breaches, to the media. Various U.S. state laws and regulations may also require us to notify affected individuals and state agencies in the event of a data breach involving individually identifiable information.

Violations of the HIPAA privacy and security regulations may result in criminal and civil penalties. The OCR enforces the regulations and performs compliance audits. In addition to enforcement by OCR, state attorneys general are authorized to bring civil actions seeking either injunction or damages in response to violations that threaten the privacy of state residents. We follow and maintain a HIPAA compliance program, which we believe complies with the HIPAA privacy and security regulations, but there can be no assurance that OCR or other regulators will agree. The HIPAA privacy regulations and security regulations have and will continue to impose significant costs on us in order to comply with these standards.

We also remain subject to state privacy-related laws, such as the CCPA, that are more restrictive than the privacy regulations issued under HIPAA. These laws vary and could impose additional penalties.

We utilize our patient adherence program to communicate with patients who are existing or potential users of our products and services for various business purposes. These activities could subject us to laws, rules and regulations relating to communications with consumers, such as the CAN-SPAM Act and the TCPA. Despite our compliance efforts, we could face allegations that we have violated these laws, rules, and regulations as we have in the past. Even if such allegations are without merit, we could face liability and harm to our reputation.

We are also subject to laws and regulations in foreign countries covering data privacy and other protection of health and employee information that may be more onerous than corresponding U.S. laws, including in particular the laws of Europe.

For instance, the GDPR applies across the European Union and includes, among other things, a requirement for prompt notice of data breaches to data subjects and supervisory authorities in certain circumstances and significant fines for non-compliance. The GDPR also requires companies processing personal data of individuals residing in the European Union to comply with EU privacy and data protection rules, even if we do not have a physical presence in the European Union. Noncompliance could result in the imposition of fines, penalties, or orders to stop noncompliant activities.

These laws and regulations, in addition to similar laws and regulations being enacted by other states and counties, impose stringent cybersecurity standards and potentially significant non-compliance penalties, involve the expenditure of significant resources, the investment of significant resources, and the investment of significant time and effort to comply. As these laws and regulations continue develop in the United States and internationally, we may be required to expend significant time and resources in order to update existing processes or implement additional mechanisms as necessary to ensure compliance with such cybersecurity laws.

Our employees, independent contractors, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct, or other illegal activity by our employees, independent contractors, consultants, commercial partners, and vendors. Misconduct by these parties could include intentional, reckless, and negligent conduct that fails to comply with the rules and regulations of the CMS, FDA, and other comparable foreign regulatory authorities; provide true, complete and accurate information to such regulatory authorities; comply with manufacturing and clinical laboratory standards; comply with healthcare fraud and abuse laws in the U.S. and similar foreign laws; or report financial information or data accurately or to disclose unauthorized activities to us. In particular, research, sales, marketing, education, and other business arrangements in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing, bribery, and other abusive practices, as well as off-label product promotion. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs, and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of participant recruitment for clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We maintain a global compliance program, including a code of business conduct and ethics and processes and systems for reporting, reviewing, and remediating allegations of potential non-compliance or other misconduct, but it is not always possible to identify and deter misconduct by employees and third parties,

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 be in compliance with such laws. 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 fines or other sanctions. Even if it is later determined after an action is instituted against us that we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions, and have to divert significant management resources from other matters.

Changes in tax laws or regulations or exposure to tax liabilities could adversely affect our financial condition and results of operations.

We are subject to tax in multiple U.S. tax jurisdictions and in foreign tax jurisdictions as we continue to expand internationally. As we grow, the development of our tax strategies requires additional expertise and may impact how we conduct our business. Our future effective tax rates could be unfavorably affected by changes in, or interpretations of, tax rules and regulations in the jurisdictions in which we do business or by changes in the valuation of our deferred tax assets and liabilities. Furthermore, we provide for certain tax liabilities that involve significant judgment. We are subject to the examination of our tax returns by federal, state, and foreign tax authorities, which could focus on our intercompany transfer pricing methodology as well as other matters. If our tax strategies are ineffective or we are not in compliance with domestic and international tax laws, our financial position, operating results, and cash flows could be adversely affected.

Risks Relating to Product Development, Commercialization, and Sales of our Products

The success of the screening and diagnostic products and services we currently offer or may offer in the future will depend on the degree of market acceptance by healthcare providers, patients, healthcare payers, and others in the medical community.

Our products and services may not gain market acceptance by healthcare providers, healthcare payers, and others in the medical community. The degree of market acceptance of our Cologuard test, Cologuard Plus test, our precision oncology tests, and other products and services that we offer will depend on a number of factors, including:

- demonstrated performance and utility;
- price;
- the availability and attractiveness of alternative tests;
- inclusion in healthcare guidelines and recommendations and quality measures;
- effective marketing and educational programs;
- recommendations and studies that may be published by government agencies, companies, professional organizations, academic or medical journals or other key opinion leaders;
- the willingness of healthcare providers to prescribe our products and services;
- the ease of use of our ordering process for healthcare providers; and
- adequate third-party coverage or reimbursement.

Uncertainty in the development and commercialization of our new tests or services could materially adversely affect our business, financial condition and results of operations.

Our success will depend in part on our ability to effectively introduce and increase market adoption of new offerings. The development and launch of new tests requires the completion of certain clinical development and commercialization activities that are complex, costly, time-intensive and uncertain, and requires us to accurately anticipate the preferences and needs of patients, clinicians, payers, and other counterparties, as well as emerging technology and industry trends. This process is conducted in various stages, and each stage presents the risk that we will not achieve our goals. We may not be successful in our current or future efforts to develop and commercialize tests in industries that are newer to us. Moreover, we have limited experience forecasting our future financial performance from our new products in these industries that are newer to us, and our actual results may fall below our financial guidance or other projections, or the expectations of analysts or investors, which could cause the price of our common stock to decline.

We may experience research and development, regulatory, marketing, and other difficulties that could delay or prevent our introduction of enhanced or new tests and result in increased costs and the diversion of management's attention and resources from other business matters, such as from our existing product offerings. For example, any tests that we may enhance or

develop may not prove to be clinically effective in clinical trials or commercially, or may not ultimately meet our desired target product profile, be offered at acceptable cost and with the sensitivity, specificity, and other test performance metrics necessary to address the relevant clinical need or commercial opportunity; our test performance in commercial experience may be inconsistent with our validation or other clinical data; we may not be successful in achieving market awareness and demand, whether through our own sales and marketing operations or through collaborative arrangements; healthcare providers may not order or use, or third-party payers may not reimburse for, any tests that we may enhance or develop; or we may otherwise have to abandon a test or service in which we have invested substantial resources. We cannot assure you that we can successfully complete the clinical development of any new or enhanced product, or that we can establish or maintain the collaborative relationships that may be essential to our clinical development and commercialization efforts.

Clinical development requires large numbers of patient specimens and, for certain products, requires large, prospective clinical trials. We may not be able to enroll patients or collect a sufficient number of appropriate specimens in a timely manner; or we may experience delays during clinical development due to slower than anticipated enrollment or due to changes in study design or other unforeseen circumstances; or we may be unable to afford or manage the large-sized clinical trials that some of our planned future products may require.

The publication of clinical data in peer-reviewed journals is a crucial step in commercializing and obtaining reimbursement for tests like ours, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenues from any test that is the subject of a study. Peer-reviewed publications regarding our tests may be limited by many factors, including delays in the completion of, poor design of, or lack of compelling data from, clinical studies, as well as delays in the review, acceptance, and publication process. If our tests or the technology underlying our current or future tests do not receive sufficient favorable exposure in peer-reviewed publications, the rate of clinician adoption of our tests and positive reimbursement coverage determinations for our tests could be negatively affected.

In addition, development of the data necessary to obtain regulatory clearance and approval of a test is time-consuming, requires us to incur significant costs, and carries with it the risk of not yielding the desired results. The performance achieved in published studies may not be repeated in later studies that may be required to obtain FDA premarket clearance or approval or regulatory approvals in foreign jurisdictions. Limited results from earlier-stage verification studies may not predict results from studies in larger numbers of subjects drawn from more diverse populations over longer periods of time. Unfavorable results from ongoing preclinical and clinical studies may delay, limit or prevent regulatory approvals or clearances or commercialization of our product candidates, or could result in delays, modifications or abandonment of ongoing analytical or future clinical studies, or abandonment of a product development program, any of which could have a material adverse effect on our business, operating results or financial condition. These and other factors beyond our control could result in delays or other difficulties in the research and development, approval, production, launch, ongoing commercialization, or distribution of enhanced or new tests and could adversely affect our competitive position and results of operations.

If we do not successfully manage the launch and marketing of new products or services, our financial results could be adversely affected.

We face risks associated with launching new products and pre-announcing products and services when the products or services have not been fully developed or tested. In addition, we may experience difficulty in managing or forecasting customer reactions, purchasing decisions, transition requirements, or programs with respect to newly-launched products (or products in development). If our products and services are not able to deliver the performance or results expected by our target markets or are not delivered on a timely basis, our reputation and credibility may suffer. If we encounter development challenges or discover errors in our products late in our development cycle, we may delay the product launch date. The expenses or losses associated with unsuccessful product development or launch activities, or a lack of market acceptance of our new products, could adversely affect our business, financial condition, or results of operations.

In 2025, we are preparing to launch new screening and diagnostic tests including Cologuard Plus, our Oncodetect MRD test for patients with colorectal cancer, and our Cancerguard MCED test. The expenses associated with these launch activities are expected to be significant. Successful launches of these tests will involve a number of critical items including securing adequate reimbursement from both government and private payers, and developing effective marketing and sales programs. The knowledge and experience we gained commercializing our Cologuard and precision oncology tests may not translate into successful commercialization efforts with respect these or other new products.

Although our Cologuard Plus test has demonstrated superior performance to our Cologuard test, it will nevertheless require significant effort on our part and take time to transition physicians to ordering the new test. These transition efforts include processing both the Cologuard and Cologuard Plus tests in our facilities and updating our information technology platforms. In November 2024 our Cologuard Plus test, received reimbursement coverage from Medicare beginning on January 1, 2025. However, securing reimbursement from other payers will also require significant efforts on our part and take time to achieve.

Although we believe our Oncodetect data demonstrates the utility of the test, successful commercialization will depend on our ability to garner acceptance in the medical community. We have submitted data from the clinical validation study for our Oncodetect MRD test to MolDX, which identifies and establishes Medicare coverage and reimbursement for molecular diagnostic tests, but there is no guarantee we will secure such coverage and reimbursement from Medicare or other payers. After its initial launch, our Oncodetect test may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payers, such as Medicare and Medicaid programs and managed care organizations, and others in the medical community.

Recommendations, guidelines, and quality metrics issued by various organizations may significantly affect payers' willingness to cover, and healthcare providers' willingness to prescribe or order, our products.

Securing influential recommendations, inclusion in healthcare guidelines, and inclusion in quality measures are keys to our healthcare provider and payer engagement strategies. These guidelines, recommendations, and quality metrics may shape payers' coverage decisions and healthcare providers' cancer screening procedures.

The USPSTF, a panel of primary care providers and epidemiologists and other national experts funded by the U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality, makes influential recommendations on clinical preventive services. USPSTF updates its screening recommendations periodically, approximately every five to eight years. The USPSTF's most recent recommendation statement for colorectal cancer screening gave an "A" grade to colorectal cancer screening starting at age 50 and continuing until age 75 and gave a "B" grade to colorectal cancer screening for ages 45 to 49. Any update to the USPSTF recommendations that may have the effect of reducing screening, that does not include FIT-DNA in a favorable manner, or that adds new technologies could have a material adverse effect on our business.

Maintaining a high USPSTF recommendation for our Cologuard test and Cologuard Plus test may have certain potentially significant implications. For example, the ACA mandates that certain non-grandfathered health insurers cover evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of USPSTF without imposing any patient cost-sharing. Similarly, federal regulations require that Medicare Advantage plans cover "A" or "B" graded preventive services without patient cost-sharing. Following the updated 2016 USPSTF recommendation statement, CMS issued an updated Evidence of Coverage notice for Medicare Advantage plans that affirms such plans must include coverage of our Cologuard test every three years without patient cost-sharing. While we believe the ACA Mandate requires certain health insurers to cover our Cologuard test and Cologuard Plus test for individuals between the ages of 45 and 75 without patient cost-sharing, some health insurers have disagreed. Enforcement of the ACA Mandate is difficult and depends on state, federal, or other third-party enforcement actions that we do not control. Further, a court or regulatory agency may agree with arguments that have been made, or that may in the future be made, by insurers and determine that the ACA Mandate does not require that they cover our Cologuard test, Cologuard Plus test, or future tests we may develop or may otherwise interpret the ACA Mandate in a manner unfavorable to us. Also, Congress may modify or repeal all or part of the ACA, and any such modification or repeal may repeal or limit the ACA Mandate for preventive services. Additionally, the ACA has also been the subject of various legal challenges and, if the plaintiffs are successful in any such challenges, insurance coverage for our Cologuard test, Cologuard Plus test, or future tests we develop could be materially and adversely affected. If for any of these reasons the ACA Mandate ceases to require coverage of our Cologuard test, Cologuard Plus test, or future tests we may develop or we are otherwise unable to secure effective enforcement of such mandate, our business prospects may be adversely affected.

The healthcare industry in the U.S. has experienced a trend toward cost containment and value-based purchasing of healthcare services. Some government and private payers are adopting pay-for-performance programs that differentiate payments for healthcare services based on the achievement of documented quality metrics, cost efficiencies, or patient outcomes. Payers may look to quality measures such as the NCQA, HEDIS, and the CMS Medicare Advantage Star Ratings to assess quality of care. These measures are intended to provide incentives to service providers to deliver the same or better results while consuming fewer resources. Our Cologuard test has been included in NCQA's HEDIS measures since 2017 and in CMS's Medicare Advantage Star Ratings since 2018. If for some reason our Cologuard test was removed from or not included in HEDIS, the Star Ratings, or other quality metrics, payers may be less inclined to reimburse our Cologuard test at adequate levels, if at all, which could adversely impact our business. Additionally, if our Cologuard test was removed from or not

included in HEDIS, the Star Ratings, or other quality metrics, healthcare providers may not earn quality credit for prescribing our Cologuard test and therefore may be less inclined to do so. If our Cologuard test or Cologuard Plus test fails to maintain its current position within any updated USPSTF colorectal cancer screening recommendations, our Cologuard test or Cologuard Plus test may, as a result, become excluded from the HEDIS measures and the Star Ratings.

We expect to continue to make significant investments in our research and development efforts, which may not be successful.

We expect to incur significant expenses on development efforts to improve our current products and develop a pipeline for future products and services, but such efforts may not be successful. Developing new or improved cancer tests is a speculative and risky endeavor. Candidate products and services that may initially show promise may fail to achieve the desired results in larger clinical studies or may not achieve acceptable levels of clinical accuracy. Results from early studies or trials are not necessarily predictive of future clinical study or trial results, and interim results of a trial are not necessarily indicative of final results. Significant adverse differences between initial or interim data and final data could significantly harm our reputation and business prospects.

Any cancer screening or diagnostic test we develop will need to demonstrate in clinical studies a high level of accuracy. Because cancer screening tests seek to identify relatively rare occurrences, if in a clinical study a candidate product or service fails to identify even a small number of cancer cases, the sensitivity rate may be materially and adversely affected and we may have to abandon the candidate product or service. Any cancer diagnostic test we develop will need to address an unmet medical need with accurate performance and utility.

We may need to explore a number of different biomarker combinations, alter our candidate products or platform technologies, and repeat clinical studies before we identify a potentially successful candidate. We may need to acquire, whether through purchase, license or otherwise, technologies owned by third parties, and we may not be able to acquire such technologies on commercially reasonable terms or at all. We also require human sample types, such as blood, tissue, and stool for our research and product development, which may not be available to us on a timely basis or commercially reasonable terms. Our inability to negotiate access to such clinical samples or the ability of other laboratories or our competitors to secure access to these samples before us could limit or delay our ability to research, develop, and commercialize future products. Product development is expensive, may take years to complete, and can have uncertain outcomes. Failure can occur at any stage of development. If, after development, a candidate product or service appears successful, we may, depending on the nature of the product or service, still need to obtain FDA and other regulatory clearances or approvals before we can market it. There can be no guarantee that the FDA would clear or approve any future product or service we may develop.

Even if the FDA and other regulatory authorities clear or approve a new product or service we develop, we would need to commit substantial resources to commercialize, sell, and market it before it could be profitable, and the product or service may never be commercially viable. In developing a test, we must make numerous assumptions regarding the commercial viability of a test, including with respect to healthcare providers' and patients' interest in a test, payers' willingness to pay for a test, our costs to perform a test, and availability and attractiveness of competing offerings. Frequently, we must make those assumptions many years before a test is ready for clinical use.

If we determine that any of our current or future development programs is unlikely to succeed, we may abandon it without any return on our investment into the program. We may need to raise significant additional capital to bring any new products or services to market, which may not be available on acceptable terms, if at all.

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

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies or 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 evaluate all data at time of disclosure. As a result, the topline or preliminary 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 preclinical and 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 patient enrollment continues and more patient data become available. Differences between preliminary, topline or interim data and final data could significantly harm our business prospects. Further, disclosure of such data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, such as the FDA, 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 clinical study is based on what is typically extensive information, and you or others may not agree with what we determine is 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 a particular product, product candidate or our business.

If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Our industry is subject to rapid change, which could make our current products and any future products we may develop, obsolete.

Our industry is characterized by rapid changes, including technological and scientific breakthroughs, frequent new product introductions and enhancements and evolving industry standards, all of which could make our current and future products obsolete. Our future success will depend on our ability to keep pace with the evolving needs of our customers 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 platform and develop new products to keep pace with evolving standards of care. If we do not update our product offerings 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 may develop could decline or fail to grow as expected.

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

Our estimates of the annual total addressable markets for our current products and products under development are based on a number of internal and third-party estimates, including, without limitation, the size of screening and patient populations, adoption rates and screening intervals, and the assumed prices at which we can sell tests for 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 total addressable market 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 our products, or the annual total addressable market for our products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business.

Our dependence on distributors for sales in many countries outside of the U.S. could limit or prevent us from selling our tests in those countries and impact our revenue.

As of December 31, 2024, we have entered into exclusive distribution agreements for the sale of our Oncotype tests with distributors covering dozens of countries. We may enter into other similar arrangements to distribute our tests in other countries in the future. We intend to continue growing our business internationally, and to do so we may need to attract additional distributors to expand the territories in which we sell our tests. Despite contractual obligations, distributors may not commit the necessary resources to market and sell our tests to the level of our expectations. If current or future distributors do not perform adequately, or we are unable to enter into or maintain arrangements with distributors to market our tests in particular geographic areas, we may not realize long-term international revenue growth. Additionally, local laws may make it very difficult or costly for us to terminate or replace distributors, and local public procurement law may complicate providing our centralized laboratory services through a distributor. Furthermore, our revenue from distributors could be negatively impacted as a result of changes in business cycles, business or economic conditions, coverage determinations, reimbursement rates, changes in foreign currency exchange rates that make our tests more expensive in our distributors' local currencies, or other factors that could affect their ability to pay us for tests on a timely basis or at all.

Risks Relating to our Intellectual Property

We rely on strategic collaborative and licensing arrangements with third parties to develop critical intellectual property. We may not be able to successfully establish and maintain such intellectual property.

The development and commercialization of our products and services rely, directly or indirectly, upon strategic collaborations and licensing agreements with third parties. We have collaborative and licensing arrangements with Mayo Foundation for Medical Education and Research, under which Mayo provides us with certain exclusive and non-exclusive intellectual property rights and ongoing product development and research and development assistance. In addition, we have licensing agreements with other partners that provide us with intellectual property and other business rights crucial to our product development and commercialization. We have incorporated licensed technology into our commercialized tests and expect to continue relying on, and incorporating, licensed technology into our pipeline products. Our dependence on licensing, collaboration, and other similar agreements with third parties may subject us to a number of risks. There can be no assurance that any current contractual arrangements between us and third parties or between our strategic partners and other third parties will be continued on materially similar terms and will not be breached or terminated early. Any failure to obtain or retain the rights to necessary technologies on acceptable commercial terms could require us to re-configure our products and services, which could negatively impact their commercial sale or increase the associated costs, either of which could materially harm our business and adversely affect our future revenues and ability to achieve sustained profitability.

In addition, establishing new strategic collaborations and licensing arrangements is difficult and time-consuming. Discussions with potential collaborators or licensors may not lead to the establishment of collaborations on favorable terms, if at all. To the extent we agree to work exclusively with one collaborator in a given area, our opportunities to collaborate with other entities could be limited. Potential collaborators or licensors may reject collaborations with us based upon their assessment of our financial, regulatory, or intellectual property position or other factors. Even if we successfully establish new collaborations, these relationships may never result in the successful commercialization of any product or service. In addition, the success of the projects that require collaboration with third parties will be dependent on the continued success of such collaborators. There is no guarantee that our collaborators will continue to be successful and, as a result, we may expend considerable time and resources developing products or services that will not ultimately be commercialized.

We may be subject to substantial costs and liability or be prevented from using technologies incorporated in our screening or diagnostic tests as a result of litigation or other proceedings relating to patent or other intellectual property rights.

Third parties may assert infringement or other intellectual property claims against our licensors, our licensees, our suppliers, our strategic partners, or us. We pursue a patent strategy that we believe provides us with a competitive advantage in the early detection of cancer and pre-cancer as well as in the guidance of cancer treatment decisions, and is designed to maximize our patent protection against third parties. We have filed patent applications that we believe cover the methods we have designed and use in our Cologuard and Cologuard Plus tests to detect colorectal cancer and pre-cancer, our Oncotype tests to provide prognosis and guide treatment decisions, and for pipeline cancer tests still in development. In order to protect or enforce our patent and other intellectual property rights, we may have to initiate actions against third parties. Any actions regarding patents could be costly and time-consuming and divert the attention of our management and key personnel from our business. Additionally, such actions could result in challenges to the validity, enforceability, or applicability of our patents. Because the U.S. Patent and Trademark Office ("USPTO") maintains patent applications in secrecy until a patent application publishes or the patent is issued, we have no way of knowing if others may have filed patent applications covering technologies used by our partners or us. Additionally, there may be third-party patents, patent applications, and other intellectual property relevant to our technologies that may block or compete with our technologies. From time to time we have received correspondence from third parties alleging to hold intellectual property rights that could block our development or commercialization of products. While none of these inquiries to date have had any material effect on us, we may receive inquiries in the future that could have a material effect on our business. Even if third-party claims are without merit, defending a lawsuit may result in substantial expense to us and may divert the attention of management and key personnel. In addition, we cannot provide assurance that we would prevail in any such suits to the extent necessary to conduct our business according to our strategic plan or that the damages or other remedies, if any, awarded against us would not be substantial. Claims of intellectual property infringement may require that we, or our strategic partners, enter into royalty or license agreements with third parties that may only be available on unacceptable terms, if at all. These claims may also result in injunctions against the further development and commercial sale of services or products containing our technologies, which would have a material adverse effect on our business, financial condition, and results of operations.

If we are unable to protect or enforce our intellectual property effectively, we may be unable to prevent third parties from using our intellectual property, which would impair any competitive advantage we may otherwise have.

We rely on patent protection as well as a combination of trademark, copyright, and trade secret protection and other contractual restrictions to protect our proprietary technologies and other intellectual property rights, 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 and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property, which may not be entirely successful, if at all. Additionally, certain of our patents have begun to expire. This loss of intellectual property protection may permit third parties to use certain intellectual property assets previously exclusively reserved for our use.

We cannot assure you that any of our currently pending or future patent applications will result in issued patents, and we cannot predict how long it will take for any such patents to be issued. Further, we cannot assure you that other parties will not challenge any patents issued to us or that courts will hold our patents to be valid or enforceable. We have been in the past, and may be in the future, the subject of pre- or post- grant proceedings challenges at the USPTO or international patent offices to determine priority of invention or validity of a patent, which could result in substantial cost to us as well as a possible adverse decision as to the priority of invention or validity of the patent involved. An adverse decision in any such challenge may result in the loss of rights under a patent or patent application. We cannot guarantee that we will be successful in defending challenges made against our patents and patent applications. Any successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents. Additionally, agency workforce reductions or turnover could delay or change the outcome of approvals or decisions on which we rely to protect our intellectual property.

Even where we have valid patents, third parties may be able to successfully design their products and services around those patents, such that their products and services do not infringe our patents. We may face competition internationally in jurisdictions where we do not have intellectual property protection. Our business may be adversely affected to the extent third parties are able to develop or commercialize competing products and services that do not infringe our patents. We may also be adversely affected to the extent third parties develop or commercialize competing products or services in countries where we did not apply for patents, where our patents have not issued, or where our intellectual property rights are not recognized or are poorly enforced.

We depend on trademarks to establish a market identity for our company and our products and services. To maintain the value of our trademarks, we may have to file lawsuits against third parties to prevent them from using trademarks confusingly similar to or dilutive of our registered or unregistered trademarks. We also may not obtain registrations for our pending or future trademark applications, and might have to defend our registered trademarks and pending applications from challenges by third parties. Enforcing or defending our registered and unregistered trademarks might result in significant litigation costs and, if we are unsuccessful, might result in damages, including the inability to continue using certain trademarks.

We are currently engaged in patent infringement lawsuits against Geneoscopy for its infringement of multiple Company patents. Geneoscopy has in response alleged several claims against us, in addition to asking for the USPTO to reexamine the patentability of the patents in dispute. More information on these matters can be found in Note 15 of our Notes to Consolidated Financial Statements. Defending these lawsuits and patent challenges may result in substantial expense to us and may divert the attention of management and key personnel.

If patent regulations or standards are modified, such changes could have a negative impact on our business.

From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress, or the USPTO may change the standards of patentability and validity of patents within the cancer screening and diagnostics space, and any such changes could have a negative impact on our business.

There have been several cases involving "gene patents" and diagnostic claims that have been considered by the U.S. Supreme Court that have affected the legal concept of subject matter eligibility by seemingly narrowing the scope of the statute defining patentable inventions.

Additionally, in December 2014 and again in 2019, the USPTO published revised guidelines for patent examiners to apply when examining process claims that narrow the scope of patentable subject matter. While these guidelines may be subject to review and modification by the USPTO over time, we cannot assure you that our patent portfolio will not be negatively impacted by the decisions mentioned above, rulings in other cases, or changes in guidance or procedures issued by the USPTO.

Additional substantive changes to patent law, whether new or associated with the America Invents Act — which substantially revised the U.S. patent system — may affect our ability to obtain, enforce or defend our patents. Accordingly, it is not clear what, if any, impact these substantive changes will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries, and our ability to enforce or defend our issued patents, all of which could have a material adverse effect on our business.

Risks Relating to our Securities

If we fail to maintain an effective system of internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our reported financial information and our stock price may be adversely impacted.

As a public company, we are subject to the Sarbanes-Oxley Act of 2002 and the related rules and regulations promulgated by the SEC, which require us, among other things, to maintain effective disclosure controls and procedures and internal control over financial reporting. Maintaining effective disclosure controls and procedures and internal control over financial reporting is necessary for us to produce reliable financial statements and to prevent fraud. In addition, we are required to disclose publicly for each fiscal year the conclusion of our management as to the effectiveness of our internal control over financial reporting and to report any material weaknesses identified by management. The Sarbanes-Oxley Act also requires that our management report on internal control over financial reporting be attested to by our independent registered public accounting firm. Although we determined that our internal control over financial reporting was effective as of December 31, 2024, we must continue to monitor and assess our internal control over financial reporting. If we identify material weaknesses in our internal control over financial reporting or if we are unable to assert that our internal control over financial reporting is effective when required in the future, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected.

Our stock price has fluctuated widely and is likely to continue to be volatile.

The market price for our common stock, like the securities of many other companies in the life sciences industry, has been highly volatile and could continue to be volatile and subject to significant price and volume fluctuations in response to various factors, many of which are beyond our control. Such factors include those listed in this "Item 1A. Risk Factors" section as well as:

- comments by securities analysts regarding our business or prospects;
- our quarterly operating performance;
- our issuance of common stock or other securities;
- our inability to accurately forecast future performance;
- our inability to meet analysts' expectations;
- announcements by us or our competitors, including strategic actions, management changes, and material transactions; and
- general financial, domestic, international, economic, and market conditions, including overall fluctuations in the U.S. equity and credit markets, which may be unrelated or disproportionate to the operating performance of particular companies.

In the past, companies whose securities have experienced periods of volatility in market price have been subjected to securities class action or derivative litigation. In this regard, sharp drops in the market price of our common stock, could expose us to claims and litigation alleging violations of the securities laws or other related claims. Such litigation could result in substantial expenses and diversion of management's attention and corporate resources, which would seriously harm our business, financial condition, and results of operations.

We have recorded significant impairment charges and could do so again in the future, which could have a material adverse impact on our results of operations.

Our balance sheet includes goodwill and intangible assets that represent 57% of our total assets at December 31, 2024, which are primarily associated with our acquisitions. These assets are not amortized but reviewed for impairment at least annually, or when events or changes in the business environment indicate the carrying value not be recoverable. If the carrying value of the asset is determined to be impaired, then it is written down to fair value by a charge to operating earnings. An impairment of a significant portion of goodwill or intangible assets could have a material negative effect on our results of operations. During the fourth quarter of 2024, we performed a quantitative impairment assessment for the in-process research and development ("IPR&D") intangible asset acquired as part of the acquisition of Thrive related to the development of a blood-based MCED test. The impairment assessment required a fair value measurement, and we determined that the fair value of the IPR&D was $420.0 million resulting in a non-cash, pre-tax impairment loss of $830.0 million.

Our significant indebtedness could adversely affect our business, financial condition and results of operations, and our ability to meet our payment obligations under such indebtedness and limit our ability to raise additional capital to fund our operations.

We have a significant amount of indebtedness. As of December 31, 2024, we had total indebtedness of $2.60 billion consisting of aggregate principal and interest due under our convertible senior notes. We also had $4.4 million of letters of credit issued. This level of debt could have significant consequences on our future operations, including:

- increasing our vulnerability to adverse economic and industry conditions;
- making it more difficult for us to meet our payment and other obligations;
- making it more difficult to obtain any necessary future financing for working capital, capital expenditures, debt service requirements, or other purposes;
- requiring the dedication of a substantial portion of any cash flow from operations to service our indebtedness, thereby reducing the amount of cash flow available for other purposes, including capital expenditures;
- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital than we have; and
- limiting our flexibility in planning for, or reacting to, changes in our business and the markets in which we compete.

Any of the above-listed factors could have an adverse effect on our business, financial condition, and results of operations and our ability to meet our payment obligations under our indebtedness.

Our ability to meet our payment and other obligations under our indebtedness depends on our ability to generate significant cash flow in the future. This, to some extent, is subject to general economic, financial, competitive, legislative, and regulatory factors as well as other factors that are beyond our control. We cannot assure you that our business will generate cash flow from operations, or that future borrowings will be available to us, in an amount sufficient to enable us to meet our payment obligations under our indebtedness and to fund other liquidity needs. If we are not able to generate sufficient cash flow to service our debt obligations, we may need to refinance or restructure our debt, sell assets, reduce or delay capital investments, share-settling the convertible notes or seek to raise additional capital, any of which events could have an adverse effect on our business, financial condition, and results of operations or be highly dilutive to our shareholders.

Our credit facilities contain certain customary representations, and warranties, affirmative covenants and negative covenants for credit facilities of this nature, including covenants that require delivery of financial statements and notices of events of default and restrictions on the incurrence of debt or guarantees, the creation of liens, the making of certain investments, loans and acquisitions, mergers and dissolutions, the sale of assets, the payment of dividends, and the repayment of certain junior debt, among others. Our obligations under our revolving credit facility are secured, pursuant to a guarantee and collateral agreement pursuant to which we granted to the lenders liens on substantially all of our assets, subject to certain exceptions and exclusions. A breach of any covenant in our credit facilities or the agreements and indentures governing any other indebtedness that we may have outstanding from time to time would result in a default under that agreement or indenture after any applicable grace periods. A default, if not waived, could result in, among other things, (i) acceleration of the debt outstanding under the agreement and the lenders exercising remedies, including with respect to the collateral we granted to them, which includes substantially all of our assets, and (ii) a default with respect to, and an acceleration of the debt outstanding under, other debt agreements. If that occurs, we may not be able to make all of the required payments or borrow sufficient funds to refinance such debt. Even if new financing were available at that time, it may not be on terms that are acceptable to us or terms as favorable as our current agreements. If our debt is in default for any reason, our business, results of operations and financial condition could be materially and adversely affected.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Governance

Our Board of Directors administers its cybersecurity risk oversight function directly through our Audit and Finance Committee ("AFC"). Our AFC has primary responsibility for overseeing our risk management practices, programs, and policies related to data privacy, data protection, and cybersecurity. The AFC reviews and evaluates the processes utilized by management to identify and assess the material internal and external risks that may affect our business. Our AFC regularly discusses the our major risk exposures with management, legal counsel, and the internal audit department. This includes potential financial impact on the Company and the steps taken to monitor and control those risks. Annual reviews with management include a summary of legal and regulatory compliance matters, risk management activities, and including a review of our cybersecurity program. Additionally, our AFC oversees the process by which our Board of Directors is informed regarding the risks facing the Company and coordinates with our legal counsel to ensure our Board of Directors receives regular risk assessment updates from management.

The Chief Information Security Officer ("CISO") is responsible for identifying, assessing, and managing our risks from cybersecurity threats. The CISO has been with the Company for three years, bringing more than 30 years of technology experience, including 15 years in cybersecurity, and has held the CISO position at other companies before joining Exact Sciences. The CISO leads the cybersecurity team consisting of experts in strategy, governance, risk management, compliance, engineering and development, security operations, and incident management.

Our Artificial Intelligence Council, which includes the CISO, oversees adherence to AI ethical principles and regulatory requirements in the development and utilization of AI systems, including generative AI tools. AI governance is integrated within the broader governance framework discussed above.

The CISO provides our AFC with periodic updates about our cybersecurity program and material risks. This includes updates on cybersecurity practices and projects designed to strengthen internal cybersecurity and data protection.

Risk Management and Strategy

Processes for identifying and assessing cybersecurity risks

The CISO, with the support of the cybersecurity team and the owners of information technology across the business, monitors current events and trends related to cybersecurity and assesses impact on current systems and operations. There are several processes in place to monitor and review our systems, including third-party solutions, to identify potential risks. Third-party service providers are required to notify us in the event of a cybersecurity incident within their systems, and annual reviews are conducted on the Company's critical third-party vendors. Cybersecurity risks, threats, and incidents, including those from third-party service providers, are tracked and regularly provided to the CISO. The Cybersecurity Leadership Team, which includes the CISO and executives from all business functions across the organization, meets at least quarterly to review and discuss cybersecurity risks facing the Company.

Processes for managing cybersecurity risks

The cybersecurity team tracks risks and incidents related to cybersecurity until the risk is mitigated to an acceptable level or fully remediated. When risks are identified, the cybersecurity team oversees mitigation plans with the risk owner. The plans communicated to necessary teams and remediation steps are taken.

Processes for incorporating cybersecurity risks into the overall risk management process

Our process for identifying, assessing, and managing risks related to cybersecurity is incorporated into our Enterprise Risk Management ("ERM") process. The Risk Management team meets at least annually with cybersecurity leadership to discuss identified cybersecurity-related risks and the potential likelihood and severity of each risk. Through the ERM process, cybersecurity risks are presented to the executive leadership team, including the CEO and CFO, as well as reported to the AFC.

Currently, we are not aware of any risks from cybersecurity threats or cybersecurity incidents that have materially affected or are reasonably likely to materially affect the Company.

Item 2. Properties

As of December 31, 2024, our material facilities are as follows:

Location	Primary Function	Total Square Feet (approx.)	Leased or Owned
Madison, Wisconsin	Research and development, corporate, operations, and clinical laboratory	1,566,000	Leased/Owned
Redwood City, California	Research and development, corporate, operations, and clinical laboratory	243,000	Leased

See Note 15 in the Notes to Consolidated Financial Statements for further discussion surrounding our leased facilities.

Item 3. Legal Proceedings

From time to time we are a party to various legal proceedings arising in the ordinary course of our 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. The information called for by this item is incorporated by reference to the information in Note 15 of the Notes to Consolidated Financial Statements.

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

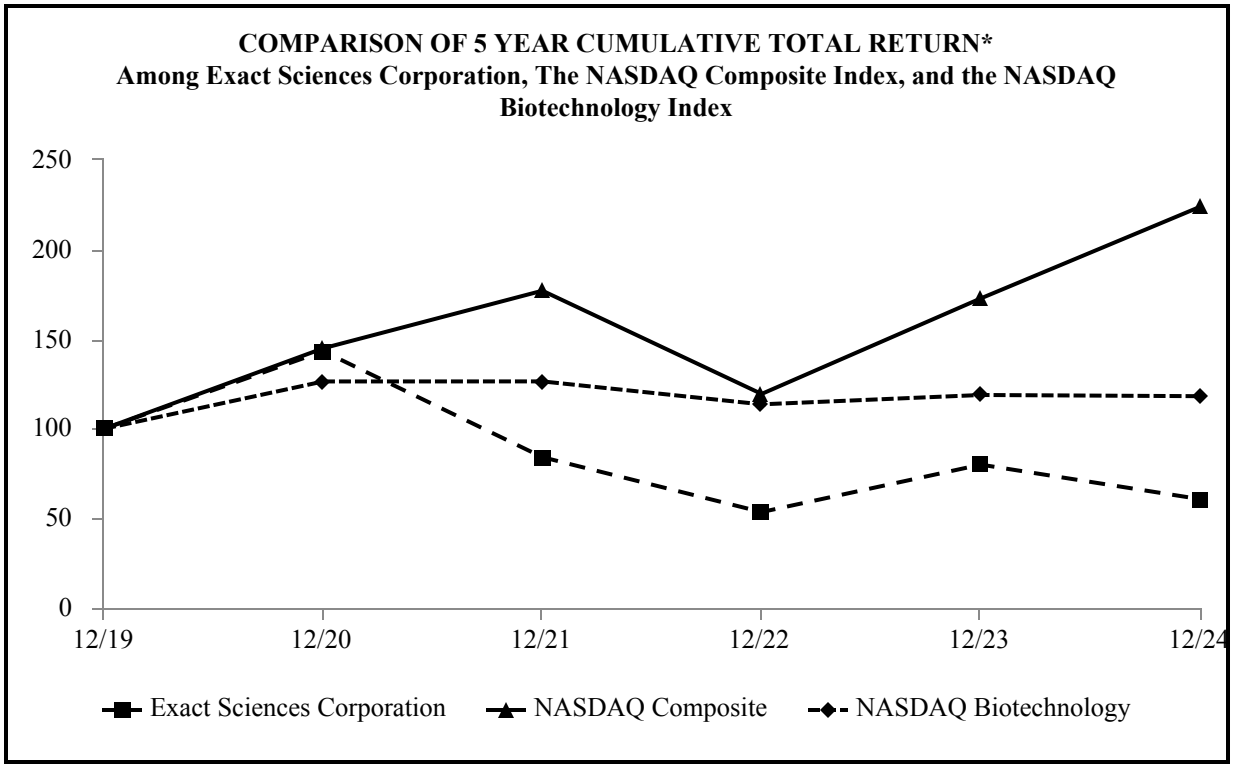
Our common stock is currently listed on the NASDAQ Capital Market under the symbol "EXAS."

As of February 18, 2025, there were 185,755,406 shares of our common stock outstanding held by approximately 172 holders of record.

We have never paid any cash dividends on our common stock and do not plan to pay any cash dividends in the foreseeable future.

See Note 14 in the Notes to Consolidated Financial Statements for further information on our stock-based compensation plans.

The following graph compares the cumulative total return on our common stock with the cumulative total return of the NASDAQ Composite Index and the NASDAQ Biotechnology Index for the five-year period ended December 31, 2024. The graph assumes that the value of the investment in our stock and in each index was $100 on December 31, 2019 and assumes that all dividends were reinvested.



* $100 invested on December 31, 2019 in stock or index including reinvestment of dividends.

Unregistered Sales of Equity Securities

Not applicable.

Item 6. Reserved

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

Objective

The purpose of this Management's Discussion and Analysis ("MD&A") is to better allow our investors to understand and view our Company from management's perspective. We are providing an overview of our business and strategy including a discussion of our financial condition and results of operations. The following discussion of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and the related notes thereto included elsewhere in this Annual Report on Form 10-K. We have omitted discussion of certain 2022 results where it would be redundant to the discussion previously included in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations of our Form 10-K for the year ended December 31, 2023, which was filed with the SEC on February 21, 2023.

Overview

A leading provider of cancer screening and diagnostic tests, Exact Sciences Corporation gives patients and health care professionals the clarity needed to take life-changing action earlier. Building on the success of the Cologuard and Oncotype DX tests, we are investing in our pipeline to develop innovative solutions for use before, during, and after a cancer diagnosis.

2025 Priorities

Our top priorities for 2025 are to (1) champion our customers and team, (2) elevate our product portfolio, and (3) amplify our impact.

Champion our Customers and Team

We will enhance our world-class customer experience, expand screening access to underserved populations, and ensure Exact Sciences remains a great place to work.

Elevate our Product Portfolio

We will increase adoption of current tests, launch our Cologuard Plus, Oncodetect, and Cancerguard tests, and invest in clinical trials to enhance existing products and bring new diagnostics to patients and providers. We will also focus on improving patient adherence to screen more people.

Amplify our Impact

By reaching more patients through an expanded portfolio and growing customer base, we will increase revenue and profitability. Sustained profits will enable continued investment in life-changing cancer diagnostics to help achieve our mission.

Recent Developments and Trends

We estimate there are up to 55 million Americans that are not up to date with their colon cancer screenings. The capacity for screening colonoscopies in the U.S. is relatively fixed because it is dependent on the number of gastroenterologists available to perform the procedures. Health systems, payers, and health care providers are motivated to increase screening rates because they are measured as part of the HEDIS and Medicare Stars quality measure systems. More health systems and payers are recognizing the opportunity to partner with Exact Sciences to address their screening rates and related quality measures through large, organized screening programs. We aim to partner with them to implement our Cologuard test within these programs as a solution for patients who infrequently visit their health care provider. Cologuard utilization is increasing in this setting, helping us screen more Americans.

We have an opportunity to impact even more lives by increasing adoption of Oncotype DX tests internationally. In 2023, we secured reimbursement for the Oncotype DX test in Japan. Breast cancer is the most common cancer among Japanese women, with about 45,000 new diagnoses of early-stage HR+, HER2- breast cancer each year. With reimbursement in place, we estimate our Oncotype DX test could help more than 100 women per day understand if their cancer is likely to recur and whether chemotherapy should be used in their treatment plan.

Results of Operations

Comparison of the years ended December 31, 2024 and 2023

Revenue. Our Screening revenue primarily includes laboratory service revenue from our Cologuard and PreventionGenetics LLC ("PreventionGenetics") tests while our Precision Oncology revenue includes laboratory service revenue from global Oncotype DX and therapy selection tests.

(Amounts in millions)	2024	2023	Change
Screening	$ 2,103.9	$ 1,864.7	$ 239.2
Precision Oncology	655.0	629.1	25.9
COVID-19 Testing	—	6.0	(6.0)
Total	$ 2,758.9	$ 2,499.8	$ 259.1

The increase in Screening revenue was primarily due to an increase in the number of completed Cologuard tests. This was primarily driven by increased Cologuard adoption by patients, providers, health systems, and payers. The increase in Precision Oncology revenue was primarily due to an increase in the number of completed Oncotype DX breast cancer tests, both domestically and internationally. This was led by an increased number of ordering providers outside the U.S., particularly in Japan. We discontinued COVID-19 testing in the second quarter of 2023 due to lower demand, which led to a decrease in COVID-19 testing revenue.

Adjustments to revenue recognized during the years ended December 31, 2024 and 2023 from changes in transaction price were less than 1% and 2%, respectively. The impacts to revenue related to change in transaction price are a function of differences in realized collections compared to original estimates, which includes upward adjustments stemming from optimizations in our reimbursement operations and downward adjustments from things such as payer denials.

We expect continuing revenue growth for our Cologuard and Oncotype tests subject to seasonal variability. Our revenues are affected by the test volume of our products, patient adherence rates, payer mix, the levels of reimbursement, our order to cash operations, and payment patterns of payers and patients.

Cost of sales. The increase in cost of sales for the year ended December 31, 2024 was primarily due to an increase in production costs, personnel expenses, and facility and support services. This was a result of an increase in completed Cologuard and Oncotype tests and the corresponding increase in headcount and facilities related costs to support the increase in tests completed. Gross margin decreased in 2024 primarily due to higher Cologuard test volume from organized screening programs, which have lower adherence rates. We expect that cost of sales will generally continue to increase in future periods as a result of an increase in our existing laboratory testing services and as we launch our pipeline products. We also expect to see a corresponding increase in personnel and support services associated with this growth.

(Amounts in millions)	2024	2023	Change
Production costs	$ 467.3	$ 393.4	$ 73.9
Personnel expenses	197.3	182.0	15.3
Intangible asset amortization	84.1	83.3	0.8
Facility and support services	68.5	54.4	14.1
Stock-based compensation	20.5	20.8	(0.3)
Other cost of sales expenses	2.5	3.7	(1.2)
Total cost of sales expense	$ 840.2	$ 737.6	$ 102.6

Research and development expenses. The increase in research and development expenses was primarily due to the termination of a license agreement with The Translational Genomics Research Institute, which resulted in $25.8 million expense in the second quarter of 2024. This increase was partially offset by a decrease in direct research and development expenses and facility and support services costs due to a reduction in resources needed to support our ongoing clinical studies as our pipeline tests approach commercialization as discussed in "Item 1. Business — Upcoming Test Launches" included in this Annual Report on Form 10-K. We expect that research and development expenses will generally continue to increase in future periods as we continue to enhance our current products and invest in our pipeline.

(Amounts in millions)	2024	2023	Change
Personnel expenses	$ 182.2	$ 180.3	$ 1.9
Direct research and development expenses	110.1	129.7	(19.6)
Facility and support services	56.2	64.1	(7.9)
Stock-based compensation	39.7	41.2	(1.5)
License agreement termination	25.8	—	25.8
Professional fees	10.9	7.2	3.7
Intangible asset amortization	3.3	1.0	2.3
Other research and development expenses	3.0	3.4	(0.4)
Total research and development expenses	$ 431.2	$ 426.9	$ 2.0

Sales and marketing expenses. The increase in sales and marketing expenses was primarily due to continued investment in high impact opportunities, which was partially offset by reductions in certain incentive-based compensation arrangements due to lower than expected revenue as discussed above. We anticipate sales and marketing expenses will generally increase in future periods as we reinvest in efforts to increase adoption of current products and support the launches of new products. We expect these expenses will continue to decrease as a percentage of revenue over time, driven by the growth of Cologuard and Oncotype testing services. Refer to Note 1 of our Notes to Consolidated Financial Statements for discussion of the reclassification of customer care and customer experience related costs from general and administrative expenses to sales and marketing expenses.

(Amounts in millions)	2024	2023	Change
Personnel expenses	$ 500.3	$ 471.6	$ 28.7
Direct marketing costs	212.8	183.7	29.1
Professional and legal fees	70.4	49.8	20.6
Stock-based compensation	68.2	73.0	(4.8)
Other sales and marketing expenses	19.3	24.3	(5.0)
Facility and support services	15.4	17.7	(2.3)
Intangible asset amortization	7.7	7.7	—
Total sales and marketing expenses	$ 894.1	$ 827.8	$ 66.3

General and administrative expenses. The decrease in general and administrative expenses was primarily due to the settlement of certain legal matters in 2023 as further described in Note 15 of our Notes to Consolidated Financial Statements and a reduction in certain incentive-based compensation arrangements due to lower than expected revenue as discussed above. This reduction was partially offset by an increase in other general and administrative expense as a result of the change in fair value of our outstanding contingent consideration liabilities. Refer to Note 7 of our Notes to Consolidated Financial Statements for further discussion of our outstanding contingent consideration liabilities. We expect general and administrative expenses will decrease over time as we leverage efficiencies in our personnel and information technology systems. Refer to Note 1 of our Notes to Consolidated Financial Statements for discussion of the reclassification of customer care and customer experience related costs from general and administrative expenses to sales and marketing expenses.

(Amounts in millions)	2024	2023	Change
Personnel expenses	$ 346.4	$ 336.9	$ 9.5
Facility and support services	185.0	181.4	3.6
Professional and legal fees	125.6	166.8	(41.2)
Stock-based compensation	86.5	96.3	(9.8)
Other general and administrative	38.2	18.8	19.4
Intangible asset amortization	0.1	0.1	—
Total general and administrative expenses	$ 781.8	$ 800.3	$ (18.5)

Impairment of long-lived and indefinite-lived assets. Impairment of long-lived and indefinite-lived assets increased to $869.5 million for the year ended December 31, 2024 compared to $0.6 million for the year ended December 31, 2023. The impairment charges recorded during the year ended December 31, 2024 included impairments to our IPR&D asset acquired as part of our acquisition of Thrive and building leases and corresponding leasehold improvements at certain of our domestic facilities. The impairment of the IPR&D asset is further discussed in Note 6 of our Notes to Consolidated Financial Statements.

Other operating income (loss). Other operating income was $9.2 million for the year ended December 31, 2024 compared to $78.4 million for the year ended December 31, 2023. The income recorded for the year ended December 31, 2024 represents the remeasurement of the contingent consideration asset from the sale of the Oncotype DX Genomic Prostate Score test ("GPS test") to MDxHealth. The income recorded for the year ended December 31, 2023 primarily relates to a $73.3 million contingent consideration gain and $3.1 million in additional consideration received from MDxHealth as a result of an amendment to the asset purchase agreement in August 2023. The sale of the GPS test is further discussed in Note 18 of our Note to Consolidated Financial Statements.

Investment income (loss), net. Net investment income increased to $39.6 million for the year ended December 31, 2024 compared to a net investment income of $32.7 million for the year ended December 31, 2023. The net investment income for the year ended December 31, 2024 and 2023 was primarily due to gains recorded on our marketable and non-marketable securities.

Interest expense. Interest expense increased to $27.0 million for the year ended December 31, 2024 compared to $19.4 million for the year ended December 31, 2023. Interest expense recorded from our outstanding convertible notes totaled $22.3 million, which was partially offset by a gain on settlement of convertible notes of $10.3 million, for the year ended December 31, 2024. Interest expense recorded from our outstanding convertible notes totaled $13.2 million, which was partially offset by a net gain on settlement of convertible notes of $10.3 million, for the year ended December 31, 2023. The convertible notes are further described in Note 10 of our Notes to Consolidated Financial Statements.

Income tax benefit (expense). Income tax benefit was $7.3 million for the year ended December 31, 2024 compared to an expense of $2.4 million for the year ended December 31, 2023. Income tax benefit for the year ended December 31, 2024 was primarily related to current foreign and state tax expense offset by a U.S. deferred tax benefit. The income tax expense recorded during the year ended December 31, 2023 was primarily related to current foreign and state tax expense.

Comparison of the years ended December 31, 2023 and 2022

As discussed in Note 1 of our Notes to Consolidated Financial Statements, we reclassified the presentation of amortization of acquired intangible assets and certain other operating expenses included within the consolidated statement of operations. The cost of sales and operating expense line items impacted by these reclassifications are presented below for the years ended December 31, 2023 and 2022. The reclassifications did not impact the discussion of our financial condition and results of operations previously included in our Form 10-K for the year ended December 31, 2023, and as such, the redundant discussion was omitted below.

Cost of sales

(Amounts in millions)	2023	2022	Change
Production costs	$ 393.4	$ 329.5	$ 63.9
Personnel expenses	182.0	160.1	21.9
Intangible asset amortization	83.3	87.0	(3.7)
Facility and support services	54.4	63.6	(9.2)
Stock-based compensation	20.8	19.2	1.6
Other cost of sales expenses	3.7	2.0	1.7
Total cost of sales expense	$ 737.6	$ 661.4	$ 76.2

Research and development expenses

(Amounts in millions)	2023	2022	Change
Personnel expenses	$ 180.3	$ 143.3	$ 37.0
Direct research and development expenses	129.7	158.7	(29.0)
Facility and support services	64.1	45.5	18.6
Stock-based compensation	41.2	33.8	7.4
Professional fees	7.2	3.9	3.3
Other research and development expenses	3.4	8.2	(4.8)
Intangible asset amortization	1.0	0.8	0.2
Total research and development expenses	$ 426.9	$ 394.2	$ 32.5

Sales and marketing expenses

(Amounts in millions)	2023	2022	Change
Personnel expenses	$ 471.6	$ 494.1	$ (22.5)
Direct marketing costs	183.7	238.1	(54.4)
Stock-based compensation	73.0	69.3	3.7
Professional and legal fees	49.8	54.7	(4.9)
Other sales and marketing expenses	24.3	13.4	10.9
Facility and support services	17.7	50.4	(32.7)
Intangible asset amortization	7.7	9.6	(1.9)
Total sales and marketing expenses	$ 827.8	$ 929.6	$ (99.9)

General and administrative expenses

(Amounts in millions)	2023	2022	Change
Personnel expenses	$ 336.9	$ 341.6	$ (4.7)
Facility and support services	181.4	135.0	46.4
Professional and legal fees	166.8	110.0	56.8
Stock-based compensation	96.3	84.5	11.8
Other general and administrative	18.8	(7.8)	26.6
Intangible asset amortization	0.1	0.1	—
Total general and administrative expenses	$ 800.3	$ 663.4	$ 136.9

Liquidity and Capital Resources

Overview

We have incurred losses since our inception, and have historically financed our operations primarily through public offerings of our common stock and convertible debt and through revenue generated by the sale of our laboratory testing services. We expect our operating expenditures to continue to increase to support future growth of our laboratory testing services, as well as an increase in research and development and clinical trial costs to support the advancement of our pipeline products and bringing new tests to market. We expect that cash, cash equivalents, and marketable securities on hand at December 31, 2024, along with cash flows generated through our operations, will be sufficient to fund our current operations for at least the next twelve months based on current operating plans.

We may raise additional capital to expand our business, to pursue strategic investments, to take advantage of financing opportunities or for other reasons. If we are unable to obtain sufficient additional funds to enable us to fund our business plans and strategic investments, our results of operations and financial condition could be materially adversely affected, and we may be required to delay the implementation of our plans or otherwise scale back our operations. There can be no certainty that we will ever be successful in generating sufficient cash flow from operations to achieve and maintain profitability and meet all of our obligations as they come due.

Cash, Cash Equivalents, and Marketable Securities

As of December 31, 2024, we had approximately $600.9 million in unrestricted cash and cash equivalents and approximately $437.1 million in marketable securities.

The majority of our investments in marketable securities consist of fixed income investments, and all are deemed available-for-sale. The objectives of this portfolio are to provide liquidity and safety of principal while striving to achieve the highest rate of return. Our investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer.

Cash Flows

(Amounts In millions)	2024	2023
Net cash provided by operating activities	$ 210,536	$ 156,119
Net cash provided by (used in) investing activities	(442,155)	49,679
Net cash provided by financing activities	231,874	159,766

Operating activities

The increase in cash provided by operating activities for the year ended December 31, 2024 compared to the year ended December 31, 2023 was primarily due to an increase in revenue and a decrease in certain of our operating expenses as a percentage of revenue. This was partially offset by an increase in cost of sales to support the increase in revenue as discussed in the Results of Operations section above and timing of payments on our accounts payable and accrued expenses.

Investing activities

The increase in cash used by investing activities for the year ended December 31, 2024 compared to the year ended December 31, 2023 was due to a net increase of $482.5 million in cash used for purchases, maturities, and sales of marketable securities as a result of a change in investing strategy towards more fixed income securities compared to money market funds as money market yields have decreased. We also increased our purchases of property, plant and equipment by $11.8 million due to additional investments in information technology infrastructure and lab automation. The increase in cash used in investing activities was partially offset by a decrease in cash used related to business combinations, asset acquisitions, and investments in non-marketable securities. We made payments of $45.0 million for our license of intellectual property from TwinStrand during the third quarter of 2024 compared to a cash payment of $50.0 million for our acquisition of Resolution Bioscience in the third quarter of 2023. In addition, there was a decrease of $14.8 million in our in investments in non-marketable securities.

Financing activities

The increase in cash provided by financing activities for the year ended December 31, 2024 compared to the year ended December 31, 2023 was primarily due to proceeds of $266.8 million from the issuance of convertible notes in the second quarter of 2024 compared to proceeds of $138.0 million from the issuance of convertible notes in the first quarter of 2023. This was partially offset by a payment of $50.0 million in settlement of our previously outstanding accounts receivable securitization facility upon maturity in June 2024.

Material Cash Requirements

Convertible Notes

As of December 31, 2024, we had outstanding aggregate principal of $2.60 billion on our convertible notes with maturity dates of January 15, 2025 (the "2025 Notes"), March 15, 2027 (the "2027 Notes"), March 1, 2028 Notes (the "2028 Notes"), March 1, 2030 (the "2030 Notes"), and April 15, 2031 (the "2031 Notes" and collectively, the "Notes"). The 2025 Notes have an outstanding principal balance of $249.2 million, which was settled in cash upon maturity in January 2025. The 2027 Notes have an outstanding principal balance of $563.8 million. The 2028 Notes have an outstanding principal balance of $589.4 million. The 2030 Notes have an outstanding principal balance of $573.0 million. The 2031 Notes have an outstanding principal balance of $620.7 million. The 2025 Notes, 2027 Notes, 2028 Notes, 2030 Notes, and 2031 Notes accrue interest at a fixed rate of 1.0%, 0.375%, 0.375%, 2.0%, and 1.750% per year, respectively, which is payable in cash semi-annually in arrears each year until the maturity date. See Note 10 of our Notes to Consolidated Financial Statements for further information. Until the six months immediately preceding the maturity date of the applicable series of Notes, each series of Notes is convertible only upon the occurrence of certain events and during certain periods. The Notes will be convertible into cash, shares of our common stock (plus, if applicable, cash in lieu of any fractional share), or a combination of cash and shares of our common stock, at our election. If the notes are not converted prior to the maturity date, the principal amount will be settled in cash upon maturity.

Lease Commitments

We act as lessee in our lease agreements, which include operating leases for corporate offices, laboratory space, warehouse space, vehicles, and certain laboratory and office equipment, and finance leases for certain equipment and vehicles. As of December 31, 2024, we had minimum operating and finance lease payments of $235.8 million and $23.0 million, respectively. Of the outstanding operating lease obligations, $37.4 million matures in 2025, and the remaining $198.4 million will mature in periods subsequent to 2025. Of the outstanding finance lease obligations, $8.9 million matures in 2025, and the remaining $14.1 million will mature in periods subsequent to 2025. See Note 15 of our Notes to Consolidated Financial Statements for further information.

Contingent Consideration

Certain of our business combinations and asset acquisitions involve potential payment of future consideration that is contingent upon the achievement of certain regulatory and product revenue milestones. A liability is recorded for the estimated fair value of the contingent consideration on the acquisition date for business combinations. A liability is recorded when achievement of a milestone becomes probable for asset acquisitions.

As a result of the acquisition of Thrive in January 2021, an additional $450.0 million would be payable in cash to Thrive's former shareholders upon the achievement of two discrete events, FDA approval and CMS coverage, for $150.0 million, and $300.0 million, respectively, in relation to the development and commercialization of a blood-based, MCED test. The projected fiscal year of payment range is from 2030 to 2031. See Note 7 of our consolidated financial statements included in this Annual Report on Form 10-K for further information.

As a result of the acquisition of Ashion in April 2021, an additional $20.0 million would be payable in cash to Ashion's former shareholders upon the commercial launch, on or before the tenth anniversary of the acquisition of Ashion, of a test for MRD detection and/or treatment. The projected fiscal year of payment is 2025. An additional $30.0 million would be payable in cash to Ashion's former shareholders upon reaching cumulative revenues of $500.0 million from MRD products, on or before the fifth anniversary of the acquisition of Ashion. See Note 7 of our Notes to Consolidated Financial Statements for further information.

License Agreements

We license certain technologies that are, or may be, incorporated into our technology under several license agreements, as well as the rights to commercialize certain diagnostic tests through collaboration agreements. Generally, the license agreements require us to pay single-digit royalties and sales-based milestone payments based on net revenues received using the technologies and may require minimum royalty amounts or maintenance fees.

The timing and amounts of any such royalty or milestone payments is unknown due to the uncertain nature of product development and associated net revenues using these technologies. Refer to Note 11 and Note 18 of our Notes to Consolidated Financial Statements for further information.

Capital Expenditures

We expect to continue to invest in capital expenditures to support the growth of our existing products and our research and development activities. Our current projects primarily include the build out of certain lab automation projects at our existing facilities in Madison, WI. These projects are expected to be completed in 2025 and beyond. We also have assets under construction related to laboratory equipment, leasehold and building improvements, and software projects.

Sources of Cash

As of December 31, 2024, we had access to a revolving line-of-credit (the "Revolver") with PNC Bank, National Association of up to $150.0 million, which we had not drawn any funds from since it was initially executed in November 2021. In January 2025, we entered into a senior secured revolving credit agreement (the "Revolving Credit Agreement") with JPMorgan Chase Bank, N.A., which replaces the Revolver and provides us with access to $500.0 million on a revolving basis, including a letter of credit sublimit. The Revolving Credit Agreement also provides for uncommitted incremental facilities in an amount up to $200.0 million plus an unlimited additional amount so long as we are in pro forma compliance with certain financial covenants. The Revolving Credit Agreement expires in January 2028. The Revolver and Revolving Credit Agreement are further described in Note 9 and Note 21, respectively, of our Notes to Consolidated Financial Statements.

We believe that our anticipated income from operations, cash and marketable securities on hand, and borrowing capacity under our Revolving Credit Agreement will be adequate to meet our commitments for at least 12 months from the issuance of this Annual Report on Form 10-K. However, we may need to raise additional capital to fully fund our current business plan and meet all commitments discussed above. We continuously evaluate our liquidity and capital resources, including access to external capital, in light of current economic and market conditions and our operational performance.

As of December 31, 2024, we had no off-balance sheet arrangements.

Net Operating Loss Carryforwards

As of December 31, 2024, we had federal, state, and foreign net operating loss ("NOL") carryforwards of approximately $374.9 million, $65.4 million, and $12.1 million, respectively. We also had federal and state research tax credit carryforwards of approximately $82.5 million and $38.2 million, respectively. The net operating loss and tax credit carryforwards will expire at various dates through 2041, if not utilized. The Internal Revenue Code and applicable state laws impose substantial restrictions on a corporation's utilization of net operating loss and tax credit carryforwards if an ownership change is deemed to have occurred. Additionally, tax law limitations may result in our NOLs expiring before we have the ability to use them. The Tax Cuts and Jobs Act (H.R. 1) of 2017 limits the deduction for NOLs to 80% of current year taxable income and provides for an indefinite carryover period for federal NOLs. Both provisions are applicable for losses arising in tax years beginning after December 31, 2017. As of December 31, 2024, we had $281.2 million of NOLs incurred after December 31, 2017. For these reasons, even if we attain profitability, our ability to utilize our NOLs may be limited, potentially significantly so.

A valuation allowance is provided for deferred tax assets if it is more likely than not these items will either expire before we are able to realize their benefit, or that future deductibility is uncertain. In general, companies that have a history of operating losses are faced with a difficult burden of proof on their ability to generate sufficient future income in order to realize the benefit of the deferred tax assets. We have recorded a valuation against our deferred tax assets based on our history of losses and current uncertainty as to timing of future taxable income. Given the future limitations on and expiration of certain Federal and State deferred tax assets, the recording of a valuation allowance resulted in a deferred tax liability of approximately $7.2 million remaining as of December 31, 2024, which is included in other long-term liabilities on our consolidated balance sheet.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience and on various other factors that are believed to be appropriate under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 1 of our Notes to Consolidated Financial Statements, we believe that the following judgments are most critical to aid in fully understanding and evaluating our reported financial results.

Revenue Recognition. We recognize revenues when we release an approved patient test result to the ordering healthcare provider, in an amount that reflects the consideration we expect to collect in exchange for those services. The amount of revenue we recognize is based on the established billing rates less contractual and other adjustments, which yields the unconstrained amount that we expect to ultimately collect.

We determine the amount we expect to ultimately collect using historical collections, established reimbursement rates, and other adjustments. The expected amount is typically lower than, if applicable, the agreed-upon reimbursement amount due to several factors, such as the amount of any patient co-payments, out-of-network payers, the existence of secondary payers, and claim denials. The consideration derived from our contracts is fixed when we contract with a direct bill payer as our ability to collect is not contingent on the customer's ability to collect through their downstream billing efforts. A change in the estimated transaction price derived by the aforementioned inputs would ultimately impact the amount of revenue recognized during the period. We have historically recognized an upward or downward adjustment to revenues from a change in transaction price representing approximately 1% of prior year revenues. A 1% change in our estimated transaction price for revenue recognized for the year ended December 31, 2024 would result in an adjustment to revenue of approximately $27.6 million in 2025.

In the case of some of our agreements, the right to bill and collect exists prior to the receipt of a specimen and release of a test result to the ordering healthcare provider, which results in deferred revenue. The deferred revenue balance is generally relieved upon the release of the applicable patient's test result to the ordering healthcare provider or as of the date the customer has surpassed the window of time in which they are able to exercise their rights for testing services. We believe these points in time represent our fulfillment of our obligations to the customer.

The quality of our billing operations, most notably those activities that relate to obtaining the correct information in order to bill effectively for services provided, directly impacts the collectability of our receivables and revenue estimates. As such, we continually assess the state of our order to cash operations in order to identify areas of risk and opportunity that allow us to appropriately estimate receivables and revenue. Upon ultimate collection, the aggregate amount received from payers and patients where reimbursement was estimated is compared to previous collection estimates and, if necessary, the transaction price is adjusted. Finally, should we later determine the judgments underlying estimated collections change, our financial results could be negatively impacted in future quarters.

Tax Positions. We record a valuation allowance to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized.

We compute our provision for income taxes based on the statutory tax rates and tax planning opportunities available to us in the various jurisdictions that we operate. Judgment is required in evaluating our tax positions and determining our annual tax provision.

We have incurred significant losses since our inception and due to the uncertainty of the amount and timing of future taxable income, it may be necessary to record an allowance to reduce the tax assets we have recognized.

Management has determined that a valuation allowance of $708.8 million and $465.8 million at December 31, 2024 and 2023, respectively, is necessary to reduce the tax assets to the amount that is more likely than not to be realized. Due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact our effective tax rate.

Acquired Intangible Assets. We acquire finite-lived intangible assets through our business combinations and asset acquisitions, which primarily consist of developed technology. As of December 31, 2024, our developed technology intangible assets have a carrying value of $474.6 million. Key assumptions used to value developed technology under the income approach include projected revenue growth, projected gross margin and operating expenses, discount rate, tax rate, and obsolescence factor. We believe that the estimates applied are based on reasonable assumptions, but the estimates are inherently uncertain. As a result, the actual results may differ from the assumptions and judgments used to determine fair value of the assets acquired, which could result in material impairment charges in the future. Determining the useful life of the developed technology also requires judgment and actual useful life may differ.

Certain of our acquisitions include the acquisition of indefinite-lived IPR&D. As a result of the acquisition of Thrive, we recorded an IPR&D asset of $1.25 billion in January 2021. As of December 31, 2024, the carrying value of our IPR&D asset was reduced to $420.0 million as a result of the impairment charge discussed in further detail below. There are major risks and uncertainties associated with IPR&D due to the regulatory approvals needed, which rely on the success of clinical trials that demonstrate product effectiveness. Key assumptions used to calculate the fair value of the IPR&D asset included inputs such as projected revenues, projected gross margin and operating expenses, discount rate, tax rate, obsolescence factor, and probability of commercial success. We believe that the estimates applied are based on reasonable assumptions, but the estimates are inherently uncertain. As a result, the eventual realized value of the IPR&D project may vary from its fair value at the date of acquisition, and material IPR&D impairment charges may occur in future periods. Further changes in key assumptions made in determining the fair value of the IPR&D asset could result in a change in the estimated fair value of up to the amounts shown in the following table:

Assumption	Unit of Measure Change	Fair Value Impact (In Thousands)
Discount rate	1%	$ 100,000
Total after-tax discounted cash flows	5%	21,200

Refer to the Impairment of indefinite-lived assets section below for further discussion of the IPR&D associated with the acquisition of Thrive.

Contingent Consideration Liabilities. Business combinations may include contingent consideration to be paid based on the occurrence of future events, such as the achievement of certain development, regulatory, and sales milestones. Contingent consideration is a financial liability recorded at fair value at the acquisition date. We remeasure the fair value of outstanding contingent consideration liabilities at each reporting period.

The estimate of fair value contains uncertainties as it involves judgement about the likelihood and timing of achieving milestones as well as the present-value factor. A change in the assumptions made for probability of success, projected fiscal year of payment, and present-value factor could have a material impact on the estimated fair value. Our contingent consideration liability is primarily due to our acquisition of Thrive, which resulted in a contingent consideration liability of $352.0 million upon acquisition. Due to changes in macroeconomic conditions and a delay in the projected fiscal year of payment for the regulatory and product development milestones associated with our acquisition of Thrive, the weighted average present-value factor increased from 5.8% as of December 31, 2023 to 6.2% as of December 31, 2024, and the fair value of the contingent consideration liability was remeasured from $270.1 million as of December 31, 2023 to $262.5 million as of December 31, 2024. Further changes in the key assumptions made in determining the fair value of the contingent consideration liability recorded related to the acquisition of Thrive could result in a change in the estimated fair value of up to the amounts shown in the following table:

Assumption	Unit of Measure Change	Fair Value Impact (In Thousands)
Probability of success	5%	$ 14,600
Projected fiscal year of payment	1 Year	15,400
Present-value factor	1%	14,800

Impairment of Indefinite-Lived Assets. We test indefinite-lived assets for impairment on an annual basis during the fourth quarter, or more frequently if events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Based on the qualitative assessment, if it is determined that the fair value of indefinite-lived intangible assets is more likely than not to be less than its carrying amount, the fair value will be calculated and compared with its carrying amount and an impairment charge will be recognized for the amount that the carrying value exceeds the fair value. Determining whether impairment indicators exist and estimating the fair value of our indefinite-lived intangible assets if necessary for impairment testing requires significant judgment. We performed our annual goodwill assessment using a qualitative assessment and concluded there were no impairments. Qualitative factors considered in this assessment included industry and market conditions, overall financial performance, and other relevant events and factors. For the year ended December 31, 2024, we elected to bypass the qualitative assessment and performed a quantitative assessment for our annual IPR&D assessment. We determined that the carrying value exceeded the fair value and recorded an impairment loss of $830.0 million. Key assumptions used to calculate the fair value of the IPR&D asset for the quantitative assessment included inputs such as projected revenues, projected gross margin, projected operating expenses, discount rate, tax rate, obsolescence factor, and probability of commercial success.

Impairment of Long-Lived Assets. We evaluate the fair value of long-lived assets, which include property, plant and equipment, leases, finite-lived intangible assets, and investments in non-marketable securities, for impairment whenever events or changes in circumstances indicate that the carrying amounts of the assets may not be fully recoverable. The review of qualitative factors requires significant judgement. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. We recorded impairment charges totaling $39.5 million during the year ended December 31, 2024 related to the closure of certain of our domestic facilities. We recorded impairment charges totaling $0.6 million during the year ended December 31, 2023 related to building leases on certain of our domestic facilities. We recorded impairment charges totaling $16.0 million during the year ended December 31, 2022 related to the supply agreement intangible asset acquired as part of the combination with Genomic Health, the developed technology intangible asset acquired as part of the acquisition of Paradigm, and building leases at certain of our domestic locations. We utilized the income approach to measure the fair value of the acquired developed technology intangible asset, supply agreement intangible asset, and building leases and associated leasehold improvements, which required management to make estimates including revenue projections, cash flow projections, and discount rates. We believe that the estimates applied are based on reasonable assumptions, but the estimates are inherently uncertain. As a result, the eventual realized value of the impaired asset may vary from its fair value.

Recent Accounting Pronouncements

See Note 1 of our consolidated financial statements included in this Annual Report on Form 10-K for the discussion of Recent Accounting Pronouncements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our exposure to market risk is principally confined to our cash, cash equivalents and marketable securities, and our outstanding variable-rate debt. We invest our cash, cash equivalents, and marketable securities in securities of the U.S. governments and its agencies and in investment-grade, highly liquid investments consisting of commercial paper, bank certificates of deposit, and corporate bonds, which as of December 31, 2024 and December 31, 2023 were classified as available-for-sale. We place our cash, cash equivalents, restricted cash, and marketable securities with high-quality financial institutions, limit the amount of credit exposure to any one institution, and have established investment guidelines relative to diversification and maturities designed to maintain safety and liquidity.

Based on a hypothetical 100 basis point decrease in market interest rates, the potential losses in future earnings, fair value of risk-sensitive financial instruments, and cash flows are immaterial, although the actual effects may differ materially from the hypothetical analysis. While we believe our cash, cash equivalents, restricted cash, and marketable securities do not contain excessive risk, we cannot provide absolute assurance that, in the future, our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash, cash equivalents, restricted cash, and marketable securities at one or more financial institutions that are in excess of federally insured limits. Given the potential instability of financial institutions, we cannot provide assurance that we will not experience losses on these deposits. We do not utilize interest rate hedging agreements or other interest rate derivative instruments.

As of December 31, 2024, we had no outstanding variable rate debt. If we were to draw down amounts under our Revolving Loan, we would be impacted by increases in prevailing market interest rates. All of our other significant interest-bearing liabilities bear interest at fixed rates and therefore are not subject to fluctuations in market interest rates; however, because these interest rates are fixed, we may be paying a higher interest rate, relative to market, in the future if circumstances change.

Foreign Currency Risk

The functional currency for most of our international subsidiaries is the U.S. dollar, and as a result we are not subject to material gains and losses from foreign currency translation of the subsidiary financial statements. Substantially all of our revenues are recognized in U.S. dollars, although a small portion is denominated in foreign currency as we continue to expand into markets outside of the U.S. Certain expenses related to our international activities are payable in foreign currencies. As a result, factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets will affect our financial results.

We enter into forward contracts to mitigate the impact of adverse movements in foreign exchange rates related to the re-measurement of monetary assets and liabilities and hedge our foreign currency exchange rate exposure. As of December 31, 2024, we had open foreign currency forward contracts with notional amounts of $44.2 million. Although the impact of currency fluctuations on our financial results has been insignificant in the past, there can be no guarantee that the impact of currency fluctuations related to our international activities will not be material in the future.

Item 8. Consolidated Financial Statements and Supplementary Data

EXACT SCIENCES CORPORATION
Index to Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Exact Sciences Corporation

Opinions on the Financial Statements and Internal Control over Financial Reporting

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

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

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 Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and 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 (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) 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 (iii) 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 Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Valuation of Net Accounts Receivable - Variable Consideration

As described in Note 1 to the consolidated financial statements, the Company's revenue is primarily generated by its laboratory testing services utilizing its Cologuard and Oncotype tests. The Company's customer is primarily the patient, but the Company does not enter into a formal reimbursement contract with a patient. The Company's transaction price is comprised of fixed and variable consideration and is allocated entirely to a single performance obligation defined as the point in time an approved patient test result is released to the ordering healthcare provider. Fixed consideration exists in arrangements where the Company has agreed to provide laboratory testing services to a customer for a specified rate and is expected to be collected in full at that rate. Variable consideration is primarily derived from payer and patient billing and can be impacted by several factors such as the amount of contractual adjustments, any patient co-payments, deductibles or patient adherence incentives, the existence of secondary payers, and claim denials. Management estimates the amount of variable consideration using the expected value method and is the sum of probability-weighted amounts in a range of possible consideration amounts. When estimating the amount of variable consideration, management considers several factors, such as historical collections experience, current contractual and statutory requirements, customer mix, patient insurance eligibility and payer reimbursement contracts, and known or anticipated reimbursement trends not yet reflected in the data. The Company's net accounts receivable as of December 31, 2024 was $249 million.

The principal considerations for our determination that performing procedures relating to the valuation of net accounts receivable - variable consideration is a critical audit matter are (i) the significant judgment by management due to the significant measurement uncertainty when developing the estimated amount of variable consideration; and (ii) a high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating audit evidence obtained related to management's estimate of the amount of variable consideration.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's estimate of the amount of variable consideration, including controls over management's methodology and data used in developing the estimate. These procedures also included, among others (i) testing management's process for developing the estimated amount of variable consideration; (ii) evaluating the appropriateness of the method used by management; (iii) testing the completeness and accuracy of the underlying historical collection data used in the method; (iv) testing, on a sample basis, the accuracy of revenue transactions and cash collections from the historical billing and collection data used in management's method; and (v) performing a retrospective comparison of actual cash collected subsequent to year-end to evaluate the reasonableness of the prior year estimate of the amount of variable consideration.

In-Process Research and Development (IPR&D) Annual Impairment Assessment

As described in Notes 1 and 6 to the consolidated financial statements, the Company's IPR&D intangible asset balance was $420 million as of December 31, 2024. Capitalized IPR&D projects are tested for impairment annually in the fourth quarter, whenever events or changes in circumstances indicate that the carrying amount may not be recoverable, and upon successful completion of the project. Management performed a quantitative impairment assessment for the IPR&D, which required a fair value measurement as of its annual test date, November 15, 2024. Management determined that the fair value of the IPR&D was $420 million and recorded a non-cash, pre-tax impairment charge of $830 million. The fair value of the IPR&D asset was measured using the multi-period excess earnings method approach, which utilizes significant unobservable inputs (Level 3 inputs) including projected revenues, projected gross margin, projected operating expenses, discount rate, tax rate, obsolescence factor, and probability of commercial success.

The principal considerations for our determination that performing procedures relating to the IPR&D annual impairment assessment is a critical audit matter are (i) the significant judgment by management when developing the fair value estimate of the IPR&D intangible asset; (ii) a high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating management's multi-period excess earnings method and significant assumptions related to projected revenues, projected gross margin, projected operating expenses, discount rate, tax rate, obsolescence factor, and probability of commercial success; and (iii) the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's IPR&D annual impairment assessment, including controls over the valuation of the IPR&D intangible asset. These procedures also included, among others (i) testing management's process for developing the fair value estimate of the IPR&D intangible asset; (ii) evaluating the appropriateness of the multi-period excess earnings method used by management; (iii) testing the completeness and accuracy of the underlying data used in the multi-period excess earnings method; and (iv) evaluating the reasonableness of the significant assumptions used by management related to projected revenues, projected gross margin, projected operating expenses, discount rate, tax rate, obsolescence factor, and probability of commercial success. Evaluating management's assumptions related to projected revenues, projected gross margin, projected operating expenses, tax rate, and probability of commercial success involved considering (i) internal and external market and industry data, and (ii) whether these assumptions were consistent with evidence obtained in other areas of the audit. Professionals with specialized skill and knowledge were used to assist in evaluating (i) the appropriateness of the multi-period excess earnings method, and (ii) the reasonableness of the discount rate and obsolescence factor assumptions.

/s/ PricewaterhouseCoopers LLP
Chicago, Illinois
February 19, 2025

We have served as the Company's auditor since 2020.

EXACT SCIENCES CORPORATION
Consolidated Balance Sheets
(Amounts in thousands, except share data)

	December 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 600,889	$ 605,378
Marketable securities	437,137	172,266
Accounts receivable, net	248,968	203,623
Inventory	162,383	127,475
Prepaid expenses and other current assets	122,046	85,627
Total current assets	1,571,423	1,194,369
Long-term assets:		
Property, plant and equipment, net	693,673	698,354
Operating lease right-of-use assets	116,952	143,708
Goodwill	2,366,676	2,367,120
Intangible assets, net	1,009,693	1,890,396
Other long-term assets, net	169,722	177,387
Total assets	$ 5,928,139	$ 6,471,334
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 89,572	$ 78,816
Accrued liabilities	328,292	341,683
Operating lease liabilities, current portion	27,405	29,379
Convertible notes, net, current portion	249,153	—
Debt, current portion	—	50,000
Other current liabilities	37,765	14,823
Total current liabilities	732,187	514,701
Long-term liabilities:		
Convertible notes, net, less current portion	2,321,067	2,314,276
Other long-term liabilities	315,503	335,982
Operating lease liabilities, less current portion	157,133	161,070
Total liabilities	3,525,890	3,326,029
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Preferred stock, $0.01 par value Authorized—5,000,000 shares issued and outstanding—no shares at December 31, 2024 and December 31, 2023	—	—
Common stock, $0.01 par value Authorized—400,000,000 shares issued and outstanding—185,616,438 and 181,364,180 shares at December 31, 2024 and December 31, 2023	1,857	1,815
Additional paid-in capital	6,899,368	6,611,237
Accumulated other comprehensive income (loss)	(944)	1,428
Accumulated deficit	(4,498,032)	(3,469,175)
Total stockholders' equity	2,402,249	3,145,305
Total liabilities and stockholders' equity	$ 5,928,139	$ 6,471,334

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

EXACT SCIENCES CORPORATION
Consolidated Statements of Operations
(Amounts in thousands, except per share data)

	Year Ended December 31,		
	2024	2023	2022
Revenue	$ 2,758,867	$ 2,499,766	$ 2,084,279
Cost of sales	840,150	737,564	661,361
Gross profit	1,918,717	1,762,202	1,422,918
Operating expenses:			
Research and development	431,210	426,927	394,191
Sales and marketing	894,125	827,805	929,644
General and administrative	781,825	800,288	663,381
Impairment of long-lived and indefinite-lived assets	869,460	621	15,969
Total operating expenses	2,976,620	2,055,641	2,003,185
Other operating income (loss)	9,200	78,427	(13,244)
Loss from operations	(1,048,703)	(215,012)	(593,511)
Other income (expense)			
Investment income (loss), net	39,558	32,713	(19,425)
Interest expense	(27,016)	(19,447)	(19,634)
Total other income (expense)	12,542	13,266	(39,059)
Net loss before tax	(1,036,161)	(201,746)	(632,570)
Income tax benefit (expense)	7,304	(2,403)	9,064
Net loss	$ (1,028,857)	$ (204,149)	$ (623,506)
Net loss per share—basic and diluted	$ (5.59)	$ (1.13)	$ (3.54)
Weighted average common shares outstanding—basic and diluted	184,197	180,144	176,351

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

EXACT SCIENCES CORPORATION
Consolidated Statements of Comprehensive Loss
(Amounts in thousands)

	Year Ended December 31,		
	2024	2023	2022
Net loss	$ (1,028,857)	$ (204,149)	$ (623,506)
Other comprehensive loss, before tax:			
Unrealized gain (loss) on available-for-sale investments	922	5,343	(3,823)
Foreign currency adjustment	(3,294)	1,321	30
Comprehensive loss, net of tax	$ (1,031,229)	$ (197,485)	$ (627,299)

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

EXACT SCIENCES CORPORATION
Consolidated Statements of Stockholders' Equity
(Amounts in thousands, except share data)

	Common Stock		Additional Paid In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	$0.01 Par Value				
Balance, Balance, January 1, 2022	173,674,067	$ 1,738	$ 6,028,861	$ (1,443)	$ (2,641,520)	$ 3,387,636
Exercise of common stock options	706,134	6	6,518	—	—	6,524
Issuance of common stock to fund the Company's 2021 401(k) match	391,129	4	29,198	—	—	29,202
Issuance of common stock upon settlement of restricted stock awards, net of shares withheld for taxes	2,220,510	22	(22)	—	—	—
Compensation expense related to issuance of stock options and restricted stock awards	—	—	206,823	—	—	206,823
Purchase of employee stock purchase plan shares	668,605	7	25,484	—	—	25,491
Issuance of common stock for business combinations and asset	265,186	3	14,789	—	—	14,792
Other	—	—	(7)	—	—	(7)
Net loss	—	—	—	—	(623,506)	(623,506)
Other comprehensive loss	—	—	—	(3,793)	—	(3,793)
Balance, December 31, 2022	177,925,631	$ 1,780	$ 6,311,644	$ (5,236)	$ (3,265,026)	$ 3,043,162
Exercise of common stock options	194,597	2	3,195	—	—	3,197
Issuance of common stock to fund the Company's 2022 401(k) match	517,550	5	35,095	—	—	35,100
Issuance of common stock upon settlement of restricted stock awards, net of shares withheld for	1,801,954	18	(18)	—	—	—
Compensation expense related to issuance of stock options and restricted stock awards	—	—	231,312	—	—	231,312
Purchase of employee stock purchase plan shares	924,448	10	28,334	—	—	28,344
Replaced restricted stock awards for business combination	—	—	1,675	—	—	1,675
Net loss	—	—	—	—	(204,149)	(204,149)
Other comprehensive income	—	—	—	6,664	—	6,664
Balance, December 31, 2023	181,364,180	$ 1,815	$ 6,611,237	$ 1,428	$ (3,469,175)	$ 3,145,305
Exercise of common stock options	204,034	2	1,649	—	—	1,651
Issuance of common stock to fund the Company's 2023 401(k) match	617,384	6	40,544	—	—	40,550
Issuance of common stock upon settlement of restricted stock awards, net of shares withheld for taxes	2,475,448	25	(165)	—	—	(140)
Compensation expense related to issuance of stock options and restricted stock awards	—	—	214,885	—	—	214,885
Purchase of employee stock purchase plan shares	955,392	9	31,218	—	—	31,227
Net loss	—	—	—	—	(1,028,857)	(1,028,857)
Other comprehensive loss	—	—	—	(2,372)	—	(2,372)
Balance, December 31, 2024	185,616,438	$ 1,857	$ 6,899,368	$ (944)	$ (4,498,032)	$ 2,402,249

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

EXACT SCIENCES CORPORATION
Consolidated Statements of Cash Flows
(Amounts in thousands, except share data)

	Year Ended December 31,		
	2024	2023	2022
Cash flows from operating activities:			
Net loss	$ (1,028,857)	$ (204,149)	$ (623,506)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation	119,701	114,448	100,108
(Gain) loss on non-marketable and marketable equity investments	2,713	(4,098)	21,774
Deferred tax benefit	(10,119)	(955)	(11,901)
Stock-based compensation	214,885	231,312	206,823
Gain on settlement of convertible notes	(10,254)	(10,324)	—
Amortization of acquired intangible assets	95,158	92,160	97,450
Loss on sale of asset	—	—	13,244
Impairment of long-lived and indefinite-lived assets	869,460	621	15,969
Gain on contingent consideration from sale of asset	(9,200)	(73,300)	—
Remeasurement of contingent consideration liabilities	(3,346)	(18,044)	(56,617)
Non-cash lease expense	26,926	27,891	28,639
Other	(519)	899	10,835
Changes in assets and liabilities, net of effects of acquisition:			
Accounts receivable, net	(46,259)	(43,416)	61,088
Inventory, net	(34,911)	(7,690)	(13,231)
Operating lease liabilities	(25,783)	(26,701)	(20,646)
Accounts payable and accrued liabilities	43,538	82,750	(52,180)
Other assets	(2,323)	(11,618)	(84)
Other liabilities	9,726	6,333	(1,324)
Net cash provided by (used in) operating activities	210,536	156,119	(223,559)
Cash flows from investing activities:			
Purchases of marketable securities	(465,031)	(139,854)	(131,486)
Maturities and sales of marketable securities	205,821	363,156	453,072
Purchases of property, plant and equipment	(135,989)	(124,190)	(214,462)
Proceeds from sale of asset	—	—	25,000
Maturities and sales of investments in non-marketable securities	—	19,794	—
Investments in non-marketable securities	(1,731)	(16,564)	(42,823)
Business combination, net of cash acquired and issuance costs	—	(52,413)	(14,686)
Asset acquisitions, net of cash acquired	(45,000)	(500)	—
Other investing activities	(225)	250	(549)
Net cash provided by (used in) investing activities	(442,155)	49,679	74,066
Cash flows from financing activities:			
Proceeds from accounts receivable securitization facility	—	—	50,000
Proceeds from exercise of common stock options	1,651	3,197	6,524
Proceeds in connection with the Company's employee stock purchase plan	31,227	28,344	25,491
Proceeds from issuance of convertible notes	266,750	137,976	—
Payments on accounts receivable securitization facility	(50,000)	—	—
Other financing activities	(17,754)	(9,751)	(5,530)
Net cash provided by financing activities	231,874	159,766	76,485
Effects of exchange rate changes on cash and cash equivalents	(3,294)	1,321	30
Net increase (decrease) in cash, cash equivalents, and restricted cash	(3,039)	366,885	(72,978)
Cash, cash equivalents, and restricted cash at the beginning of period	609,675	242,790	315,768
Cash, cash equivalents, and restricted cash at the end of period	$ 606,636	$ 609,675	$ 242,790

EXACT SCIENCES CORPORATION
Consolidated Statements of Cash Flows
(Amounts in thousands, except share data)

	Year Ended December 31,		
	2024	**2023**	**2022**
Supplemental disclosure of non-cash investing and financing activities:			
Property, plant and equipment acquired but not paid	$ 13,721	$ 18,505	$ 15,943
Issuance of 617,384, 517,550, and 391,129 shares of common stock to fund the Company's 401(k) matching contribution for 2023, 2022, and 2021, respectively	$ 40,550	$ 35,100	$ 29,202
Supplemental disclosure of cash flow information:			
Interest paid	$ 27,839	$ 18,776	$ 11,519
Reconciliation of cash, cash equivalents, and restricted cash:			
Cash and cash equivalents	$ 600,889	$ 605,378	$ 242,493
Restricted cash — included in other long-term assets, net as of December 31, 2024 and 2023, and prepaid expenses and other current assets as of December 31, 2022	5,747	4,297	297
Total cash, cash equivalents, and restricted cash	$ 606,636	$ 609,675	$ 242,790

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

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Business

Exact Sciences Corporation (together with its subsidiaries, "Exact" or the "Company") was incorporated in February 1995. A leading provider of cancer screening and diagnostic tests, Exact Sciences gives patients and health care professionals the clarity needed to take life-changing action earlier. Building on the success of Cologuard® and Oncotype DX® tests, Exact Sciences is investing in its pipeline to develop innovative solutions for use before, during, and after a cancer diagnosis.

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Exact Sciences Corporation and those of its wholly-owned subsidiaries. All intercompany transactions and balances have been eliminated upon consolidation.

Use of Estimates

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Critical accounting policies are those that affect the Company's financial statements materially and involve difficult, subjective or complex judgments by management, and actual results could differ from those estimates. These estimates include revenue recognition, valuation of intangible assets and goodwill, contingent consideration, and accounting for income taxes.

Cash and Cash Equivalents

The Company considers cash on hand, demand deposits in a bank, money market funds, and all highly liquid investments with an original maturity of 90 days or less to be cash and cash equivalents.

Marketable Securities

Management determines the appropriate classification of debt securities at the time of purchase and re-evaluates such designation as of each balance sheet date. Debt securities carried at amortized cost are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to maturity. Debt securities not classified as held-to-maturity are classified as available-for-sale. Available-for-sale securities are carried at fair value. The unrealized gains and losses, net of tax, on the Company's debt securities are reported in other comprehensive income. Marketable equity securities are measured at fair value and the unrealized gains and losses, net of tax, are recognized in other income (expense) in the consolidated statements of operations. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity computed under the effective interest rate method. Such amortization is included in investment income, net. Realized gains and losses and declines in value as a result of credit losses on available-for-sale securities are included in the consolidated statements of operations as investment income, net. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in the consolidated statements of operations as investment income, net.

The Company's investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer. Investments in which the Company has the ability and intent, if necessary, to liquidate in order to support its current operations (including those with a contractual term greater than one year from the date of purchase) are classified as current.

The Company periodically evaluates its available-for-sale debt securities in unrealized loss positions to determine whether any impairment is a result of a credit loss or other factors. This evaluation includes, but is not limited to, significant quantitative and qualitative assessments and estimates regarding credit ratings, significance of a security's loss position, adverse conditions specifically related to the security, and the payment structure of the security.

Allowance for Doubtful Accounts

The Company estimates an allowance for doubtful accounts against accounts receivable using historical collection trends, aging of accounts, current and future implications surrounding the ability to collect such as economic conditions, and regulatory changes. The allowance for doubtful accounts is evaluated on a regular basis and adjusted when trends, significant events, or other substantive evidence such as an adverse change in a payer's ability to pay indicate that expected collections will be less than previously estimated. At December 31, 2024 and 2023, the allowance for doubtful accounts recorded was not significant to the Company's consolidated balance sheets. For the years ended December 31, 2024, 2023 and 2022, there was an insignificant amount of bad debt expense written off against the allowance and charged to operating expense.

Inventory

Inventory is stated at the lower of cost or net realizable value. The Company determines the cost of inventory using the first-in, first out method ("FIFO"). The Company estimates the recoverability of inventory by reference to internal estimates of future demands and product life cycles, including expiration. The Company periodically analyzes its inventory levels to identify inventory that may expire prior to expected sale, no longer meets quality specifications, or has a cost basis in excess of its estimated realizable value and records a charge to cost of sales for such inventory as appropriate.

Direct and indirect manufacturing costs incurred during process validation with probable future economic benefit are capitalized. Validation costs incurred for other research and development activities, which are not permitted to be sold, are expensed to research and development in the Company's consolidated statements of operations.

Materials that may be used for either research and development or commercial purposes are classified as inventory until the material is consumed or otherwise allocated for research and development. Materials that have alternative uses outside of commercial purposes are classified within prepaid expenses and other current assets on the consolidated balance sheet. If the material is used for research and development, it is expensed as research and development once that determination is made.

When future commercialization of new products is considered probable and the future economic benefit is expected to be realized, based on management's judgment, pre-launch inventory costs are capitalized prior to regulatory approval. Prior to the capitalization of inventory costs, the Company records such material costs within either prepaid expenses and other current assets or research and development expenses on the Company's consolidated balance sheets and consolidated statements of operations, respectively.

Property, Plant and Equipment

Property, plant and equipment are stated at cost and depreciated using the straight-line method over the assets' estimated useful lives. Land is stated at cost and does not depreciate. Additions and improvements are capitalized, including direct and indirect costs incurred to validate equipment and bring to working conditions. Revalidation costs, including maintenance and repairs are expensed when incurred.

Software Development Costs

Costs related to internal use software, including hosted arrangements, are incurred in three stages: the preliminary project stage, the application development stage, and the post-implementation stage. Costs incurred during the preliminary project and post-implementation stages are expensed as incurred. Costs incurred during the application development stage that meet the criteria for capitalization are capitalized and amortized, when the software is ready for its intended use, using the straight-line method over the estimated useful life of the software, or the duration of the hosting agreement.

Investments in Non-Marketable Securities

The Company determines whether its investments in non-marketable securities are debt or equity based on their characteristics. The Company also evaluates the investee to determine if the entity is a variable interest entity ("VIE") and, if so, whether the Company is the primary beneficiary of the VIE, in order to determine whether consolidation of the VIE is required. If consolidation is not required and the Company does not have voting control of the entity, the investment is evaluated to determine if the equity method of accounting should be applied. The equity method applies to investments in common stock or in substance common stock where the Company exercises significant influence over the investee.

Investments in non-marketable securities determined to be equity securities without readily determinable fair values are accounted for under the measurement alternative method as permitted in Accounting Standards Codification ("ASC") 321, Investments - Equity Securities. The Company adjusts the carrying value of its non-marketable equity securities for changes from observable transactions for identical or similar investments of the same issuer, less impairment. All gains and losses on non-marketable equity securities, realized and unrealized, are recognized in investment income, net in the consolidated statements of operations.

Investments in non-marketable securities determined to be debt securities are accounted for as available-for-sale or held-to-maturity securities unless the fair value option is elected.

Derivative Financial Instruments

The Company hedges a portion of its foreign currency exposures related to outstanding monetary assets and liabilities using foreign currency forward contracts. The foreign currency forward contracts are included in prepaid expenses and other current assets or in accrued liabilities in the consolidated balance sheets, depending on the contracts' net position. These contracts are not designated as hedges, and as a result, changes in their fair value are recorded in other income (expense) in the consolidated statements of operations.

Business Combinations and Asset Acquisitions

Business Combinations are accounted for under the acquisition method in accordance with ASC 805, Business Combinations. The acquisition method requires identifiable assets acquired and liabilities assumed and any non-controlling interest in the business acquired be recognized and measured at fair value on the acquisition date, which is the date that the acquirer obtains control of the acquired business. The amount by which the fair value of consideration transferred as the purchase price exceeds the net fair value of assets acquired and liabilities assumed is recorded as goodwill. Acquisitions that do not meet the definition of a business combination under ASC 805 are accounted for as asset acquisitions. Asset acquisitions are accounted for by allocating the cost of the acquisition to the individual assets acquired and liabilities assumed on a relative fair value basis. Goodwill is not recognized in an asset acquisition with any consideration in excess of net assets acquired allocated to acquired assets on a relative fair value basis. Transaction costs are expensed in a business combination and are considered a component of the cost of the acquisition in an asset acquisition.

Intangible Assets

Purchased intangible assets are recorded at fair value. The Company uses a discounted cash flow model to value intangible assets. The discounted cash flow model requires assumptions about the timing and amount of future net cash flows, risk, the cost of capital, terminal values and market participants. The Company's finite-lived intangible assets are being amortized on a straight-line basis over their estimated useful lives.

Patent costs are capitalized as incurred, only if the Company determines that there is some probable future economic benefit derived from the transaction. A capitalized patent is amortized over its estimated useful life, beginning when such patent is approved. Capitalized patent costs are expensed upon disapproval, upon a decision by the Company to no longer pursue the patent or when the related intellectual property is either sold or deemed to be no longer of value to the Company. The Company determined that all patent costs incurred during the years ended December 31, 2024, 2023, and 2022 should be expensed and not capitalized as the future economic benefit derived from the patent costs incurred cannot be determined.

Acquired In-process Research and Development ("IPR&D")

Acquired IPR&D represents the fair value assigned to research and development assets that have not reached technological feasibility. The primary basis for determining technological feasibility of these projects is obtaining regulatory approval to market the underlying product. The amounts capitalized are accounted for as indefinite-lived intangible assets and are subject to impairment testing until completion or abandonment of the research and development efforts associated with the projects. Upon successful completion of the project, the capitalized amount is amortized over its estimated useful life. If a project is abandoned, all remaining capitalized amounts are written off immediately. The value assigned to acquired IPR&D is determined using the multi-period excess earnings method approach, which utilizes significant unobservable inputs (Level 3 inputs) including projected revenues, projected gross margin, projected operating expenses, discount rate, tax rate, obsolescence factor, and probability of commercial success. There are often major risks and uncertainties associated with IPR&D projects as the Company is required to obtain regulatory approvals in order to market the resulting products. Such approvals require completing clinical trials that demonstrate the product's effectiveness. Consequently, the eventual realized value of the IPR&D project may vary from its fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods.

Capitalized IPR&D projects are tested for impairment annually in the fourth quarter, whenever events or changes in circumstances indicate that the carrying amount may not be recoverable, and upon successful completion of the project. The Company considers various factors for potential impairment, including the current legal and regulatory environment, current and future strategic initiatives, and the competitive landscape. Adverse clinical trial results, significant delays in obtaining marketing approval, the inability to bring a product to market and the introduction or advancement of competitors' products could result in partial or full impairment of the related intangible assets.

Contingent Consideration Liabilities

Certain of the Company's business combinations involve potential payment of future consideration that is contingent upon the achievement of certain regulatory and product development milestones being achieved. The Company records contingent consideration at fair value at the date of acquisition based on the consideration expected to be transferred, estimated as the probability-weighted future cash flows, discounted back to present value. The fair value of contingent consideration is measured using projected probabilities of success, projected payment dates, present value-factors, and projected revenues (for revenue-based considerations). Changes in probabilities of success, present-value factors, and projected payment dates may result in adjustments to the fair value measurements. Contingent consideration is remeasured each reporting period using Level 3 inputs, and the change in fair value, including accretion for the passage of time, is recognized as income or expense within general and administrative expenses on the Company's consolidated statements of operations. Cash contingent consideration payments up to the acquisition date fair value of the contingent consideration liability are classified as financing activities in the consolidated statements of cash flows, and amounts paid in excess of the original acquisition date fair value are classified as operating activities in the consolidated statements of cash flows.

Contingent Consideration Asset

The sale of the Company's intellectual property and know-how related to the Company's Oncotype DX Genomic Prostate Score test ("GPS test") resulted in the recognition of variable consideration in accordance with ASC 606. The Company estimates the amount of variable consideration that it is entitled to each quarter using the most likely amount method and considers whether there are any constraints on the consideration. If it is probable that a significant reversal of a gain would not occur, the Company will record a gain. To determine the classification of the consideration, the Company determines if the consideration is conditional on something other than the passage of time. Revenue-based contingent consideration that is conditional on something other than the passage of time, including future revenues from sales related to the GPS test, result in the variable consideration being classified as a contract asset. At the time the amount earned is determined, and passage of time is the only condition remaining, the contract asset is reclassified to a receivable.

Collateralized Debt Instruments

Debt instruments that are collateralized by security interests in financial assets held by the Company are accounted for as a secured borrowing and therefore: (i) the asset balances pledged as collateral are included within the applicable balance sheet line item and the borrowings are included within long-term debt in the consolidated balance sheet; (ii) interest expense is included within the consolidated statements of operations; and (iii) in the case of collateralized accounts receivable, receipts from customers related to the underlying accounts receivable are reflected as operating cash flows, and (iv) borrowings and repayments under the collateralized loans are reflected as financing cash flows within the consolidated statements of cash flows.

Goodwill

The Company evaluates goodwill for possible impairment at the reporting unit level on an annual basis during the fourth quarter, or more frequently if events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Qualitative factors considered in this assessment include industry and market conditions, overall financial performance, and other relevant events and factors affecting the Company's business. Based on the qualitative assessment, if it is determined that the fair value of goodwill is more likely than not to be less than its carrying amount, the fair value of a reporting unit will be calculated and compared with its carrying amount and an impairment charge will be recognized for the amount that the carrying value exceeds the fair value.

Impairment of Long-Lived Assets

The Company evaluates the fair value of long-lived assets, which include property, plant and equipment, leases, and finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amounts of the assets may not be fully recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

Net Loss Per Share

Basic net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted average common shares outstanding during the period. Basic and diluted net loss per share is the same because all outstanding common stock equivalents have been excluded, as they are anti-dilutive as a result of the Company’s losses.

The following potentially issuable common shares were not included in the computation of diluted net loss per share because they would have an anti-dilutive effect due to net losses for each period:

	December 31,		
(In thousands)	**2024**	**2023**	**2022**
Shares issuable upon conversion of convertible notes	26,526	23,231	20,309
Shares issuable upon the release of restricted stock awards	7,245	6,273	5,255
Shares issuable upon the release of performance share units	2,021	1,598	968
Shares issuable upon exercise of stock options	983	1,286	1,518
	36,775	32,388	28,050

Accounting for Stock-Based Compensation

The Company requires all share-based payments to employees, including grants of employee stock options, restricted stock, restricted stock units, shares purchased under an employee stock purchase plan (if certain parameters are not met), and performance share units to be recognized in the financial statements based on their grant date fair values. The estimated fair value of these awards is recognized to expense using the straight-line method over the requisite service period, which is generally the vesting period. The Company will recognize expense on an accelerated basis for restricted stock units upon an employee's death, disability, or upon retirement eligibility, provided certain criteria are met. Forfeitures of any share-based awards are recognized as they occur.

The fair values and recognition of the Company’s share-based payment awards are determined as follows:

The fair value of each service-based option award is estimated on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes pricing model utilizes the following assumptions:

Expected Term—Expected life of an option award is the average length of time over which the Company expects employees will exercise their options, which is based on historical experience with similar grants.

Expected Volatility—Expected volatility is based on the Company's historical stock volatility data over the expected term of the awards.

Risk-Free Interest Rate—The Company bases the risk-free interest rate on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent expected term.

The fair value of service-based awards for each restricted stock unit award is determined on the date of grant using the closing stock price on that day.

The fair value of performance-based equity awards that do not include a market condition is determined on the date of grant using the closing stock price on that day. The fair value of performance-based equity awards that include a market condition is determined on the date of grant using a Monte Carlo valuation technique. The expense recognized each period is also dependent on the probability of what performance conditions will be met which is determined by management's evaluation of internal and external factors. Determining the appropriate amount to expense based on the anticipated achievement of the stated goals requires judgment, including forecasting future financial results. The estimate of the timing of the expense recognition is revised periodically based on the probability of achieving the goals and adjustments are made as appropriate. The cumulative impact of any revision is reflected in the period of the change. If the financial performance targets and operational milestones are not achieved, the award would not vest resulting in no stock-based compensation being recognized and any previously recognized stock-based compensation expense being reversed.

Research and Development Costs

Research and development costs are expensed as incurred. These expenses include the costs of the Company's proprietary research and development efforts, as well as costs of IPR&D projects acquired as part of an asset acquisition that have no alternative future use. Acquired IPR&D assets that are acquired in an asset acquisition and which have no alternative future use are classified as an investing cash outflow in the consolidated statements of cash flows. Upfront and milestone payments due to third parties in connection with research and development collaborations prior to regulatory approval are expensed as incurred. Milestone payments due to third parties upon, or subsequent to, regulatory approval are capitalized and amortized into research and development costs over the shorter of the remaining license or product patent life, when there are no corresponding revenues related to the license or product. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received, rather than when the payment is made.

Advertising Costs

Advertising costs are expensed as incurred. The Company expensed approximately $180.3 million, $137.9 million, and $170.3 million of media advertising during the years ended December 31, 2024, 2023, and 2022, respectively, which is recorded in sales and marketing expenses on the Company's consolidated statements of operations.

Fair Value Measurements

The Financial Accounting Standards Board ("FASB") has issued authoritative guidance that requires fair value to be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under that standard, fair value measurements are separately disclosed by level within the fair value hierarchy. The fair value hierarchy establishes and prioritizes the inputs used to measure fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs. Observable inputs are inputs that reflect the assumptions that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances.

Leases

The Company acts as lessee in its lease agreements, which include operating leases for corporate offices, laboratory space, warehouse space, vehicles, and certain laboratory and office equipment, and finance leases for certain equipment and vehicles.

The Company determines whether an arrangement is, or contains, a lease at inception. The Company records the present value of lease payments as right-of-use ("ROU") assets and lease liabilities on the consolidated balance sheets. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent an obligation to make lease payments based on the present value of lease payments over the lease term. Classification of lease liabilities as either current or non-current is based on the expected timing of payments due under the Company's obligations.

As the implicit interest rate is not readily determinable in most of the Company's leases, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The incremental borrowing rate is the rate of interest that a lessee would have to pay to borrow on a collateralized basis over a similar term and at an amount equal to the lease payments in a similar economic environment and credit profile.

The ROU asset also consists of any lease incentives received. The lease terms used to calculate the ROU asset and related lease liability include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. "Reasonably certain" is assessed internally based on economic, industry, company, strategic and contractual factors. The leases have remaining lease terms of 1 year to 15 years, some of which include options to extend the lease for up to 10 years, and some of which include options to terminate the lease within 1 year. Operating lease expense and amortization of finance lease ROU assets are recognized on a straight-line basis over the lease term as an operating expense. Finance lease interest expense is recorded as interest expense on the Company's consolidated statements of operations.

The Company accounts for leases acquired in business combinations by measuring the lease liability at the present value of the remaining lease payments as if the acquired lease were a new lease for the Company. This measurement includes recognition of a lease intangible for any below-market terms present in the leases acquired. The below-market lease intangible is included in the ROU asset on the consolidated balance sheets and are amortized over the remaining lease term. The Company has not acquired any leases with above-market terms.

The Company has taken advantage of certain practical expedients offered to registrants at adoption of ASC 842. The Company does not apply the recognition requirements of ASC 842 to short-term leases. Instead, those lease payments are recognized in profit or loss on a straight-line basis over the lease term. Further, as a practical expedient, all lease contracts are accounted for as one single lease component, as opposed to separating lease and non-lease components to allocate the consideration within a single lease contract.

Revenue Recognition

Revenues are recognized when the satisfaction of the performance obligation occurs, in an amount that reflects the consideration the Company expects to collect in exchange for those services. The Company's revenue is primarily generated by its laboratory testing services utilizing its Cologuard, Oncotype®, PreventionGenetics LLC ("PreventionGenetics"), and COVID-19 tests. The services are considered completed when the performance obligation is fulfilled, which is upon release of an approved patient test result to the healthcare provider. The Company follows ASC 606, Revenue from Contracts with Customers, to account for its laboratory service revenues.

Laboratory testing services

The Company's customer is primarily the patient, but the Company does not enter into a formal reimbursement contract with a patient. The Company establishes a contract with a patient in accordance with other customary business practices, which is the point in time an order is received from a provider and a patient specimen has been returned to the laboratory for testing. Payment terms are a function of a patient's existing insurance benefits, including the impact of coverage decisions with Center for Medicare & Medicaid Services ("CMS") and applicable reimbursement contracts established between the Company and payers. However, when a patient is considered self-pay, or in the context of certain lab service or reference agreements, the Company requires payment prior to the commencement of the Company's performance obligations.

Additionally, the Company periodically engages with third party international distributor partners to provide patients access to the Company's laboratory testing services and is considered the principal in these arrangements as control over the intellectual property, lab processing activities, and result delivery remain with the Company. Revenues from these contracts are recorded at gross in an amount that reflects the amount ultimately paid to the distributor for the testing services if known or, if this is unknown or unable to be estimated, is recorded at an effective net fixed transaction price equal to the amount billed to and received from the distributor.

The Company's contracts have a single performance obligation, which is satisfied upon rendering of services, which culminates in the release of a patient's test result to the ordering healthcare provider. Or, in the context of some of the Company's agreements, the satisfaction of the performance obligation occurs when a specimen sample is not returned to the laboratory for processing before the end of the allotted testing window. The Company elects the practical expedient to not disclose unsatisfied performance obligations, as the duration of time between providing testing supplies, the receipt of a sample, and the release of a test result to the ordering healthcare provider is far less than one year.

The Company's transaction price is comprised of fixed and variable consideration and is allocated entirely to a single performance obligation defined as the point in time an approved patient test result is released to the ordering healthcare provider. Fixed consideration exists in arrangements where the Company has agreed to provide laboratory testing services to a customer for a specified rate and is expected to be collected in full at that rate. Variable consideration is primarily derived from payer and patient billing and can be impacted by several factors such as the amount of contractual adjustments, any patient co-payments, deductibles or patient adherence incentives, the existence of secondary payers, and claim denials. Estimates of variable consideration are calculated using the expected value method and is the sum of probability-weighted amounts in a range of possible consideration amounts. Several factors are evaluated during this process, such as historical collections experience, current contractual and statutory requirements, customer mix, patient insurance eligibility and payer reimbursement contracts, and known or anticipated reimbursement trends not yet reflected in the data. The Company limits the amount of variable consideration included in the transaction price to the unconstrained portion of such consideration. In other words, the Company recognizes revenue up to the amount of variable consideration that is not subject to a significant reversal until additional information is obtained or the uncertainty associated with the additional payments or refunds is subsequently resolved. Differences between original estimates and subsequent revisions, including final settlements, represent changes in the estimate of variable consideration and are included in the period in which such revisions are made.

The Company monitors its estimates of transaction price to depict conditions that exist at each reporting date. If the Company subsequently determines that it will collect more or less consideration than it originally estimated for a contract with a patient, it will account for the change as an increase or decrease in the estimate of the transaction price (i.e., an upward or downward revenue adjustment) in the period identified.

When the Company does not have significant historical experience or that experience has limited predictive value, the constraint over estimates of variable consideration may result in no revenue being recognized upon completion of the performance obligations associated with the Company's tests, with recognition, generally occurring at the date of cash receipt.

Contract Balances

The timing of revenue recognition, billings, and cash collections results in billed accounts receivable and deferred revenue on the consolidated balance sheets. Generally, billing occurs after the release of an approved patient test result to the healthcare provider, resulting in an account receivable. However, the Company sometimes receives advance payment from a patient or a direct bill payer before services are performed, resulting in deferred revenue. The deferred revenue recorded is recognized as revenue at the point in time an approved patient test result is released to the patient's healthcare provider. In the context of some of the Company's agreements, the satisfaction of the performance obligation occurs when a specimen sample is not returned to the laboratory for processing before the end of the allotted testing window.

Practical Expedients

The Company does not adjust the transaction price for the effects of a significant financing component, as at contract inception, the Company expects the collection cycle to be one year or less.

The Company expenses sales commissions when incurred because the amortization period would have been one year or less. These costs are recorded within sales and marketing expenses in the Company's consolidated statements of operations.

The Company incurs certain other costs that are incurred regardless of whether a contract is obtained. Such costs are primarily related to legal services and patient communications (e.g. adherence reminder letters). These costs are expensed as incurred and recorded within general and administrative expenses in the Company's consolidated statements of operations.

Cost of Sales

Cost of sales reflects the aggregate costs incurred in delivering the Company's products and services and includes material and service costs, personnel costs, including stock-based compensation expense, equipment, and infrastructure expenses associated with laboratory testing services, shipping charges, allocated overhead such as rent, information technology costs, equipment depreciation, and utilities, and amortization of acquired developed technology or license intangible assets related to products commercialized by the Company. Costs associated with the shipment of Cologuard test collection kits are recognized upon shipment, and costs associated with performing the Company's tests are recorded as the tests are performed regardless of whether revenue was recognized with respect to that test.

Foreign Currency Transactions

The functional currency for most of the Company's international subsidiaries is the United States ("U.S.") dollar. When the functional currency differs from the local currency, monetary assets and liabilities are remeasured at the current period-end exchange rate, while non-monetary assets and liabilities are remeasured at the historical rate. The gains and losses as a result of exchange rate adjustments of these subsidiaries are recognized in the consolidated statements of operations. Net foreign currency transaction gains or losses were not significant to the consolidated statements of operations for the periods presented.

For the Company's international subsidiaries where the functional currency is other than the U.S. dollar, the financial statements are translated into the U.S. dollar, and the cumulative adjustments resulting from the translation into the U.S. dollar are included in the Company's consolidated balance sheet as a component of accumulated other comprehensive income (loss) ("AOCI").

Concentration of Credit Risk

Financial instruments that subject the Company to credit risk consist of cash, cash equivalents, and marketable securities. As of December 31, 2024, the Company had cash and cash equivalents deposited in financial institutions in which the balances exceed the federal government agency insured limit of $250,000 by approximately $594.5 million. The Company has not experienced any losses in such accounts and management believes it is not exposed to any significant credit risk.

Through December 31, 2024, the Company's revenues have been primarily derived from the sale of Cologuard, Oncotype, and COVID-19 tests. The following is a breakdown of revenue and accounts receivable from major payers:

	% Revenue for the years ended December 31,			% Accounts Receivable at December 31,		
Major Payer	**2024**	**2023**	**2022**	**2024**	**2023**	**2022**
Centers for Medicare and Medicaid Services	16%	17%	14%	10%	10%	14%
UnitedHealthcare	12%	12%	12%	9%	10%	9%
State of Wisconsin	—%	—%	3%	—%	—%	5%

Tax Positions

A valuation allowance to reduce the deferred tax assets is reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The Company has incurred significant losses since its inception and due to the uncertainty of the amount and timing of future taxable income, the Company has determined that a valuation allowance at December 31, 2024 and 2023 is necessary to reduce the tax assets to the amount that is more likely than not to be realized. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact the Company's effective tax rate.

Guarantees and Indemnifications

The Company, as permitted under Delaware law and in accordance with its bylaws, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity. The term of the indemnification period is for the officer's or director's lifetime. The maximum amount of potential future indemnification is unlimited; however, the Company has a directors and officers insurance policy that limits its exposure and may enable it to recover a portion of any future amounts paid. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recorded any liabilities for these agreements as of December 31, 2024 and 2023.

Reclassifications

Certain prior year amounts have been reclassified to conform to the current year presentation in the consolidated financial statements and accompanying notes to the consolidated financial statements.

Amortization of acquired intangible assets, which was previously presented as a separate line item on the Company's consolidated statements of operations, is now presented within the line item each intangible asset relates to within cost of sales, research and development, sales and marketing, and general and administrative expenses. The following amounts of amortization of acquired intangible assets for the years ended December 31, 2023 and 2022 has been reclassified to conform to current year presentation: $83.3 million and $87.0 million in cost of sales, respectively, $1.0 million and $0.8 million in research and development, respectively, $7.7 million and $9.6 million in sales and marketing, respectively, and $0.1 million and $0.1 million in general and administrative expenses, respectively. Due to the reclassification related to cost of sales, the Company is now presenting gross profit on the Company's consolidated statements of operations.

Certain general and administrative expenses totaling $93.0 million and $74.0 million for the years ended December 31, 2023 and 2022, respectively, have been reclassified to sales and marketing expenses to conform to current year presentation. The amounts reclassified are related to customer care and customer experience.

The impact to the Company's condensed consolidated statements of operations included in previously filed Quarterly Reports on Form 10-Q for the periods ended March 31, 2024, June 30, 2024 and September 30, 2024 is presented and described in further detail in Note 22.

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued Accounting Standards Update ("ASU") No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. This update improves reportable segment disclosure requirements, primarily through enhanced disclosures of significant segment expenses. The amendments in this update should be applied retrospectively to all prior periods presented in the consolidated financial statements and are effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company adopted and retrospectively applied the amendments in this update during the fourth quarter of fiscal year 2024.

In March 2024, the FASB issued ASU No. 2024-02, *Codification Improvement – Amendments to Remove References to the Concepts Statements*. This update amends the ASC to remove references to various FASB Concepts Statements. The Company early adopted and prospectively applied the amendments in this update during the first quarter of fiscal year 2024. There was no significant impact to the Company's consolidated financial statements.

In November 2024, the FASB issued ASU No. 2024-04, *Debt – Debt with Conversion and Other Options (Subtopic 470-20): Induced Conversions of Convertible Debt Instruments*. This update enhances clarity and consistency in accounting for induced conversions of convertible debt. The amendments in this update may be applied either prospectively or retrospectively and are effective for annual reporting periods beginning after December 15, 2025, and interim reporting periods beginning after December 15, 2026. Early adoption is permitted for all entities that have adopted the amendments in Update 2020-06. The Company adopted and prospectively applied the amendments in this update during the fourth quarter of fiscal year 2024. There was no significant impact to the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In October 2023, the FASB issued ASU No. 2023-06, *Disclosure Improvements*: *Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative*. This update modifies the disclosure or presentation requirements of a variety of topics in the ASC to conform with certain Securities and Exchange Commission ("SEC") amendments in Release No. 33-10532, *Disclosure Update and Simplification*. The amendments in this update should be applied prospectively, and the effective date for each amendment will be the date on which the SEC's removal of that related disclosure from Regulation S-X or S-K becomes effective. However, if the SEC has not removed the related disclosure from its regulations by June 30, 2027, the amendments will be removed from the Codification and not become effective. Early adoption is prohibited. The Company is currently evaluating the potential impact of this guidance on its consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. This update improves income tax disclosure requirements, primarily through enhanced transparency and decision usefulness of disclosures. The amendments in this update should be applied prospectively with the option to apply retrospectively and are effective for fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company is currently evaluating the potential impact of this guidance on its consolidated financial statements.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*. This update enhances financial statement disclosures by requiring public business entities to disclose specified information about certain costs and expenses including the amounts of (a) purchases of inventory, (b) employee compensation, (c) depreciation, and (d) intangible asset amortization included in each relevant expense caption. The update also requires disclosure of certain amounts that are already required to be disclosed under current GAAP, disclosure of a qualitative description of the amounts remaining in relevant expense captions that are not separately disaggregated quantitatively, and disclosure of the total amount of selling expenses and, in annual reporting periods, an entity's definition of selling expenses. The amendments in this update may be applied either prospectively or retrospectively and are effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the potential impact of this guidance on its consolidated financial statements.

(2) REVENUE

The following table presents the Company's revenues disaggregated by revenue source:

	Year Ended December 31,		
(In thousands)	**2024**	**2023**	**2022**
Screening			
Medicare Parts B & C	$ 776,155	$ 701,400	$ 545,458
Commercial	1,118,338	992,244	743,238
Other	209,375	171,057	136,007
Total Screening	2,103,868	1,864,701	1,424,703
Precision Oncology			
Medicare Parts B & C	$ 187,948	$ 188,689	$ 197,327
Commercial	190,595	181,318	177,518
International	189,092	153,277	117,738
Other	87,364	105,826	108,905
Total Precision Oncology	654,999	629,110	601,488
COVID-19 Testing	$ —	$ 5,955	$ 58,088
Total	$ 2,758,867	$ 2,499,766	$ 2,084,279

Screening revenue primarily includes laboratory service revenue from Cologuard and PreventionGenetics tests while Precision Oncology revenue primarily includes laboratory service revenue from global Oncotype DX and therapy selection tests. The Company discontinued its COVID-19 testing operations in the second quarter of 2023.

At each reporting period end, the Company conducts an analysis of the estimates used to calculate the transaction price to determine whether any new information available impacts those estimates made in prior reporting periods. Adjustments to revenue recognized during the period relating to prior period estimates were less than 1%, 2%, and 1% of revenue recorded in the Company's consolidated statement of operations for the years ended December 31, 2024, 2023, and 2022, respectively.

The Company's deferred revenue, which is reported in other current liabilities in the Company's consolidated balance sheets, was not significant as of December 31, 2024 and 2023.

Revenue recognized for the years ended December 31, 2024 and 2023, which was included in the deferred revenue balance at the beginning of the year was not significant.

(3) MARKETABLE SECURITIES

The following table sets forth the Company's cash, cash equivalents, and marketable securities at December 31, 2024 and 2023:

	December 31,	
(In thousands)	2024	2023
Cash and cash equivalents		
Cash and money market	$ 595,548	$ 530,100
Cash equivalents	5,341	75,278
Total cash and cash equivalents	600,889	605,378
Marketable securities		
Available-for-sale debt securities	$ 431,165	$ 168,425
Equity securities	5,972	3,841
Total marketable securities	437,137	172,266
Total cash, cash equivalents, and marketable securities	$ 1,038,026	$ 777,644

Available-for-sale debt securities, including the classification within the consolidated balance sheet at December 31, 2024, consisted of the following:

(In thousands)	Amortized Cost	Gains in AOCI (1)	Losses in AOCI (1)	Estimated Fair Value
Cash equivalents				
U.S. government agency securities	$ 5,341	$ —	$ —	$ 5,341
Total cash equivalents	5,341	—	—	5,341
Marketable securities				
Corporate bonds	$ 206,063	$ 932	$ (121)	$ 206,874
U.S. government agency securities	140,992	160	(200)	140,952
Asset backed securities	83,134	256	(51)	83,339
Total marketable securities	430,189	1,348	(372)	431,165
Total available-for-sale debt securities	$ 435,530	$ 1,348	$ (372)	$ 436,506

(1) There was no tax impact from the gains and losses in AOCI.

Available-for-sale debt securities, including the classification within the consolidated balance sheet at December 31, 2023, consisted of the following:

(In thousands)	Amortized Cost	Gains in AOCI (1)	Losses in AOCI (1)	Estimated Fair Value
Cash equivalents				
Commercial paper	$ 72,243	$ —	$ —	$ 72,243
U.S. government agency securities	3,035	—	—	3,035
Total cash equivalents	75,278	—	—	75,278
Marketable securities				
U.S. government agency securities	$ 56,594	$ 166	$ (44)	$ 56,716
Corporate bonds	55,712	175	(59)	55,828
Asset backed securities	35,081	65	(249)	34,897
Commercial paper	20,984	—	—	20,984
Total marketable securities	168,371	406	(352)	168,425
Total available-for-sale debt securities	$ 243,649	$ 406	$ (352)	$ 243,703

(1) There was no tax impact from the gains and losses in AOCI.

The following table summarizes contractual underlying maturities of the Company's available-for-sale debt securities at December 31, 2024:

	Due one year or less		Due after one year through five years	
(In thousands)	Cost	Fair Value	Cost	Fair Value
Cash equivalents				
U.S. government agency securities	$ 5,341	$ 5,341	$ —	$ —
Total cash equivalents	5,341	5,341	—	—
Marketable securities				
U.S. government agency securities	$ 70,822	$ 70,943	$ 70,170	$ 70,009
Corporate bonds	39,224	39,321	166,839	167,553
Asset backed securities	11,298	11,331	71,836	72,008
Total marketable securities	121,344	121,595	308,845	309,570
Total available-for-sale securities	$ 126,685	$ 126,936	$ 308,845	$ 309,570

The following table summarizes the gross unrealized losses and fair values of available-for-sale debt securities in an unrealized loss position as of December 31, 2024, aggregated by investment category and length of time those individual securities have been in a continuous unrealized loss position:

	Less than one year		One year or greater		Total	
(In thousands)	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
Marketable securities						
U.S. government agency securities	$ 39,542	$ (199)	$ 1,990	$ (1)	$ 41,532	$ (200)
Corporate bonds	25,979	(121)	—	—	25,979	(121)
Asset backed securities	5,567	(28)	2,666	(23)	8,233	(51)
Total available-for-sale securities	$ 71,088	$ (348)	$ 4,656	$ (24)	$ 75,744	$ (372)

The following table summarizes the gross unrealized losses and fair values of available-for-sale debt securities in an unrealized loss position as of December 31, 2023, aggregated by investment category and length of time those individual securities have been in a continuous unrealized loss position:

	Less than one year		One year or greater		Total	
(In thousands)	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
Marketable securities						
Corporate bonds	$ 25,895	$ (41)	$ 2,480	$ (18)	$ 28,375	$ (59)
U.S. government agency securities	15,756	(35)	3,965	(9)	19,721	(44)
Asset backed securities	4,377	(5)	10,935	(244)	15,312	(249)
Total available-for-sale securities	$ 46,028	$ (81)	$ 17,380	$ (271)	$ 63,408	$ (352)

The Company evaluates investments that are in an unrealized loss position for impairment as a result of credit loss. It was determined that no credit losses exist as of December 31, 2024 and 2023 because the change in market value for those securities in an unrealized loss position has resulted from fluctuating interest rates rather than a deterioration of the credit worthiness of the issuers.

The gains and losses recorded on available-for-sale debt securities and equity securities are included in investment income, net in the Company's consolidated statements of operations. The gains and losses recorded were not significant for the years ended December 31, 2024, 2023, and 2022.

(4) INVENTORY

Inventory consisted of the following:

	December 31,	
(In thousands)	2024	2023
Raw materials	$ 69,730	$ 58,593
Semi-finished and finished goods	92,653	68,882
Total inventory	$ 162,383	$ 127,475

(5) PROPERTY, PLANT AND EQUIPMENT

The carrying value and estimated useful lives of property, plant and equipment are as follows:

(In thousands)	Estimated Useful Life	December 31, 2024	December 31, 2023
Property, plant and equipment			
Land	n/a	$ 4,716	$ 4,716
Leasehold and building improvements	(1)	227,885	214,562
Land improvements	15 years	6,747	6,729
Buildings	30 - 40 years	290,777	290,777
Computer equipment and computer software	3 years	206,460	168,131
Machinery and equipment	3 - 10 years	339,421	290,294
Furniture and fixtures	3 - 10 years	37,176	35,756
Assets under construction	n/a	89,065	104,592
Property, plant and equipment, at cost		1,202,247	1,115,557
Accumulated depreciation		(508,574)	(417,203)
Property, plant and equipment, net		$ 693,673	$ 698,354

(1) Lesser of remaining lease term, building life, or estimated useful life.

At December 31, 2024, the Company had $89.1 million of assets under construction, which consisted of $53.0 million in machinery and equipment, $20.0 million in leasehold and building improvements, and $16.1 million of capitalized costs related to software projects. Depreciation will begin on these assets once they are placed into service upon completion.

(6) INTANGIBLE ASSETS AND GOODWILL

Intangible Assets

The following table summarizes the net-book-value and estimated remaining life of the Company's intangible assets as of December 31, 2024:

(In thousands)	Weighted Average Remaining Life (Years)	Cost	Accumulated Amortization	Net Balance at December 31, 2024
Finite-lived intangible assets				
Trade name	10.8	$ 104,000	$ (35,153)	$ 68,847
Customer relationships	6.0	4,000	(1,333)	2,667
Patents and licenses	9.5	56,542	(12,963)	43,579
Acquired developed technology (1)	6.4	887,104	(412,504)	474,600
Total finite-lived intangible assets		1,051,646	(461,953)	589,693
In-process research and development	n/a	420,000	—	420,000
Total intangible assets		$ 1,471,646	$ (461,953)	$ 1,009,693

The following table summarizes the net-book-value and estimated remaining life of the Company's intangible assets as of December 31, 2023:

(In thousands)	Weighted Average Remaining Life (Years)	Cost	Accumulated Amortization	Net Balance at December 31, 2023
Finite-lived intangible assets				
Trade name	11.6	$ 104,000	$ (27,903)	$ 76,097
Customer relationships	7.0	4,000	(889)	3,111
Patents and licenses	4.5	11,542	(9,600)	1,942
Acquired developed technology (1)	7.3	887,789	(328,543)	559,246
Total finite-lived intangible assets		1,007,331	(366,935)	640,396
In-process research and development	n/a	1,250,000	—	1,250,000
Total intangible assets		$ 2,257,331	$ (366,935)	$ 1,890,396

(1) The gross carrying amount includes an insignificant foreign currency translation adjustment related to the intangible asset acquired as a result of the acquisition of OmicEra Diagnostics GmbH ("OmicEra").

As of December 31, 2024, the estimated future amortization expense associated with the Company's finite-lived intangible assets for each of the five succeeding fiscal years is as follows:

(In thousands)	
2025	$ 96,361
2026	95,300
2027	95,300
2028	95,300
2029	89,177
Thereafter	118,255
Total	$ 589,693

There were no impairment losses recorded on finite-lived intangible assets during the year ended December 31, 2024.

The Company recorded an IPR&D asset of $1.25 billion related to a project associated with the development of a blood-based, multi-cancer screening test ("MCED") as part of the acquisition of Thrive Earlier Detection Corporation ("Thrive") in January 2021. During the fourth quarter of 2024, the Company performed a quantitative impairment assessment for the IPR&D asset, which required a fair value measurement as of the Company's annual test date, November 15, 2024. The Company determined that the fair value of the IPR&D was $420.0 million and recorded a non-cash, pre-tax impairment charge of $830.0 million. The impairment charge recorded was the result of a decrease in projected cash flows for the asset due to external factors since the acquisition, primarily an expected decline in reimbursement rates. The ongoing legislation discussion around the proposed MCED Act legislation gave the Company new information on how reimbursement may develop. The fair value of the IPR&D asset was measured using the multi-period excess earnings method approach, which utilizes significant unobservable inputs (Level 3 inputs) including projected revenues, projected gross margin, projected operating expenses, discount rate, tax rate, obsolescence factor, and probability of commercial success. The discount rate utilized in the fair value measurement was 18.0%.

On August 2, 2022, the Company completed a sale of the developed technology intangible asset related to the GPS test to MDxHealth SA ("MDxHealth"), which was measured using the income approach to determine the fair value. The gross value of the intangible asset was $59.0 million with accumulated amortization of $16.1 million as of the closing date, resulting in a carrying value of $42.9 million, which was derecognized from intangible assets, net in the consolidated balance sheets upon completion of the divestiture. Refer to Note 18 for further information on this sale.

During the third quarter of 2022, the remaining carrying value of $2.0 million related to the supply agreement intangible asset acquired as part of the combination with Genomic Health, Inc. ("Genomic Health") was recorded as a non-cash, pre-tax impairment loss due to the termination of the agreement. The Company previously recorded a non-cash, pre-tax impairment loss of $20.2 million during the third quarter of 2021 due to lower than anticipated performance of the underlying product.

During the second quarter of 2022, the remaining carrying value of $6.6 million related to the developed technology intangible asset acquired as a result of the acquisition of Paradigm Diagnostics, Inc. was recorded as a non-cash, pre-tax impairment loss due to lower than anticipated performance of the underlying product.

The Company utilized the income approach to measure the fair value of the impaired finite-lived intangible assets, which involved significant unobservable inputs (Level 3 inputs), including revenue projections, cash flow projections, and discount rates.

Impairment losses recorded on intangible assets are included in impairment of long-lived and indefinite-lived assets in the Company's consolidated statement of operations.

Goodwill

The change in the carrying amount of goodwill for the years ended December 31, 2024 and 2023 is as follows:

(In thousands)	
Balance, January 1, 2023	$ 2,346,040
Resolution Bioscience acquisition (1)	20,692
Effects of changes in foreign currency exchange rates (2)	388
Balance, December 31, 2023	2,367,120
Resolution Bioscience acquisition adjustments	225
Effects of changes in foreign currency exchange rates	(669)
Balance, December 31, 2024	$ 2,366,676

(1) Refer to Note 18 for further discussion on the Company's acquisition of Resolution Bioscience, Inc. ("Resolution Bioscience")

(2) Represents the impact of foreign currency translation related to the goodwill acquired as a result of the acquisition of OmicEra.

There were no impairment losses recorded on goodwill for the years ended December 31, 2024, 2023, and 2022.

(7) FAIR VALUE MEASUREMENTS

The three levels of the fair value hierarchy established are as follows:

Level 1 Quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access as of the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

Level 2 Pricing inputs other than quoted prices in active markets included in Level 1, which are either directly or indirectly observable as of the reporting date. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3 Unobservable inputs that reflect the Company's assumptions about the assumptions that market participants would use in pricing the asset or liability. Unobservable inputs shall be used to measure fair value to the extent that observable inputs are not available.

The following table presents the Company's fair value measurements as of December 31, 2024 along with the level within the fair value hierarchy in which the fair value measurements, in their entirety, fall.

(In thousands)	Fair value at December 31, 2024	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash, cash equivalents, and restricted cash				
Cash and money market	$ 595,548	$ 595,548	$ —	$ —
Restricted cash (1)	5,747	5,747	—	—
U.S. government agency securities	5,341	—	5,341	—
Marketable securities				
Corporate bonds	$ 206,874	$ —	$ 206,874	$ —
U.S. government agency securities	140,952	—	140,952	—
Asset backed securities	83,339	—	83,339	—
Equity securities	5,972	5,972	—	—
Non-marketable securities	$ 796	$ —	$ —	$ 796
Liabilities				
Contingent consideration	$ (282,212)	$ —	$ —	$ (282,212)
Total	$ 762,357	$ 607,267	$ 436,506	$ (281,416)

The following table presents the Company's fair value measurements as of December 31, 2023 along with the level within the fair value hierarchy in which the fair value measurements, in their entirety, fall.

(In thousands)	Fair Value at December 31, 2023	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash, cash equivalents, and restricted cash				
Cash and money market	$ 530,100	$ 530,100	$ —	$ —
Commercial paper	72,243	—	72,243	—
Restricted cash (1)	4,297	4,297	—	—
U.S. government agency securities	3,035	—	3,035	—
Marketable securities				
U.S. government agency securities	$ 56,716	$ —	$ 56,716	$ —
Corporate bonds	55,828	—	55,828	—
Asset backed securities	34,897	—	34,897	—
Commercial paper	20,984	—	20,984	—
Equity securities	3,841	3,841	—	—
Non-marketable securities	$ 7,650	$ —	$ —	$ 7,650
Liabilities				
Contingent consideration	$ (288,657)	$ —	$ —	$ (288,657)
Total	$ 500,934	$ 538,238	$ 243,703	$ (281,007)

(1) Restricted cash primarily represents cash held by a third-party financial institution as part of a cash collateral agreement related to the Company's credit card program. The restrictions will lapse upon the termination of the agreements or the removal of the cash collateral requirement by the third-parties.

There have been no material changes in valuation techniques or transfers between fair value measurement levels during the year ended December 31, 2024. The fair value of Level 2 instruments classified as cash equivalents and marketable debt securities are valued using a third-party pricing agency where the valuation is based on observable inputs including pricing for similar assets and other observable market factors.

The Company has elected the fair value option under the income approach to measure certain Level 3 non-marketable securities. The following table provides a reconciliation of the beginning and ending balances of non-marketable securities valued using the fair value option:

(In thousands)	Non-Marketable Securities
Balance, January 1, 2023	$ 10,065
Purchases of non-marketable securities	6,957
Changes in fair value	1,127
Settlement of non-marketable securities	(10,499)
Balance, December 31, 2023	7,650
Changes in fair value	(604)
Settlement of non-marketable securities	(6,250)
Balance, December 31, 2024	$ 796

Contingent Consideration Liabilities

The fair value of the contingent consideration liabilities was $282.2 million and $288.7 million as of December 31, 2024 and 2023, respectively, of which $19.7 million was included in other current liabilities and $262.5 million was included in other long-term liabilities in the consolidated balance sheet as of December 31, 2024. The contingent consideration liabilities were included in other long-term liabilities in the consolidated balance sheet as of December 31, 2023.

The following table provides a reconciliation of the beginning and ending balances of contingent consideration:

	Year Ended December 31,		
(In thousands)	2024	2023	2022
Beginning balance	$ 288,657	$ 306,927	$ 359,021
Purchase price contingent consideration (1)	—	—	4,600
Changes in fair value (2)	(3,345)	(18,044)	(56,617)
Payments (3)	(3,100)	(226)	(77)
Ending balance	$ 282,212	$ 288,657	$ 306,927

(1) The increase in contingent consideration liability is due to the contingent consideration associated with the acquisition of OmicEra. Refer to Note 18 for further information.

(2) The change in fair value of the contingent consideration liability is included in general and administrative expenses in the consolidated statement of operations for the years ended December 31, 2024, 2023, and 2022.

(3) Payment was made in the second quarter of 2024 to settle the contingent consideration liability previously recorded related to the Company's acquisition of OmicEra.

This fair value measurement of contingent consideration is categorized as a Level 3 liability, as the measurement amount is based primarily on significant inputs not observable in the market.

The fair value of the contingent consideration liabilities recorded from the Company's acquisitions of Thrive, Ashion Analytics, LLC ("Ashion"), and OmicEra related to regulatory and product development milestones was $282.2 million and $288.7 million as of December 31, 2024 and 2023, respectively. The Company estimates the fair value of the contingent consideration liabilities related to the regulatory and product development milestones using the probability-weighted scenario based discounted cash flow model, which is consistent with the initial measurement of the contingent consideration liabilities. Probabilities of success are applied to each potential scenario and the resulting values are discounted using a present-value factor. The passage of time in addition to changes in projected milestone achievement timing, present-value factor, the degree of achievement if applicable, and probabilities of success may result in adjustments to the fair value measurement. The fair value of the contingent consideration liability recorded related to regulatory and product development milestones was determined using a weighted average probability of success of 90% and 89% as of December 31, 2024 and 2023, respectively, and a weighted average present-value factor of 6.2% and 5.8% as of December 31, 2024 and 2023, respectively. The projected fiscal year of payment range is from 2025 to 2031. Unobservable inputs were weighted by the relative fair value of the contingent consideration liabilities.

The revenue milestone associated with the Ashion acquisition is not expected to be achieved and therefore no liability has been recorded for this milestone.

Non-Marketable Equity Securities

Non-marketable equity securities without readily determinable fair values, which are classified as a component of other long-term assets, net, had the following cumulative upward and downward adjustments and aggregate carrying amounts:

	Year Ended December 31,	
(In thousands)	2024	2023
Cumulative upward adjustments (1)	$ 5,102	$ 5,093
Cumulative downward adjustments and impairments (2)	(16,850)	(15,071)
Aggregate carrying value	50,448	45,968

(1) There were no material upward adjustments recorded on non-marketable equity securities held for the years ended December 31, 2024, 2023, and 2022.

(2) There were no material downward adjustments or impairments on non-marketable equity securities held for the years ended December 31, 2024, 2023, and 2022.

There were no material realized gains or losses recorded during the years ended December 31, 2024, 2023, and 2022.

The Company has committed capital to venture capital investment funds of $18.0 million, of which $10.9 million remains callable through 2033 as of December 31, 2024. The aggregate carrying amount of these funds, which are classified as a component of other long-term assets, net in the Company's consolidated balance sheets, was $7.5 million and $5.2 million as of December 31, 2024 and 2023, respectively. Gains and losses recorded on the Company's investments in the Funds were not significant for the years ended December 31, 2024, 2023, and 2022.

Derivative Financial Instruments

The Company enters into foreign currency forward contracts on the last day of each month to mitigate the impact of adverse movements in foreign exchange rates related to the remeasurement of monetary assets and liabilities and hedge the Company's foreign currency exchange rate exposure. As of December 31, 2024 and 2023, the Company had open foreign currency forward contracts with notional amounts of $44.2 million and $39.5 million, respectively. The Company's foreign exchange derivative instruments are classified as Level 2 within the fair value hierarchy as they are valued using inputs that are observable in the market or can be derived principally from or corroborated by observable market data. The fair value of the open foreign currency forward contracts was zero at December 31, 2024 and 2023, and there were no gains or losses recorded to adjust the fair value of the open foreign currency contract held as of December 31, 2024. The contracts are closed subsequent to each month-end, and the gains and losses recorded from the contracts were not significant for the years ended December 31, 2024 and 2023.

(8) ACCRUED LIABILITIES

Accrued liabilities at December 31, 2024 and 2023 consisted of the following:

	December 31,	
(In thousands)	2024	2023
Compensation	$ 185,934	$ 247,619
Professional fees	80,452	45,405
Other	23,529	17,274
Research and trial related expenses	16,043	14,219
Licenses	15,107	5,956
Assets under construction	7,227	11,210
Total	$ 328,292	$ 341,683

(9) LONG-TERM DEBT

Accounts Receivable Securitization Facility

On June 29, 2022, the Company, through a wholly-owned special purpose entity, Exact Receivables LLC ("Exact Receivables") entered into an accounts receivable securitization program (the "Securitization Facility") with PNC Bank, National Association ("PNC"), with a scheduled maturity date of June 29, 2024. The Securitization Facility required the Company to maintain minimum borrowings under the facility of $50.0 million. Upon the maturity of the Securitization Facility in June 2024, the Company repaid the previously outstanding balance of $50.0 million in full. The Securitization Facility provided Exact Receivables with a revolving line-of-credit of up to $150.0 million of borrowing capacity, subject to certain borrowing base requirements, by collateralizing a security interest in the domestic customer accounts receivable of certain wholly-owned subsidiaries of the Company. The amount available under the Securitization Facility fluctuated over time based on the total amount of eligible customer accounts receivable generated by the Company during the normal course of operations. The debt issuance costs incurred related to the Securitization Facility were not significant and were amortized over the life of the Securitization Facility through interest expense within the consolidated statements of operations.

In connection with the Securitization Facility, the Company also entered into two Receivables Purchase Agreements ("Receivable Purchase Agreements") on June 29, 2022. The Receivable Purchase Agreements were among the Company and certain wholly-owned subsidiaries of the Company, and between the Company and Exact Receivables. Under the agreements, the wholly-owned subsidiaries sold all of their right, title and interest in their accounts receivables to Exact Receivables. The receivables were used to collateralize borrowings made under the Securitization Facility. The Company retained the responsibility of servicing the accounts receivable balances pledged as collateral under the Securitization Facility and provided a performance guaranty.

As of December 31, 2023, the Company had an outstanding balance of $50.0 million, which was included in debt, current portion on the Company's consolidated balance sheet. Prior to the repayment, the outstanding balance accrued interest at a rate equal to a daily secured overnight financing rate ("SOFR") plus a SOFR adjustment and an applicable margin. The interest rate was 6.89% as of the maturity date.

Revolving Loan Agreement

During November 2021, the Company entered into a revolving loan agreement (the "Revolving Loan Agreement") with PNC. The Revolving Loan Agreement provides the Company with a revolving line of credit of up to $150.0 million (the "Revolver"). The Revolver is collateralized by the Company's marketable securities held by PNC, which must continue to maintain a minimum market value of $150.0 million. The Revolver is available for general working capital purposes and all other lawful corporate purposes. In addition, the Company may request, in lieu of cash advances, letters of credit with an aggregate stated amount outstanding not to exceed $20.0 million. The availability of advances under the line of credit will be reduced by the stated amount of each letter of credit issued and outstanding.

Borrowings under the Revolving Loan Agreement accrue interest at an annual rate equal to the sum of the daily Bloomberg Short-Term Bank Yield Index Rate plus the applicable margin of 0.60%. Loans under the Revolving Loan Agreement may be prepaid at any time without penalty. In October 2022 the Revolving Loan Agreement was amended to extend the maturity date from November 5, 2023 to November 5, 2025.

The Company has agreed to various financial covenants under the Revolving Loan Agreement, and as of December 31, 2024, the Company was in compliance with all covenants.

In December 2021 and January 2023, PNC issued letters of credit of $2.9 million and $1.5 million, respectively, which reduced the amount available for cash advances under the line of credit to $145.6 million and $147.1 million as of December 31, 2024 and December 31, 2023, respectively. As of December 31, 2024, the Company has not drawn funds from, nor are any amounts outstanding under, the Revolving Loan Agreement. In January 2025, the Company entered into a senior secured revolving credit agreement as discussed in Note 21, which replaced the Revolving Loan Agreement.

(10) CONVERTIBLE NOTES

Convertible note obligations included in the consolidated balance sheet consisted of the following as of December 31, 2024:

				Fair Value (1)	
(In thousands)	Principal Amount	Unamortized Debt Discount and Issuance Costs	Net Carrying Amount	Amount	Leveling
2031 Convertible Notes - 1.750%	$ 620,709	$ (13,511)	$ 607,198	$ 581,648	2
2030 Convertible Notes - 2.000%	572,993	(3,642)	569,351	592,756	2
2028 Convertible Notes - 0.375%	589,380	(4,952)	584,428	512,761	2
2027 Convertible Notes - 0.375%	563,822	(3,732)	560,090	523,932	2
2025 Convertible Notes - 1.000% (2)	249,172	(19)	249,153	246,705	2

Convertible note obligations included in the consolidated balance sheet consisted of the following as of December 31, 2023:

				Fair Value (1)	
(In thousands)	Principal Amount	Unamortized Debt Discount and Issuance Costs	Net Carrying Amount	Amount	Leveling
2030 Convertible Notes - 2.000%	$ 572,993	$ (4,349)	$ 568,644	$ 684,475	2
2028 Convertible Notes - 0.375%	949,042	(10,499)	938,543	887,354	2
2027 Convertible Notes - 0.375%	563,822	(5,429)	558,393	549,839	2
2025 Convertible Notes - 1.000%	249,172	(476)	248,696	293,300	2

(1) The fair values are based on observable market prices for this debt, which is traded in less active markets and therefore is classified as a Level 2 fair value measurement.

(2) The Company's convertible notes due in 2025 (the "2025 Notes") matured on January 15, 2025 and were included in convertible notes, net, current portion on the consolidated balance sheet as of December 31, 2024. The 2025 Notes were included in convertible notes, net, less current portion as of December 31, 2023. As discussed in Note 21, the 2025 Notes were settled in cash upon maturity in January 2025.

Issuances and Settlements

In January 2018, the Company issued and sold $690.0 million in aggregate principal amount of 1.0% Convertible Notes (the "January 2025 Notes") with a maturity date of January 15, 2025. The January 2025 Notes accrue interest at a fixed rate of 1.0% per year, payable semi-annually in arrears on January 15 and July 15 of each year, beginning on July 15, 2018. The net proceeds from the issuance of the January 2025 Notes were approximately $671.1 million, after deducting underwriting discounts and commissions and the offering expenses payable by the Company.

In June 2018, the Company issued and sold an additional $218.5 million in aggregate principal amount of 1.0% Convertible Notes (the "June 2025 Notes"). The June 2025 Notes were issued under the same indenture pursuant to which the Company previously issued the January 2025 Notes (the "Indenture"). The January 2025 Notes and the June 2025 Notes have identical terms (including the same January 15, 2025 maturity date) and are treated as a single series of securities. The net proceeds from the issuance of the June 2025 Notes were approximately $225.3 million, after deducting underwriting discounts and commissions and the offering expenses payable by the Company.

In March 2019, the Company issued and sold $747.5 million in aggregate principal amount of 0.375% Convertible Notes (the "2027 Notes") with a maturity date of March 15, 2027. The 2027 Notes accrue interest at a fixed rate of 0.375% per year, payable semi-annually in arrears on March 15 and September 15 of each year, beginning on September 15, 2019. The net proceeds from the issuance of the 2027 Notes were approximately $729.5 million, after deducting underwriting discounts and commissions and the offering expenses payable by the Company.

The Company utilized a portion of the proceeds from the issuance of the 2027 Notes to settle a portion of the 2025 Notes in privately negotiated transactions. In March 2019, the Company used cash of $494.1 million and an aggregate of 2.2 million shares of the Company's common stock valued at $182.4 million for total consideration of $676.5 million to settle $493.4 million of the 2025 Notes, of which $0.7 million was used to pay off interest accrued on the 2025 Notes. The transaction resulted in a loss on settlement of convertible notes of $187.7 million.

In February 2020, the Company issued and sold $1.15 billion in aggregate principal amount of 0.375% Convertible Notes (the "2028 Notes") with a maturity date of March 1, 2028. The 2028 Notes accrue interest at a fixed rate of 0.375% per year, payable semi-annually in arrears on March 1 and September 1 of each year, beginning on September 1, 2020. The net proceeds from the issuance of the 2028 Notes were approximately $1.13 billion, after deducting underwriting discounts and commissions and the offering expenses payable by the Company.

In February 2020, the Company used $150.1 million of the proceeds from the issuance of the 2028 Notes to settle $100.0 million of the 2025 Notes, of which $0.1 million was used to pay off interest accrued on the 2025 Notes. The transaction resulted in a loss on settlement of convertible notes of $50.8 million.

In February 2023, the Company entered into a privately negotiated exchange and purchase agreement with a single holder of certain of the Company's 2027 Notes and 2028 Notes. The Company issued the holder $500.0 million aggregate principal amount of 2.0% Convertible Notes due in 2030 (the "2030 Notes") in exchange for $183.7 million of aggregate principal of 2027 Notes, $201.0 million of aggregate principal of 2028 Notes, and $138.0 million of cash. The extinguishment resulted in a gain on settlement of convertible notes of $17.7 million, which is included in interest expense in the consolidated statement of operations for the year ended December 31, 2023.

In March 2023, the Company entered into a privately negotiated exchange agreement with two holders of certain of the 2025 Notes. The Company issued the holder $73.0 million aggregate principal amount of 2030 Notes in exchange for $65.8 million of aggregate principal of 2025 Notes. The extinguishment resulted in a loss on settlement of convertible notes of $7.4 million, which is included in interest expense in the consolidated statement of operations for the year ended December 31, 2023.

The net proceeds from the issuance of the 2030 Notes were approximately $133.0 million, after deducting commissions and offering expenses payable by the Company. The 2030 Notes will mature on March 1, 2030 and bear interest at a rate of 2.0% per year, payable semi-annually in arrears on March 1 and September 1 of each year, beginning on September 1, 2023.

In April 2024, the Company entered into a privately negotiated exchange and purchase agreement with certain holders of the Company's 2028 Notes. The Company issued $620.7 million aggregate principal amount of 1.75% Convertible Notes due in 2031 (the "2031 Notes") in exchange for $359.7 million of aggregate principal of 2028 Notes, and $266.8 million of cash after deducting underwriting discounts. The extinguishment resulted in a gain on settlement of convertible notes of $10.3 million, which is included in interest expense in the condensed consolidated statement of operations for the year ended December 31, 2024.

The net proceeds from the issuance of the 2031 Notes were approximately $259.8 million, after deducting commissions and offering expenses payable by the Company.

The 2031 Notes will mature on April 15, 2031 and bear interest at a rate of 1.75% per year, payable semi-annually in arrears on October 15 and April 15 of each year, beginning on October 15, 2024. The Company has the ability to repurchase the 2031 Notes after April 17, 2029 upon the occurrence of certain events and during certain periods, as set forth in the Indenture filed at the time of the offering.

The extinguishment gains and losses recorded on the settlement of convertible notes discussed above represent the difference between (i) the fair value of the consideration transferred and (ii) the carrying value of the debt at the time of the exchange, and is included in interest expense in the consolidated statement of operations for the respective period.

Summary of Conversion Features

Until the six months immediately preceding the maturity date of the applicable series of the Company's convertible notes (the "Notes"), each series of Notes is convertible only upon the occurrence of certain events and during certain periods, as set forth in the Indentures filed at the time of the original offerings. On or after the date that is six months immediately preceding the maturity date of the applicable series of Notes until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may elect to convert such Notes at any time, and if elected, the conversion would occur on the maturity date. The Notes will be convertible into cash, shares of the Company's common stock (plus, if applicable, cash in lieu of any fractional share), or a combination of cash and shares of the Company's common stock, at the Company's election. If the Notes are not converted prior to the maturity date, the principal amount will be settled in cash upon maturity.

It is the Company's intent to settle all conversions through combination settlement. The initial conversion rate is 13.26, 8.96, 8.21, 12.37, and 10.06 shares of common stock per $1,000 principal amount for the 2025 Notes, 2027 Notes, 2028 Notes, 2030 Notes, and 2031 Notes, respectively, which is equivalent to an initial conversion price of approximately $75.43, $111.66, $121.84, $80.83, and $99.36 per share of the Company's common stock for the 2025 Notes, 2027 Notes, 2028 Notes, 2030 Notes, and 2031 Notes, respectively. The 2025 Notes, 2027 Notes, 2028 Notes, 2030 Notes, and 2031 Notes are potentially convertible into up to 3.3 million, 5.0 million, 4.8 million, 7.1 million, and 6.2 million shares, respectively. The conversion rate is subject to adjustment upon the occurrence of certain specified events as set forth in the Indentures filed at the time of the original offerings but will not be adjusted for accrued and unpaid interest. In addition, holders of the Notes who convert their Notes in connection with a "make-whole fundamental change" (as defined in the Indentures), will, under certain circumstances, be entitled to an increase in the conversion rate.

If the Company undergoes a "fundamental change" (as defined in the Indentures), holders of the Notes may require the Company to repurchase for cash all or part of their Notes at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest.

Based on the closing price of the Company's common stock of $56.19 on December 31, 2024, the if-converted values on the Notes do not exceed the principal amount.

The Notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, the issuance of other indebtedness or the issuance or repurchase of securities by the Company.

Ranking of Convertible Notes

The Notes are the Company's senior unsecured obligations and (i) rank senior in right of payment to all of its future indebtedness that is expressly subordinated in right of payment to the Notes; (ii) rank equal in right of payment to each outstanding series thereof and to all of the Company's future liabilities that are not so subordinated, unsecured indebtedness; (iii) are effectively junior to all of the Company's existing and future secured indebtedness and other secured obligations, to the extent of the value of the assets securing that indebtedness and other secured obligations; and (iv) are structurally subordinated to all indebtedness and other liabilities of the Company's subsidiaries.

Issuance Costs

Issuance costs are amortized to interest expense over the term of the Notes. The following table summarizes the original issuance costs at the time of issuance for each set of Notes:

(In thousands)	
2031 Convertible Notes	$ 6,780
2030 Convertible Notes	4,938
2028 Convertible Notes	24,453
2027 Convertible Notes	14,285
2025 Convertible Notes	17,646

Interest Expense

Interest expense on the Notes includes the following:

	Year Ended December 31,		
(In thousands)	2024	2023	2022
Debt issuance costs amortization	$ 5,296	$ 5,350	$ 5,727
Debt discount amortization	933	106	147
Gain on settlement of convertible notes	(10,254)	(10,324)	—
Coupon interest expense	26,339	18,072	10,266
Total interest expense on convertible notes	$ 22,314	$ 13,204	$ 16,140

The following table summarizes the effective interest rates of the Notes:

	Year Ended December 31,		
	2024	2023	2022
2031 Convertible Notes	2.06 %	— %	— %
2030 Convertible Notes	2.09 %	2.09 %	— %
2028 Convertible Notes	0.63 %	0.63 %	0.64 %
2027 Convertible Notes	0.67 %	0.67 %	0.68 %
2025 Convertible Notes	1.16 %	1.17 %	1.18 %

The remaining period over which the unamortized debt discount will be recognized as non-cash interest expense is 0.04 years, 2.20 years, 3.17 years, 5.17 years, and 6.29 years for the 2025 Notes, 2027 Notes, 2028 Notes, 2030 Notes, and 2031 Notes, respectively.

(11) LICENSE AND COLLABORATION AGREEMENTS

The Company licenses certain technologies that are, or may be, incorporated into its technology under several license agreements, as well as the rights to commercialize certain diagnostic tests through collaboration agreements. Generally, the license agreements require the Company to pay single-digit royalties based on net revenues received using the technologies and may require minimum royalty amounts, milestone payments, or maintenance fees.

Mayo Foundation for Medical Education and Research

In June 2009, the Company entered into an exclusive, worldwide license agreement with the Mayo Foundation for Medical Education and Research ("Mayo"), under which Mayo granted the Company an exclusive, worldwide license to certain Mayo patents and patent applications, as well as a non-exclusive, worldwide license with regard to certain Mayo know-how. The scope of the license covers any screening, surveillance or diagnostic test or tool for use in connection with any type of cancer, pre-cancer, disease or condition. The Company's license agreement with Mayo was most recently amended and restated in September 2020.

The licensed Mayo patents and patent applications contain both method and composition claims that relate to sample processing, analytical testing and data analysis associated with nucleic acid screening for cancers and other diseases. The jurisdictions covered by these patents and patent applications include the U.S., Australia, Canada, the European Union, China, Japan and Korea. Under the license agreement, the Company assumed the obligation and expense of prosecuting and maintaining the licensed Mayo patents and is obligated to make commercially reasonable efforts to bring to market products using the licensed Mayo intellectual property.

Pursuant to the Company's agreement with Mayo, the Company is required to pay Mayo a low-single-digit royalty on the Company's net sales of current and future products using the licensed Mayo intellectual property each year during the term of the Mayo agreement.

The Company is also required to pay Mayo up to $3.0 million in sales-based milestone payments upon cumulative net sales of each product using the licensed Mayo intellectual property reaching specified levels.

The license agreement will remain in effect, unless earlier terminated by the parties in accordance with the agreement, until the last of the licensed patents expires in 2039 (or later, if certain licensed patent applications are issued). However, if the Company is still using the licensed Mayo know-how or certain Mayo-provided biological specimens or their derivatives on such expiration date, the term shall continue until the earlier of the date the Company stops using such know-how and materials and the date that is five years after the last licensed patent expires. The license agreement contains customary termination provisions and permits Mayo to terminate the license agreement if the Company sues Mayo or its affiliates, other than any such suit claiming an uncured material breach by Mayo of the license agreement.

In addition to granting the Company a license to the covered Mayo intellectual property, Mayo provides the Company with product development and research and development assistance pursuant to the license agreement and other collaborative arrangements. In September 2020, Mayo also agreed to make available certain personnel to provide such assistance through January 2025. In connection with this collaboration, the Company has incurred insignificant charges for the years ended December 31, 2024, 2023, and 2022, respectively. The charges incurred in connection with this collaboration are recorded in research and development expenses in the Company's consolidated statements of operations.

Johns Hopkins University

Through the acquisition of Thrive, the Company acquired a worldwide exclusive license agreement with Johns Hopkins University ("JHU") for use of several JHU patents and licensed know-how. The license is designed to enable the Company to leverage JHU intellectual property in the development and commercialization of a blood-based, MCED test. The agreement terms would require the Company to pay single-digit sales-based royalties and up to $45.0 million in sales-based milestone payments for each JHU licensed product that reaches specified net sales levels. The Company will record the sales-based royalties once sales of licensed products have occurred and sales-based milestones once achievement is deemed probable. The Company recorded insignificant charges related to sales-based royalties during the year ended December 31, 2024, and the Company has not incurred charges related to the achievement of any sales-based milestones as of December 31, 2024.

Targeted Digital Sequencing ("TARDIS") License Agreement

In January 2021, the Company entered into an exclusive, worldwide license to the proprietary TARDIS technology from The Translational Genomics Research Institute ("TGen"). Under the agreement, the Company acquired a royalty-free, worldwide exclusive license to proprietary TARDIS patents and know-how. Under the agreement, the Company was obligated to make milestone payments to TGen of up to $45.0 million in sales-based milestone payments upon cumulative net sales related to molecular residual disease ("MRD") detection and/or treatment reaching specified levels. These payments were contingent upon achievement of these cumulative revenues on or before December 31, 2030, which was not achieved prior to the termination.

Effective May 1, 2024, the Company entered into termination agreements (the "Termination Agreements") with TGen for the purpose of terminating the license and sponsored research agreement relating to the TARDIS technology and an additional sponsored research agreement with a broader scope (collectively, the "Original Agreements"). As part of the Termination Agreements, the Company will pay TGen $27.6 million in compensation for the termination of the Original Agreements, which will be allocated into three annual installments of $9.2 million per year beginning in the second quarter of 2024. The fair value of the termination payments as of the date of the Termination Agreements was $25.8 million, which was recorded as research and development expense in the condensed consolidated statement of operations for the year ended December 31, 2024. The remaining $1.8 million in expense is being recognized ratably through the date of the final payment in the second quarter of 2026. The Company has recorded a liability of $17.4 million representing the fair value of the remaining payments, of which $9.0 million is included in accrued liabilities and $8.4 million is included in other long-term liabilities on the consolidated balance sheet as of December 31, 2024. The termination payments eliminate the Company's obligation to pay TGen any further payments, equities, fees, costs, or other amounts that would have been due under the Original Agreements, including the milestone payments. The Company's ongoing development efforts for its pipeline tests are not impacted by the Termination Agreements.

Broad Institute, Inc.

In June 2023, the Company entered into an exclusive license agreement with Broad Institute, Inc. ("Broad Institute") to utilize the Minor Allele Enriched Sequencing Through Recognition Oligonucleotides ("MAESTRO") technology in the Company's MRD testing. Under the license agreement, the Company is obligated to make development milestone payments to Broad Institute of up to $6.5 million upon achievement of certain development milestones related to prospective MRD tests that use the MAESTRO technology. In addition, the Company is obligated to make sales-based milestone payments to Broad Institute that equate up to a mid-single-digit royalty upon the achievement of certain cumulative net sales targets of licensed products using the MAESTRO technology beginning at $500.0 million. The Company will record the development milestones once achieved and the sales milestones once achievement is deemed probable. The Company has not incurred charges related to the achievement of development milestones or sales milestones as of December 31, 2024.

Watchmaker Genomics, Inc.

In July 2023, the Company entered into a co-exclusive development and license agreement with Watchmaker Genomics, Inc. ("Watchmaker") under which the Company granted Watchmaker a co-exclusive license to the non-bisulfite technology for the detection of methylated DNA and other epigenetic modifications ("TAPS"). TAPS is based on patents obtained by the Company through an exclusive license agreement with the Ludwig Institute for Cancer Research. Under the agreement, both parties have the right to use and develop TAPS for commercial purposes. The Company has the potential to receive up to $82.0 million in sales-based milestone payments and mid-single-digit royalties based on future Watchmaker net sales of licensed products including TAPS. Additionally, Watchmaker has the right to sublicense TAPS, and the Company has the potential to receive royalties based on future Watchmaker sublicense receipts. The Company has not received any sales-based milestone payments, royalties on Watchmaker net sales of licensed products, or royalties on Watchmaker sublicense receipts as of December 31, 2024.

TwinStrand Biosciences, Inc.

On July 1, 2024, the Company entered into an agreement with TwinStrand Biosciences, Inc. ("TwinStrand"), under which TwinStrand licensed to the Company intellectual property related to the error correction technology in next-generation sequencing. The Company's rights are broadly exclusive with respect to cell-free nucleic acid sequencing, subject to certain non-exclusive relationships in the field. Under the license agreement, the Company made upfront payments to TwinStrand totaling $45.0 million in July 2024. The upfront payments were capitalized as a patent and license intangible asset in the condensed consolidated balance sheet, which is amortized through amortization of acquired intangible assets in the condensed consolidated statement of operations over its estimated useful life of 10 years. In addition, the Company agreed to pay TwinStrand a low-single-digit royalty on the Company's net sales of certain licensed products and services. The Company will record the sales-based royalties once sales using relevant licensed products and services have occurred. The Company has not incurred charges related to the sales-based royalties as of December 31, 2024.

(12) PFIZER PROMOTION AGREEMENT

In August 2018, the Company entered into a Promotion Agreement (the "Original Promotion Agreement") with Pfizer, Inc. ("Pfizer"), which was amended and restated in October 2020 (the "Restated Promotion Agreement"). The Restated Promotion Agreement extended the relationship between the Company and Pfizer and restructured the manner in which the Company compensates Pfizer for promotion of the Cologuard test through a service fee, and provision of certain other sales and marketing services related to the Cologuard test. The Restated Promotion Agreement included fixed and performance-related fees, some of which retroactively went into effect on April 1, 2020. In November 2021, the Company and Pfizer entered into an amendment to the Restated Promotion Agreement (the "November 2021 Amendment"), which provided that after November 30, 2021, Pfizer will no longer promote the Cologuard test to healthcare providers. The November 2021 Amendment provided that the Company pay Pfizer a total of $35.9 million in three installments, which occurred during the second, third, and fourth quarters of 2022. The November 2021 Amendment eliminated the Company's obligation to pay Pfizer royalties or other fees except for certain media fees, advertising fees, and any detail fees owed to Pfizer for promoting the Cologuard test prior to November 30, 2021. The $35.9 million fee incurred as a result of the November 2021 Amendment was recognized in full during the fourth quarter of 2021. All payments to Pfizer are recorded in sales and marketing expenses in the Company's consolidated statements of operations.

Under the Original Promotion Agreement, the service fee was calculated based on incremental gross profits over specified baselines during the term. Under the Restated Promotion Agreement (and prior to giving effect to the November 2021 Amendment), the service fee provided a fee-for-service model that included certain fixed fees and performance-related bonuses. The performance-related bonuses were contingent upon the achievement of certain annual performance criteria with any applicable expense being recognized ratably upon achievement of the payment becoming probable. The Company incurred charges of $7.5 million for the service fee during the year ended December 31, 2022. The Company incurred charges of $85.8 million for promotion, sales and marketing services performed by Pfizer on behalf of the Company during the year ended December 31, 2022. All services provided by Pfizer under the November 2021 Amendment ended in the third quarter of 2022, and there were no payments made or charges incurred during the years ended December 31, 2024 and 2023.

(13) STOCKHOLDERS' EQUITY

Stock Issuances

When the Company completes a business combination or asset acquisition, which are further described in Note 18, the Company may issue shares of the Company's common stock. Stock issuances in relation to acquisitions during the years ended December 31, 2024, 2023, and 2022 were as follows:

(In thousands, except for per share data)	Period of Acquisition	Shares Issued	Fair Value of Shares Issued
OmicEra	May 2022	265,186	$ 14,792

Changes in Accumulated Other Comprehensive Income (Loss)

The amount recognized in AOCI for the years ended December 31, 2024, 2023 and 2022 were as follows:

(In thousands)	Cumulative Translation Adjustment	Unrealized Gain (Loss) on Securities (1)	AOCI
Balance at January 1, 2022	$ 23	$ (1,466)	$ (1,443)
Other comprehensive income (loss) before reclassifications	30	(4,049)	(4,019)
Amounts reclassified from accumulated other comprehensive income (loss)	—	226	226
Net current period change in accumulated other comprehensive loss	30	(3,823)	(3,793)
Balance at December 31, 2022	$ 53	$ (5,289)	$ (5,236)
Other comprehensive income (loss) before reclassifications	1,321	1,416	2,737
Amounts reclassified from accumulated other comprehensive income (loss)	—	3,927	3,927
Net current period change in accumulated other comprehensive loss	1,321	5,343	6,664
Balance at December 31, 2023	$ 1,374	$ 54	$ 1,428
Other comprehensive income (loss) before reclassifications	(3,294)	873	(2,421)
Amounts reclassified from accumulated other comprehensive income (loss)	—	49	49
Net current period change in accumulated other comprehensive income (loss)	(3,294)	922	(2,372)
Balance at December 31, 2024	$ (1,920)	$ 976	$ (944)

(1) There was no tax impact from the amounts recognized in AOCI for the years ended December 31, 2024, 2023, and 2022. The unrealized gain (loss) recorded on available-for-sale securities is a non-cash investing activity.

Amounts reclassified from AOCI for the years ended December 31, 2024, 2023, and 2022 were as follows:

Details about AOCI Components (In thousands)	Affected Line Item in the Statements of Operations	Year Ended December 31, 2024	2023	2022
Change in value of available-for-sale investments				
Sales and maturities of available-for-sale investments	Investment income (loss)	$ 49	$ 3,927	$ 226
Total reclassifications		$ 49	$ 3,927	$ 226

(14) STOCK-BASED COMPENSATION

Stock-Based Compensation Plans

The Company maintains the following plans for which awards were granted from or had awards outstanding in 2024: the 2010 Omnibus Long-Term Incentive Plan (As Amended and Restated Effective July 27, 2017), the 2019 Omnibus Long-Term Incentive Plan, and the 2010 Employee Stock Purchase Plan. These plans are collectively referred to as the "Stock Plans."

The Stock Plans are administered by the Human Capital Committee of the Company's Board of Directors ("Human Capital Committee"). The 2019 Omnibus Long-Term Incentive Plan provides that upon an acquisition of the Company, all equity will accelerate by a period of one year. In addition, upon the termination of an employee without cause or for good reason prior to the first anniversary of the completion of the acquisition, all equity awards then outstanding under the respective plan held by that employee will immediately vest.

2019 Omnibus Long-Term Incentive Plan. The Company adopted the 2019 Omnibus Long-Term Incentive Plan (the "2019 Stock Plan") on July 25, 2019 to grant share-based awards to employees, officers, directors, consultants, and advisors. Awards granted under the 2019 Stock Plan may include incentive stock options, as defined under the Internal Revenue Code, non-qualified options, restricted stock awards and other stock awards in amounts and with terms and conditions determined by the Human Capital Committee, subject to the provisions of the 2019 Stock Plan. The 2019 Stock Plan will expire on July 25, 2029 and after such date no further awards may be granted under the plan. Options granted under the 2019 Stock Plan expire ten years from the date of grant. Grants made from the 2019 Stock Plan generally vest over a period of three to four years. At December 31, 2024, options to purchase 358,292 shares were outstanding under the 2019 Stock Plan and 8,424,465 shares of restricted stock and restricted stock units were outstanding. The Company's stockholders approved amendments to the 2019 Stock Plan to increase the number of shares available for future grant thereunder by 14,000,000 and 4,340,000 shares on June 9, 2022 and June 8, 2023, respectively. At December 31, 2024, there were 9,840,015 shares available for future grant under the 2019 Stock Plan.

2010 Omnibus Long-Term Incentive Plan. The Company adopted the 2010 Omnibus Long-Term Incentive Plan (the "2010 Stock Plan") on July 16, 2010 to grant share-based awards to employees, officers, directors, consultants, and advisors. Awards granted under the 2010 Stock Plan may include incentive stock options, as defined under the Internal Revenue Code, non-qualified options, restricted stock awards and other stock awards in amounts and with terms and conditions determined by the Human Capital Committee, subject to the provisions of the 2010 Stock Plan. The 2010 Stock Plan expired on July 16, 2020 and after such date no further awards may be granted under the plan. Options granted under the 2010 Stock Plan expire ten years from the date of grant. Grants made from the 2010 Stock Plan generally vest over a period of three to four years. At December 31, 2024, options to purchase 624,450 shares were outstanding under the 2010 Stock Plan and 3,340 shares of restricted stock and restricted stock units were outstanding. At December 31, 2024, there were no shares available for future grant under the 2010 Stock Plan.

2010 Employee Stock Purchase Plan. The 2010 Employee Stock Purchase Plan (the "2010 Purchase Plan") was adopted by the Company on July 16, 2010 to provide participating employees the right to purchase shares of common stock at a discount through a series of offering periods. The 2010 Purchase Plan will expire on October 31, 2030. The Company's stockholders approved amendments to the 2010 Employee Stock Purchase Plan to increase the number of shares available for purchase thereunder by 500,000 shares, 2,000,000 shares, and 3,000,000 shares on July 24, 2014, July 28, 2016, and June 9, 2022, respectively. At December 31, 2024, there were 878,801 shares of common stock available for purchase by participating employees under the 2010 Purchase Plan.

Generally, all employees whose customary employment is more than 20 hours per week and more than five months in any calendar year are eligible to participate in the 2010 Purchase Plan. Participating employees authorize an amount, between 1% and 15% of the employee's compensation, to be deducted from the employee's pay during the offering period. On the last day of the offering period, the employee is deemed to have exercised the employee's option to purchase shares of Company common stock, at the option exercise price, to the extent of accumulated payroll deductions. Under the terms of the 2010 Purchase Plan, the option exercise price is an amount equal to 85% of the fair market value, as defined under the 2010 Purchase Plan, and no employee can purchase more than $25,000 of Company common stock under the 2010 Purchase Plan in any calendar year. Rights granted under the 2010 Purchase Plan terminate upon an employee's voluntary withdrawal from the 2010 Purchase Plan at any time or upon termination of employment. At December 31, 2024, there were 4,921,199 cumulative shares issued under the 2010 Purchase Plan.

Stock-Based Compensation Expense

The Company records stock-based compensation expense in connection with the amortization of restricted stock and restricted stock unit awards ("RSUs"), performance share units ("PSUs"), stock purchase rights granted under the Company's employee stock purchase plan ("ESPP") and stock options granted to employees, non-employee consultants, and non-employee directors. A summary of non-cash stock-based compensation expense by expense category included in the Company's consolidated statements of operations for the years ended December 31, 2024, 2023, and 2022 is as follows:

	Year Ended December 31,		
(In thousands)	2024	2023	2022
Cost of sales	$ 20,518	$ 20,761	$ 19,218
Research and development	39,684	41,242	33,825
Sales and marketing	68,236	73,016	69,267
General and administrative	86,447	96,293	84,513
Total stock-based compensation	$ 214,885	$ 231,312	$ 206,823

As of December 31, 2024, there was approximately $325.9 million of expected total unrecognized compensation cost related to non-vested stock-based compensation arrangements granted under all equity compensation plans. The Company expects to recognize that cost over a weighted average period of 2.50 years.

Stock Options

The Company determined the fair value of each service-based option award on the date of grant using the Black-Scholes option-pricing model, which utilized several key assumptions including risk-free interest rate, expected term, expected volatility, and dividend yield. There were no option awards granted during the years ended December 31, 2024, 2023 and 2022.

A summary of stock option activity under the Stock Plans is as follows:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (1)
(Aggregate intrinsic value in thousands)				
Outstanding, January 1, 2024	1,286,173	$ 47.67	3.8	
Exercised	(265,816)	19.57		
Forfeited	(37,615)	91.46		
Outstanding, December 31, 2024	982,742	$ 53.60	3.1	$ 17,639
Vested and expected to vest, December 31, 2024	982,742	$ 53.60	3.1	$ 17,639
Exercisable, December 31, 2024	982,742	$ 53.60	3.1	$ 17,639

(1) The total intrinsic value of options exercised, net of shares withheld for taxes, during the years ended December 31, 2024, 2023, and 2022 was $7.8 million, $11.7 million, and $36.4 million, respectively, determined as of the date of exercise.

Restricted Stock and Restricted Stock Units

The fair value of restricted stock and RSUs is determined on the date of grant using the closing stock price on that day.

A summary of restricted stock and RSU activity is as follows:

	Restricted Shares	Weighted Average Grant Date Fair Value (1)
Outstanding, January 1, 2024	6,272,763	$ 73.39
Granted	4,331,532	56.94
Released (2)	(2,396,874)	75.76
Forfeited	(962,625)	62.44
Outstanding, December 31, 2024	7,244,796	$ 63.18

(1) The weighted average grant date fair value of the RSUs granted during the years ended December 31, 2023 and 2022 was $62.36 and $68.18, respectively.

(2) The fair value of RSUs vested and converted to shares of the Company's common stock was $184.2 million, $158.2 million, and $117.6 million for the years ended December 31, 2024, 2023, and 2022, respectively.

Performance Share Units

The Company has issued performance-based equity awards to certain employees which vest upon the achievement of certain performance goals, including financial performance targets and operational milestones.

A summary of PSU activity is as follows:

	Performance Share Units (1)	Weighted Average Grant Date Fair Value (2)
Outstanding, January 1, 2024	1,597,801	$ 92.73
Granted	913,533	63.68
Released (3)	(70,662)	140.20
Forfeited	(419,464)	100.62
Outstanding, December 31, 2024	2,021,208	$ 75.86

(1) The PSUs listed above assumes attainment of maximum payout rates as set forth in the performance criteria. Applying actual or expected payout rates, the number of outstanding PSUs as of December 31, 2024 was 773,824.

(2) The weighted average grant date fair value of the PSUs granted during the years ended December 31, 2023 and 2022 was $80.50 and $89.43, respectively.

(3) The fair value of PSUs vested and converted to shares of the Company's common stock was $9.9 million, $1.0 million, and $27.2 million for the years ended December 31, 2024, 2023, and 2022, respectively.

Employee Stock Purchase Plan

A summary of ESPP activity is as follows:

	Year Ended December 31,		
(in thousands, except share and per share amounts)	**2024**	**2023**	**2022**
Shares issued under the 2010 Purchase Plan	955,392	924,448	668,605
Cash received under the 2010 Purchase Plan	$ 31,227	$ 28,344	$ 25,491
Weighted average fair value per share of stock purchase rights granted during the period	$ 16.26	$ 16.32	$ 17.52

The 955,392 shares issued during the year ended December 31, 2024 were as follows:

Offering period ended	**Number of Shares**	**Weighted Average price per Share**
April 30, 2024	604,226	$ 32.11
October 31, 2024	351,166	$ 33.68

The fair value of shares purchased under the ESPP is based on the assumptions in the following table:

	Year Ended December 31,		
	2024	**2023**	**2022**
Risk-free interest rates	4.71% - 5.30%	4.68% - 4.71%	1.49% - 4.71%
Expected term (in years)	1.17 - 1.25	1.25	0.5 - 2
Expected volatility	44.40% - 63.13%	63.13% - 67.30%	50.94% - 63.13%
Dividend yield	0%	0%	0%

Shares Reserved for Issuance

The Company has reserved shares of its authorized common stock for issuance pursuant to its employee stock purchase and equity plans, including all outstanding stock option grants noted above at December 31, 2024, as follows:

Shares reserved for issuance	
2019 Stock Plan	9,840,015
2010 Purchase Plan	878,801
	10,718,816

(15) COMMITMENTS AND CONTINGENCIES

Leases

The components of lease expense were as follows:

	Year Ended December 31,		
(In thousands)	2024	2023	2022
Finance lease cost			
Amortization of right-of-use assets	$ 7,311	$ 3,845	$ 4,612
Interest on lease liabilities	1,406	800	808
Operating lease cost	31,797	36,576	36,291
Short-term lease cost	1,036	750	476
Variable lease cost	9,055	8,449	7,985
Total lease Cost	$ 50,605	$ 50,420	$ 50,172

Supplemental disclosure of cash flow information related to the Company's cash and non-cash activities with its leases are as follows:

	Year Ended December 31,		
(In thousands)	2024	2023	2022
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows from operating leases	$ 38,135	$ 39,301	$ 33,448
Operating cash flows from finance leases	1,359	783	699
Finance cash flows from finance leases	6,827	3,569	4,345
Non-cash investing and financing activities:			
Right-of-use assets obtained in exchange for new operating lease liabilities	19,674	4,986	24,572
Right-of-use assets obtained in exchange for new finance lease liabilities	16,425	5,443	11,276
Weighted-average remaining lease term - operating leases (in years)	7.37	6.87	7.43
Weighted-average remaining lease term - finance leases (in years)	2.90	2.80	3.27
Weighted-average discount rate - operating leases	6.54 %	6.59 %	6.37 %
Weighted-average discount rate - finance leases	6.69 %	7.43 %	6.60 %

As of December 31, 2024 and 2023, the Company's right-of-use assets from operating leases are $117.0 million and $143.7 million, respectively, which are reported in operating lease right-of-use assets in the Company's consolidated balance sheets. As of December 31, 2024, the Company has outstanding operating lease obligations of $184.5 million, of which $27.4 million is reported in operating lease liabilities, current portion and $157.1 million is reported in operating lease liabilities, less current portion in the Company's consolidated balance sheets. As of December 31, 2023, the Company had outstanding operating lease obligations of $190.4 million, of which $29.4 million is reported in operating lease liabilities, current portion and $161.1 million is reported in operating lease liabilities, less current portion in the Company's consolidated balance sheets.

In the third quarter of 2024, the Company recorded an impairment charge of $18.7 million, which consisted of a right-of-use asset of $11.8 million and associated leasehold improvements of $6.9 million relating to one of its domestic facilities that was vacated in the fourth quarter of 2024 as a result of a change in strategic priorities. The Company used the income approach, under which the recoverability of the assets was measured by comparing the carrying amount of the asset to future undiscounted, pre-tax cash flows generated by the assets held. The fair value of the assets was determined using discounted cash flows, and the impairment charge recorded represents the difference between the carrying value and fair value of the impaired assets. The impairment charge recorded is included in impairment of long-lived and indefinite-lived assets in the Company's consolidated statement of operations for the year ended December 31, 2024.

As of December 31, 2024 and 2023, the Company's right-of-use assets from finance leases are $19.8 million and $11.3 million, respectively, which are reported in other long-term assets, net in the Company's consolidated balance sheets. As of December 31, 2024, the Company has outstanding finance lease obligations of $21.0 million, of which $7.8 million is reported in other current liabilities and $13.2 million is reported in other long-term liabilities in the Company's consolidated balance sheets. As of December 31, 2023, the Company had outstanding finance lease obligations of $11.9 million, of which $4.4 million is reported in other current liabilities and $7.5 million is reported in other long-term liabilities in the Company's consolidated balance sheets.

Maturities of operating lease liabilities on an annual basis as of December 31, 2024 were as follows:

(In thousands)	
2025	$ 37,400
2026	36,242
2027	35,873
2028	29,703
2029	20,526
Thereafter	76,081
Total minimum lease payments	235,825
Imputed interest	(51,287)
Total	$ 184,538

Maturities of finance lease liabilities on an annual basis as of December 31, 2024 were as follows:

(In thousands)	
2025	$ 8,857
2026	7,262
2027	5,345
2028	1,303
2029	93
Thereafter	129
Total minimum lease payments	22,989
Imputed interest	(2,006)
Total	$ 20,983

Legal Matters

The Company accrues costs for certain legal proceedings and regulatory matters to the extent that it determines an unfavorable outcome is probable and the amount of the loss can be reasonably estimated. While such accrued costs reflect the Company's best estimate of the probable loss for such matters, the recorded amounts may differ materially from the actual amount of any such losses. In some cases, no estimate of the possible loss or range of loss in excess of amounts accrued, if any, can be made because of the inherently unpredictable nature of legal and regulatory proceedings, which may be exacerbated by various factors, including but not limited to, that they may involve indeterminate claims for monetary damages or may involve fines, penalties or punitive damages; present novel legal theories or legal uncertainties; involve disputed facts; represent a shift in regulatory policy; involve a large number of parties, claimants or regulatory bodies; are in the early stages of the proceedings; involve a number of separate proceedings and/or a wide range of potential outcomes; or result in a change of business practices.

As of the date of this Annual Report on Form 10-K, amounts accrued for legal proceedings and regulatory matters were not significant except for the amounts accrued related to the matters discussed below. However, it is possible that in a particular quarter or annual period the Company's financial condition, results of operations, cash flow and/or liquidity could be materially adversely affected by an ultimate unfavorable resolution of, or development in, legal and/or regulatory proceedings, including as described below. Except for the proceedings discussed below, the Company believes that the ultimate outcome of any of the regulatory and legal proceedings that are currently pending against it should not have a material adverse effect on financial condition, results of operations, cash flow or liquidity.

Intellectual Property Litigation Matters

In May 2023, after receiving a cease-and-desist letter from the Company regarding its patent infringement, Geneoscopy Inc. ("Geneoscopy") requested a reexamination of the Company's U.S. Patent No. 11,634,781 (the "'781 Patent") by the United States Patent and Trademark Office (the "USPTO"). Upon completion of the reexamination in October 2023, the USPTO rejected Geneoscopy's challenge. In November 2023, the Company filed suit against Geneoscopy in the United States District Court for the District of Delaware, alleging that certain of Geneoscopy's products infringe the '781 Patent and seeking unspecified monetary damages and injunctive relief (the "'781 Action") and in May 2024, the Company filed a second complaint against Geneoscopy alleging infringement of the Company's U.S. Patent No. 11,970,746 (the "'746 Patent"), which has been consolidated with the '781 Action. On June 28, 2024, Geneoscopy filed counterclaims against the Company challenging the validity of the patents at issue and alleging breach of contract, misappropriation of trade secrets, unfair competition, and other violations of state and federal law seeking unspecified monetary damages and injunctive relief, which were amended on August 16, 2024. On July 16, 2024, the Company filed a motion for preliminary injunction seeking an order prohibiting Geneoscopy from selling its infringing Colosense test in the United States. On August 8, 2024, Geneoscopy filed a motion to stay pending inter partes review of the '781 Patent, which was denied on November 1, 2024 with leave to refile if the '746 Patent IPR is instituted. On August 30, 2024, the Company filed a motion to dismiss the amended counterclaim. On January 31, 2025, the Court held a hearing and (i) took the Company's preliminary injunction motion under advisement; (ii) denied Geneoscopy's motion to dismiss the false advertising claims and (iii) granted in part and denied in part the Company's motion to dismiss the amended counterclaims, with leave for Geneoscopy to amend and refile the dismissed counterclaims. The Court set trial for November 2026.

In January 2024, Geneoscopy petitioned the USPTO to institute an inter partes review ("IPR") challenging the validity of the '781 Patent before the Patent Trial and Appeals Board ("PTAB"). On July 26, 2024, the PTAB notified the Company that it decided to institute review. The Company filed its Patent Owner Response on October 25, 2024, and the parties are currently engaged in discovery. Geneoscopy filed its reply to the Patent Owner Response on January 27, 2025 and the Company's sur-reply is due March 10, 2025. The Company intends to defend the validity of the '781 Patent, and a final decision of that review will be made on or before July 26, 2025.

In August 2024, Geneoscopy filed a petition for inter partes review of the '746 Patent before the PTAB. On November 26, 2024, the Company filed its Patent Owner Preliminary Response. On February 14, 2025, the PTAB notified the Company that it decided to institute review. The Company's Patent Owner Response is due May 9, 2025. The Company intends to defend the validity of the '746 Patent, and a final decision of that review is expected to be made on or before February 14, 2026.

DOS Rule Matter

In September 2023, the Company's wholly owned subsidiary Genomic Health, Inc., which was acquired in November 2019, entered into a settlement agreement with the United States of America, acting through the Department of Justice ("DOJ") and on behalf of the Office of Inspector General of the Department of Health and Human Services, and two qui tam relators to resolve the previously disclosed civil investigation concerning Genomic Health's compliance with the Medicare Date of Service billing regulations (the "DOS Rule Matter"). Genomic Health entered into the settlement agreement to avoid the delay, uncertainty and expense of protracted litigation. The settlement agreement contains no admission of liability by Genomic Health.

Under the terms of the settlement agreement, the Company made a payment of $32.5 million in September 2023, of which $22.4 million and $10.1 million is included in general and administrative expenses in the Company's consolidated statements of operations for the years ended December 31, 2023 and 2021, respectively. Following the United States' receipt of the settlement payment, the Company was released from any civil or administrative monetary claims under the civil False Claims Act and other specified civil statutes and common law theories of liability concerning the conduct identified in the settlement agreement.

On September 29, 2023, the United States District Court for the Eastern District of New York unsealed two qui tam actions filed under the False Claims Act involving the DOS Rule Matter, and on October 2, 2023, those two actions were dismissed with prejudice pursuant to the terms of the settlement agreement.

Gift Card Matter

In September 2023, the Company entered into a settlement agreement to resolve the previously disclosed False Claims Act qui tam suit that alleged a violation of the Federal Anti-Kickback Statute and False Claims Act for offering gift cards to patients in exchange for returning the Cologuard screening test (the "Qui Tam Suit"). In accordance with the settlement agreement, the Company made payment of $13.8 million plus legal fees in October 2023, which is included in general and administrative expenses in the Company's consolidated statement of operations for the year ended December 31, 2023. Following payment of the settlement amount, the Company was released from any civil or administrative monetary claims under the civil False Claims Act and other specified civil statutes and common law theories of liability concerning the conduct identified in the settlement agreement. On November 1, 2023, the court dismissed the qui tam suit with prejudice pursuant to the terms of the settlement agreement.

(16) EMPLOYEE BENEFIT PLAN

The Company maintains a qualified 401(k) retirement savings plan for Exact Sciences employees (the "401(k) Plan"). The Company also maintains additional retirement savings plans that are acquired as a result of business combinations. These plans are maintained for a period of time before being merged into the 401(k) Plan. Under the terms of the 401(k) Plan, participants may elect to defer a portion of their compensation into the 401(k) Plan, subject to certain limitations. Company matching contributions may be made at the discretion of the Company's Human Capital Committee.

The Human Capital Committee approved 401(k) Plan matching contributions for the years ended December 31, 2024, 2023, and 2022 in the form of Company common stock equal to 100% of a participant's elective deferrals up to 6% of the participant's eligible compensation for that year. The Company recorded compensation expense of approximately $44.1 million, $40.6 million, and $36.5 million, respectively, in the statements of operations for the years ended December 31, 2024, 2023, and 2022.

(17) WISCONSIN ECONOMIC DEVELOPMENT TAX CREDITS

During December 2021, the Company entered into an amended agreement ("Amended WEDC Agreement") with the Wisconsin Economic Development Corporation ("WEDC") to earn an additional $18.5 million in refundable tax credits on the condition that the Company expends $350.0 million in capital investments and establishes and maintains 1,300 additional full-time positions over a five-year period. The capital investment credits are earned at a rate of 10% of eligible capital investments up to a maximum of $7.0 million, while the jobs creation credits are earned annually pursuant to the Amended WEDC Agreement.

The tax credits earned are first applied against the tax liability otherwise due, and if there is no such liability present, the claim for tax credits will be reimbursed in cash to the Company. The maximum amount of the refundable tax credit to be earned for each year is fixed, and the Company earns the credits by meeting certain capital investment and job creation thresholds over the term of the Amended WEDC Agreement. Should the Company earn and receive the job creation tax credits but not maintain those full-time positions through the end of the agreement, the Company may be required to pay those credits back to the WEDC.

The Company records the earned tax credits as job creation and capital investments occurs. The tax credits earned from capital investment are recognized as a reduction to capital expenditures at the time the costs are incurred, and then as an offset to depreciation expense over the expected life of the acquired capital assets. The tax credits earned related to job creation are recognized as an offset to operational expenses in the period in which the credits are earned.

As of December 31, 2024, the Company has earned $14.3 million of the refundable tax credits under the Amended WEDC Agreement. The unpaid portion is $8.8 million, of which $4.2 million is reported in prepaid expenses and other current assets and $4.6 million is reported in other long-term assets, net in the Company's consolidated balance sheets reflecting when collection of the refundable tax credits is expected to occur. During the years ended December 31, 2024, 2023, and 2022, the amounts recorded as an offset to capital expenditures and operating expenses for the tax credits earned were not significant.

(18) ACQUISITIONS AND DIVESTITURES

Business Combinations

Resolution Bioscience, Inc.

On September 12, 2023, the Company completed the acquisition of all of the outstanding capital stock of Resolution Bioscience, Inc. from Agilent Technologies, Inc. Resolution Bioscience develops and commercializes next-generation sequencing-based precision oncology solutions through its Clinical Laboratory Improvement Amendments ("CLIA") certified lab based in Kirkland, Washington. The acquisition provides the Company with a high-quality blood-based therapy selection platform, complementing its comprehensive, tissue-based OncoExTra® test. The Company has included the financial results of Resolution Bioscience in the consolidated financial statements from the date of the acquisition.

The acquisition date fair value of the consideration transferred for Resolution Bioscience was approximately $54.2 million, which consisted of the following:

(In thousands)		
Cash	$	52,527
Fair value of replaced equity awards		1,675
Total purchase price	$	54,202

The Company replaced unvested RSUs with a combination-date fair value of $4.6 million. Of the total consideration for replaced equity awards, $1.7 million was allocated to the consideration transferred, and $2.9 million was deemed compensatory as it was attributable to post acquisition vesting. The compensatory replaced equity awards will be expensed over the remaining service periods on a straight-line basis.

The purchase price was allocated to the underlying assets acquired and liabilities assumed based upon their estimated fair values including insignificant measurement period adjustments as follows:

(In thousands)		
Net operating assets	$	14,643
Developed technology		26,000
Total identifiable assets acquired		40,643
Net operating liabilities		(7,357)
Net identifiable assets acquired		33,286
Goodwill		20,916
Net assets acquired	$	54,202

The Company recorded a $26.0 million identifiable intangible asset related to the developed technology associated with Resolution Bioscience's liquid biopsy therapy selection tests. Developed technology represents purchased technology that had reached technological feasibility and for which Resolution Bioscience had substantially completed development as of the acquisition date. The fair value of the developed technology has been determined using the multi-period excess earnings method of the income approach, which involves significant unobservable inputs (Level 3 inputs). These inputs include projected revenues, gross margins, operating expenses, obsolescence, and an estimated discount rate. The developed technology intangible asset is amortized on a straight-line basis over its estimated useful life of 17 years.

The calculation of the excess of the purchase price over the estimated fair value of the tangible net assets and intangible assets acquired was recorded to goodwill, which is primarily attributed to the acquired workforce expertise and expected sales force and therapy selection product portfolio synergies. The total goodwill related to this acquisition is deductible for tax purposes.

The following unaudited pro forma financial information summarizes the combined results of operations for the Company and Resolution Bioscience, as though the companies were combined as of the beginning of January 1, 2022.

	Twelve Months Ended December 31,	
(In thousands)	2023	2022
Total revenues	$ 2,507,111	$ 2,097,680
Net loss before tax	(237,854)	(675,091)

The unaudited pro forma financial information is presented for informational purposes only and is not indicative of the results that would have been achieved if the acquisition had taken place at such time. Expected cost savings and other synergistic benefits resulting from the acquisition were not reflected in the unaudited pro forma financial information. The Company did not have any significant, nonrecurring pro forma adjustments directly attributable to the acquisition included in the reported unaudited pro forma financial information. Revenue and net loss before tax from Resolution Bioscience included in the Company's consolidated statements of operations for the year ended December 31, 2023 was not significant.

Acquisition-related costs were not significant and were recorded within general and administrative expenses in the consolidated statement of operations. These costs include fees associated with financial, legal, accounting, and other advisors incurred to complete the acquisition.

OmicEra Diagnostics, GmbH

On May 2, 2022, the Company completed the acquisition (the "OmicEra Acquisition") of all of the outstanding equity interests of OmicEra Diagnostics GmbH. The OmicEra Acquisition provided the Company a state-of-the-art proteomics lab based in Planegg, Germany. OmicEra combines its mass spectrometry-based proteome analysis technology with its in-house proteomics scientific expertise to discover more reliable and valuable protein biomarkers, which will expand the Company's research and development capabilities. The Company has included the financial results of OmicEra in the consolidated financial statements from the date of the acquisition.

The acquisition date fair value of the consideration transferred for OmicEra was approximately $19.4 million, which consisted of the following:

(In thousands)	
Common stock issued	$ 14,792
Contingent consideration	4,600
Cash paid related to working capital adjustment	16
Total purchase price	$ 19,408

The fair value of the 265,186 common shares issued as part of the consideration transferred was determined on the basis of the average of the high and low market price of the Company's shares on the acquisition date, which was $55.78.

The purchase agreement required the Company to pay a maximum of $6.0 million of additional cash consideration to OmicEra upon the achievement of certain earnout conditions related to the identification of protein biomarkers, as well as the growth of the proteomics research and development team. The fair value of the contingent consideration at the acquisition date was $4.6 million, which is a non-cash investing activity. The fair value of the contingent consideration was estimated using a probability-weighted scenario-based discounted cash flow model. This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in ASC 820. The key assumptions and settlement of the contingent consideration liability are described in Note 7.

Pro forma impact and results of operations disclosures have not been included due to insignificance.

Acquisition-related costs were not significant and were recorded within general and administrative expenses in the consolidated statement of operations. These costs include fees associated with financial, legal, accounting, and other advisors incurred to complete the merger.

Divestitures

Oncotype DX Genomic Prostate Score Test

On August 2, 2022, pursuant to an asset purchase agreement (the "Asset Purchase Agreement") with MDxHealth SA, the Company completed the sale of the intellectual property and know-how related to the Company's Oncotype DX Genomic Prostate Score test, which will allow the Company to focus on the highest impact projects core to the Company's vision.

The closing date fair value of the consideration received for the asset was approximately $29.6 million, which consisted of the following:

(In thousands)		
Cash	$	25,000
MDxHealth American Depository Shares		4,631
Contingent consideration		—
Total consideration	$	29,631

The fair value of the 691,171 American Depository Shares received as part of the consideration transferred was determined on the basis of the average of the high and low market price of the MDxHealth's shares on the date of divestiture, which was $6.70, and is included in marketable securities on the consolidated balance sheet.

The Asset Purchase Agreement required MDxHealth to pay the Company up to an additional $70.0 million of contingent consideration that would be earned and receivable in cash and/or equity based on the achievement of certain revenue milestones by MDxHealth between 2023 and 2025. Under the Asset Purchase Agreement, contingent consideration would have been recognized in the consolidated statement of operations when it was probable a significant reversal of a gain would not occur. As of December 31, 2022, no contingent consideration was probable of not resulting in a significant gain reversal due to minimum revenue thresholds in place and therefore it was fully constrained.

The carrying value of the developed technology intangible asset, which was previously included in intangible assets, net on the consolidated balance sheet, was $42.9 million as of the closing date. As a result of the sale, the Company recorded a loss of $13.2 million, which is included in other operating income (loss) in the consolidated statement of operations for the year ended December 31, 2022.

Further, the Company agreed to provide certain transitional services to MDxHealth through December 31, 2022 and lab testing services for a period of up to 24 months.

On August 23, 2023, the Company and MDxHealth executed the Second Amendment to the Asset Purchase Agreement (the "Second Amendment") related to the sale of the GPS test. Under the Second Amendment, the Company agreed to allow MDxHealth to defer the 2023 contingent consideration payment by three years in exchange for additional consideration and more favorable contingent consideration terms. The Company received additional consideration with a fair value of $3.1 million, which was recorded as a gain for the year ended December 31, 2023, and is included in other operating income (loss) in the consolidated statement of operations.

Under the Second Amendment, the maximum contingent consideration increased from $70.0 million to $82.5 million and the minimum revenue thresholds previously required to be met under the Asset Purchase Agreement were eliminated. As a result of the elimination of the minimum revenue thresholds, the Company determined that a significant reversal of a gain is not probable and therefore the contingent consideration is no longer constrained. The Company recorded a contingent consideration gain of $9.2 million and $73.3 million during the years ended December 31, 2024 and 2023, respectively, which are included in other operating income (loss) in the consolidated statement of operations. The gains recorded were estimated using historical GPS test revenues by MDxHealth under the most likely amount method.

As of December 31, 2024, a portion of the contingent consideration is classified as a contract asset. As of December 31, 2024, the contract asset was $25.9 million, which is included in other long-term assets, net on the consolidated balance sheet. As of December 31, 2023, the contract asset was $41.7 million, which is included in other long-term assets on the consolidated balance sheet. As of December 31, 2024, the remaining consideration balance, which includes the amount earned during the

2023 and 2024 earnout years classified as a receivable, was $56.6 million, of which $27.9 million is included in prepaid expenses and other current assets and $28.7 million is included in other long-term assets, net on the consolidated balance sheet. As of December 31, 2023, the remaining consideration balance, which included the amount earned during the 2023 earnout year, was $31.6 million, which is classified as a receivable included in other long-term assets, net on the consolidated balance sheet.

Transaction-related costs were not significant and were recorded within general and administrative expenses in the consolidated statement of operations. These costs include fees associated with financial, legal, accounting, and other advisors incurred to complete the divestiture.

(19) SEGMENT INFORMATION

Management determined that the Company is managed as one operating segment, and thus reports as a single reportable segment. This operating segment is focused on the development and global commercialization of clinical laboratory services allowing healthcare providers and patients to make individualized treatment decisions. Management assessed the financial information routinely reviewed by the Company's Chief Operating Decision Maker (“CODM”), its President and Chief Executive Officer, to monitor the Company's operating performance and support decisions regarding allocation of resources to its operations, and determined that performance is continuously monitored at the consolidated level. The measure of segment profit or loss used by the CODM in assessing performance and deciding how to allocate resources is based on net loss, as reported on the consolidated statement of operations. The measure of segment assets provided to and reviewed by the CODM is reported on the consolidated balance sheet as total assets, and long-lived assets located in countries outside the U.S. are not significant. The CODM uses consolidated net loss to monitor budget versus actual results on a monthly basis to timely identify deviations from expected results, which is used in assessing performance and deciding where to reinvest profits and allocate resources predominantly in the annual budget and forecasting process.

Significant segment expenses are presented in the Company's consolidated statements of operations. Additional disaggregated significant segment expenses on a functional basis, that are not separately presented on the Company's consolidated statements of operations, are presented below, along with total revenue from customers by geographic region.

	Year Ended December 31,		
(In thousands)	2024	2023	2022
Revenue:			
United States	$ 2,569,775	$ 2,346,489	$ 1,966,541
Outside of United States	189,092	153,277	117,738
Total revenues (1)	2,758,867	2,499,766	2,084,279
Less:			
Cost of sales:			
Production costs	467,347	393,367	329,492
Personnel expenses	197,338	182,015	160,136
Intangible asset amortization	84,068	83,316	86,967
Facility and support services (2)	68,535	54,417	63,608
Stock-based compensation	20,518	20,761	19,218
Other cost of sales	2,344	3,688	1,940
Research and development expenses:			
Personnel expenses	182,190	180,281	143,259
Direct research and development costs	110,054	129,691	158,731
Facility and support services (2)	56,184	64,088	45,512
Stock-based compensation	39,684	41,242	33,825
Other research and development (3)	28,900	3,371	8,179
Professional & legal	10,906	7,209	3,912
Intangible asset amortization	3,292	1,045	773
Sales and marketing expenses:			
Personnel expenses	500,286	471,613	494,116
Direct marketing costs	212,838	183,720	238,111
Professional & legal	70,399	49,739	54,698
Stock-based compensation	68,236	73,016	69,267
Other sales and marketing (3)	19,287	24,348	13,432
Facility and support services (2)	15,385	17,675	50,419
Intangible asset amortization	7,694	7,694	9,601
General and administrative expenses:			
Personnel expenses	346,432	336,865	341,595
Facility and support services (2)	184,984	181,425	134,954
Professional & legal	125,608	166,760	110,039
Stock-based compensation	86,447	96,293	84,513
Other general and administrative (3)	38,250	18,841	(7,827)
Intangible asset amortization	104	104	107
Other:			
Impairment of long-lived and indefinite-lived assets	869,460	621	15,969
Other segment items (4)	(21,742)	(91,693)	52,303
Income tax expense (benefit)	(7,304)	2,403	(9,064)
Segment and consolidated net loss	$ (1,028,857)	$ (204,149)	$ (623,506)

(1) Product revenues are attributed to countries based on ship-to location. Refer to Note 2 for the Company's disaggregated revenue disclosures.

(2) Facilities and support services is inclusive of depreciation expense. Refer to the consolidated statements of cash flows for presentation of total depreciation expense.

(3) Other research and development primarily includes a $25.8 million for a license agreement termination for the year ended December 31, 2024. Other sales and marketing primarily includes miscellaneous customer-oriented support activities. Other general and administrative primarily includes changes in fair value to outstanding contingent consideration liabilities, foreign currency gains and losses, corporate liability insurance, and other miscellaneous charges.

(4) Inclusive of other operating income (loss), investment income (loss), net, and interest expense as presented in the consolidated statement of operations.

(20) INCOME TAXES

Under financial accounting standards, deferred tax assets or liabilities are computed based on the differences between the financial statement and income tax bases of assets and liabilities using the enacted tax rates. Deferred income tax expense or benefit represents the change in the deferred tax assets or liabilities from period to period. At December 31, 2024, the Company had federal net operating loss, state net operating loss, and foreign net operating loss carryforwards of approximately $374.9 million, $65.4 million, and $12.1 million, respectively, for financial reporting purposes, which may be used to offset future taxable income. The Tax Cuts and Jobs Act (H.R. 1) of 2017 limits the deduction for net operating losses to 80% of current year taxable income and provides for an indefinite carryover period for federal net operating losses. Both provisions are applicable for losses arising in tax years beginning after December 31, 2017. As of December 31, 2024 the Company has $281.2 million of federal net operating loss carryovers incurred after December 31, 2018 with an unlimited carryover period and $93.7 million of federal net operating loss carryovers expiring at various dates through 2038. State and foreign net operating loss carryovers expire at various dates through 2044. All net operating loss carryforwards are subject to review and possible adjustment by federal, state, and foreign taxing jurisdictions. The Company also had federal and state research tax credit carryforwards of $82.5 million and $38.2 million, respectively, which may be used to offset future income tax liability. The federal credit carryforwards expire at various dates through 2044 and are subject to review and possible adjustment by the Internal Revenue Service. The state credit carryforwards expire at various dates through 2039 with the exception of $22.5 million of California research and development tax credits that have an indefinite carryforward period. All state tax credits are subject to review and possible adjustment by local tax jurisdictions. In the event of a change of ownership, the federal and state net operating loss and research and development tax credit carryforwards may be subject to annual limitations provided by the Internal Revenue Code and similar state provisions.

Loss before provision for taxes consisted of the following:

	Year Ended December 31,		
(In thousands)	**2024**	**2023**	**2022**
Loss before income taxes:			
Domestic	$ (1,036,306)	$ (204,128)	$ (617,240)
Foreign	145	2,382	(15,330)
Total loss before income taxes	$ (1,036,161)	$ (201,746)	$ (632,570)

The expense (benefit) for income taxes consists of:

(In thousands)	Year Ended December 31, 2024	2023	2022
Current expense (benefit):			
Federal	$ —	$ —	$ —
State	933	2,266	2,170
Foreign	1,882	2,561	1,131
Deferred tax expense (benefit):			
Federal	(4,775)	2,395	(3,292)
State	(5,145)	(1,829)	(8,926)
Foreign	(199)	(2,990)	(147)
Total income tax expense (benefit)	$ (7,304)	$ 2,403	$ (9,064)

The Company recorded an income tax benefit for the year ended December 31, 2024 of $7.3 million primarily related to current foreign and state tax expense offset by a U.S. deferred tax benefit.

The components of the net deferred tax asset with the approximate income tax effect of each type of carryforward, credit and temporary differences are as follows:

(In thousands)	December 31, 2024	2023
Deferred tax assets:		
Operating loss carryforwards	$ 452,410	$ 477,420
Tax credit carryforwards	121,635	104,580
Compensation related differences	72,349	85,007
Lease liabilities	47,199	47,118
Capitalized research and development	251,760	191,468
Other temporary differences	7,271	10,275
Tax assets before valuation allowance	952,624	915,868
Less - Valuation allowance	(708,788)	(465,832)
Total deferred tax assets	243,836	450,036
Deferred tax liabilities		
Amortization	$ (205,764)	$ (415,064)
Property, plant and equipment	(7,160)	(9,465)
Lease assets	(31,266)	(35,786)
Other temporary differences	(6,816)	(7,010)
Total deferred tax liabilities	(251,006)	(467,325)
Net deferred tax liabilities	$ (7,170)	$ (17,289)

A valuation allowance to reduce the deferred tax assets is reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The Company has incurred significant losses since its inception and due to the uncertainty of the amount and timing of future taxable income and the realization of deferred tax liabilities, management has determined that a valuation allowance of $708.8 million and $465.8 million at December 31, 2024 and 2023, respectively, is necessary to reduce the tax assets to the amount that is more likely than not to be realized. Given the future limitations on and expiration of certain federal and state deferred tax assets, the recording of a valuation allowance resulted in a deferred tax liability of approximately $7.2 million remaining as of December 31, 2024, which is included in other long-term liabilities on the Company's consolidated balance sheet. The overall change in valuation allowance for December 31, 2024 and 2023 was an increase of $243.0 million and an increase of $46.5 million, respectively.

Activity associated with the Company's valuation allowance is as follows:

	December 31,		
(In thousands)	2024	2023	2022
Balance as of January 1,	$ (465,832)	$ (419,356)	$ (262,238)
Valuation allowances established	(241,849)	(44,759)	(159,919)
Changes to existing valuation allowances	(1,107)	(1,242)	2,780
Acquisition and purchase accounting	—	(475)	21
Balance as of December 31,	$ (708,788)	$ (465,832)	$ (419,356)

The effective tax rate differs from the statutory tax rate due to the following:

	December 31,		
	2024	2023	2022
U.S. Federal statutory rate	21.0 %	21.0 %	21.0 %
State taxes	3.0	3.9	3.9
Federal and state tax rate changes	—	1.1	(0.2)
Foreign tax rate differential	0.1	—	(0.1)
Research and development tax credits	1.6	7.6	2.3
Stock-based compensation expense	(1.0)	(4.4)	(2.0)
Non-deductible executive compensation	(0.5)	(3.5)	(0.4)
Loss on extinguishment - convertible debt	—	(0.7)	—
Other adjustments	(0.1)	(2.5)	1.2
Valuation allowance	(23.5)	(23.7)	(24.4)
Effective tax rate	0.6 %	(1.2)%	1.3 %

For the year ended December 31, 2024, the Company recognized an income tax benefit, representing an effective tax rate of 0.6%. The difference between the expected statutory federal tax rate of 21.0% and the effective tax rate of 0.6% for the year ended December 31, 2024, was primarily attributable to the valuation allowance established against the Company's current period losses.

For the year ended December 31, 2023, the Company recognized an income tax expense, representing an effective tax rate of (1.2)%. The difference between the expected statutory federal tax rate of 21.0% and the effective tax rate of (1.2)% for the year ended December 31, 2023, was primarily attributable to the valuation allowance established against the Company's current period losses.

For the year ended December 31, 2022, the Company recognized an income tax benefit, representing an effective tax rate of 1.3%. The difference between the expected statutory federal tax rate of 21.0% and the effective tax rate of 1.3% for the year ended December 31, 2022, was primarily attributable to the valuation allowance established against the Company's current period losses.

The Company had unrecognized tax benefits related to federal and state research and development tax credits of $43.3 million, $36.4 million, and $28.3 million as of December 31, 2024, 2023, and 2022, respectively. These amounts have been recorded as a reduction to the Company's deferred tax asset, if recognized they would not have an impact on the effective tax rate due to the existing valuation allowance. Certain of the Company's unrecognized tax benefits could change due to activities of various tax authorities, including possible settlement of audits, or through normal expiration of various statutes of limitations. The Company does not expect a material change in unrecognized tax benefits in the next twelve months.

The following is a tabular reconciliation of the amounts of unrecognized tax benefits:

	December 31,		
(In thousands)	2024	2023	2022
January 1,	$ 36,399	$ 28,270	$ 21,780
Increase due to current year tax positions	7,322	7,447	5,861
Increase due to prior year tax positions	—	1,108	629
Decrease due to prior year tax positions	(377)	(426)	—
December 31,	$ 43,344	$ 36,399	$ 28,270

As of December 31, 2024, due to the carryforward of unutilized net operating losses and research and development credits, the Company is subject to U.S. federal income tax examinations for the tax years 2004 through 2024, and to state income tax examinations for the tax years 2004 through 2024. There were no interest or penalties related to income taxes that have been accrued or recognized as of and for the years ended December 31, 2024, 2023, and 2022.

The Organization for Economic Co-operation and Development has endorsed a framework (“Pillar Two”) with model rules introducing a global minimum corporate tax rate via a system where multinational groups with consolidated revenue over €750.0 million are subject to a minimum effective tax rate of 15% on income arising in low-tax jurisdictions on a country-by-country basis. Many countries have implemented laws based on these model rules, with effective dates beginning January 1, 2024. These rules do not have a material impact on the Company for the current period and, as currently designed, are not expected to materially increase the Company’s global tax costs. The Company will continue to monitor U.S. and global legislative action related to Pillar Two for potential impacts.

(21) SUBSEQUENT EVENTS

Revolving Credit Agreement

On January 13, 2025, the Company entered into a senior secured revolving credit agreement (the "Revolving Credit Agreement") with JPMorgan Chase Bank, (the "Agent"), which replaces the Company's previous Revolver with PNC dated as of November 5, 2021. The Revolving Credit Agreement permits a maximum borrowing in the amount of $500.0 million on a revolving basis, including a letter of credit sublimit. Up to $50.0 million of borrowings may be made, at the Company's election, in Euros, Swiss Francs, Japanese Yen and Pounds Sterling, or any additional foreign currencies determined by mutual agreement of the parties. The Revolving Credit Agreement will be used for working capital and other general corporate purposes. The Revolving Credit Agreement matures on the earlier of January 13, 2028 and the date that is 91 days prior to the maturity date of indebtedness of the Company and any restricted subsidiary in the event that the aggregate outstanding principal amount of such maturing indebtedness equals or exceeds $300.0 million. The Revolving Credit Agreement also provides for uncommitted incremental facilities in an amount up to $200.0 million plus an unlimited additional amount so long as the Company is in compliance with certain financial covenants.

Outstanding revolving loans denominated in U.S. dollars under the Revolving Credit Agreement will bear interest at a floating rate of either (A) Term SOFR plus 0.10% (subject to a 0.00% floor) plus the applicable rate (“Applicable Rate”) or (B) a base rate (subject to a 1.00% per annum floor) plus the Applicable Rate, as elected by the Company. Revolving loans denominated in foreign currencies will bear interest at floating reference rates plus the Applicable Rate. The Applicable Rate means (A) in the case of U.S. dollar base rate loans, a margin ranging from 1.50% to 2.00% per annum, depending on the Company's consolidated secured gross leverage ratio, and (B) in the case of U.S. dollar Term SOFR loans and all foreign

currency loans, a margin ranging from 2.5% to 3.00% per annum, depending on the Company's consolidated secured gross leverage ratio.

2025 Notes Settlement

Upon maturity of the 2025 Notes on January 15, 2025, the Company made a cash payment of $250.4 million in settlement of the total principal of the 2025 Notes and accrued interest that was previously outstanding as of December 31, 2024. Refer to Note 10 for further discussion of the 2025 Notes.

(22) QUARTERLY RESULTS OF OPERATIONS

The following table sets forth unaudited quarterly statements of operations data for each of the eight quarters ended December 31, 2024 and 2023. In the opinion of management, this information has been prepared on the same basis as the audited consolidated financial statements and contains all adjustments, consisting only of normal recurring adjustments, considered necessary for a fair statement of the unaudited quarterly results for the periods presented. The quarterly data should be read in conjunction with the Company’s audited consolidated financial statements and the notes to the consolidated financial statements appearing elsewhere in this Form 10-K.

	Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
	(Amounts in thousands, except per share data)			
2024				
Revenue	$ 637,524	$ 699,264	$ 708,655	$ 713,424
Cost of sales (1)	191,201	210,948	217,170	220,831
Gross profit	446,323	488,316	491,485	492,593
Operating expenses:				
Research and development (1)	110,869	121,145	101,487	97,709
Sales and marketing (1) (2)	217,780	211,552	220,264	244,529
General and administrative (1) (2)	219,652	177,524	193,539	191,110
Impairment of long-lived and indefinite-lived assets	4,446	8,152	18,698	838,164
Other operating income (loss)	(268)	3,800	3,100	2,568
Loss from operations	(106,692)	(26,257)	(39,403)	(876,351)
Other income (expense)	(1,730)	11,912	1,975	385
Income tax benefit (expense)	(1,806)	(1,463)	(808)	11,381
Net loss	$ (110,228)	$ (15,808)	$ (38,236)	$ (864,585)
Net loss per share—basic and diluted	$ (0.60)	$ (0.09)	$ (0.21)	$ (4.67)
Weighted average common shares outstanding—basic and diluted	182,350	184,313	184,795	185,312
2023				
Revenue	$ 602,450	$ 622,093	$ 628,338	$ 646,885
Cost of sales (1)	177,584	177,709	189,307	192,964
Gross profit	424,866	444,384	439,031	453,921
Operating expenses:				
Research and development (1)	95,680	104,356	111,707	115,184
Sales and marketing (1) (2)	212,015	201,028	198,172	216,590
General and administrative (1) (2)	194,193	215,377	194,330	196,388
Impairment of long-lived and indefinite-lived assets	69	552	—	—
Other operating income (loss)	—	—	72,027	6,400
Loss from operations	(77,091)	(76,929)	6,849	(67,841)
Other income (expense)	4,597	(2,990)	(5,806)	17,465
Income tax benefit (expense)	(1,657)	(1,107)	(249)	610
Net income (loss)	$ (74,151)	$ (81,026)	$ 794	$ (49,766)
Net income (loss) per share—basic	$ (0.42)	$ (0.45)	$ 0.00	$ (0.27)
Net income (loss) per share—diluted	$ (0.42)	$ (0.45)	$ 0.00	$ (0.27)
Weighted average common shares outstanding—basic	178,574	180,204	180,649	181,114
Weighted average common shares outstanding—diluted	178,574	180,204	184,075	181,114

(1) Amortization of acquired intangible assets, which was previously presented as a separate line item on the Company's consolidated statements of operations, is now presented within the line item each intangible asset relates to within cost of sales, research and development, sales and marketing, and general and administrative expenses. Cost of sales is inclusive of amortization of acquired intangible assets of $21.1 million, $21.1 million, and $21.1 million for the quarters ended March 31, 2024, June 30, 2024, and September 30, 2024, respectively, and $20.7 million, $20.7 million, $20.8 million, and $21.1 million for the quarters ended March 31, 2023, June 30, 2023, September 30, 2023, and December 31, 2023, respectively. Amortization of acquired intangible assets included within research and development, sales and marketing, and general and administrative expenses were not significant for the quarterly periods presented.

(2) Certain general and administrative expenses have been reclassified to sales and marketing expenses related to customer care and customer experience. Sales and marketing expenses is inclusive of $23.5 million, $24.4 million, and $23.7 million for the quarters ended March 31, 2024, June 30, 2024, and September 30, 2024, respectively, which was previously included in general and administrative expenses. Sales and marketing expenses is inclusive of $23.1 million, $22.6 million, $23.1 million, and $24.2 million for the quarters ended March 31, 2023, June 30, 2023, September 30, 2023, and December 31, 2023, respectively, which was previously included in general and administrative expenses.

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

There have been no disagreements with accountants on accounting or financial disclosure matters.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934 (the "Exchange Act"), our management, including our principal executive officer and principal financial officer, conducted an evaluation as of the end of the period covered by this report, of the effectiveness of our disclosure controls and procedures as defined in Rule 13a-15(e) under the Exchange Act. Based on that evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective as of December 31, 2024 to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in Securities and Exchange Commission rules and forms and that material information relating to the Company is accumulated and communicated to management, including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting.

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) under the Exchange Act during the quarter ended December 31, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting.

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. The 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.

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.

We conducted an evaluation, under the supervision and with the participation of our management, of the effectiveness of our internal control over financial reporting as of December 31, 2024. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control—Integrated Framework (2013)*. Based on our assessment, management, including our principal executive officer and principal financial officer, concluded that, as of December 31, 2024, our internal control over financial reporting was effective based on those criteria.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2024 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Item 9B. Other Information

Rule 10b5-1 Trading Plans

During the three months ended December 31, 2024, none of our directors or officers (as defined in Rule 16a-1 under the Exchange Act) adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement" (as those terms are defined in Item 408 of Regulation S-K), except as follows:

On November 25, 2024, Katherine Zanotti, a member of our board of directors, adopted a Rule 10b5-1 trading arrangement for the sale of up to 14,178 shares of our common stock. The arrangement's expiration date is February 27, 2026, subject to early termination for certain specified events set forth in the arrangement.

On November 27, 2024, Sarah Condella, our Executive Vice President, Human Resources, adopted a Rule 10b5-1 trading arrangement for (i) the disposition of $50,000 in shares of our common stock in the form of a charitable gift and (ii) the sale of up to 14,000 shares of our common stock. The arrangement's expiration date is October 1, 2025, subject to early termination for certain specified events set forth in the arrangement.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required under this item is incorporated by reference to the following sections of our proxy statement for our 2025 Annual Meeting of Stockholders: "Information Concerning Directors and Nominees for Director," "Information Concerning Executive Officers," "Nominees for Election as Directors and Continuing Directors," "Section 16(a) Reports," "Corporate Governance Principles, Board Matters, and Non-Employee Director Compensation," and "Our Board of Directors and its Committees."

Item 11. Executive Compensation

The information required under this item is incorporated by reference to the following sections of our proxy statement for our 2025 Annual Meeting of Stockholders: "Compensation and Other Information Concerning Named Executive Officers," "Corporate Governance Principles, Board Matters, and Non-Employee Director Compensation," "Executive Compensation Tables," "Our Board of Directors and its Committees," "Report of The Human Capital Committee," and "CEO Pay Ratio."

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

The information required under this item is incorporated by reference to the following sections of our proxy statement for our 2025 Annual Meeting of Stockholders: "Equity Compensation Plan Information," and "Securities Ownership of Certain Beneficial Owners and Management."

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

The information required under this item is incorporated by reference to the following sections of our proxy statement for our 2025 Annual Meeting of Stockholders: "Certain Relationships and Related Transactions" and "Corporate Governance Principles, Board Matters, and Non-Employee Director Compensation."

Item 14. Principal Accountant Fees and Services

The information required under this item is incorporated by reference to the following sections of our proxy statement for our 2025 Annual Meeting of Stockholders: "Independent Registered Public Accounting Firm" and "Pre-Approval Policies and Procedures."

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this Form 10-K:

(1) Financial Statements (see "Consolidated Financial Statements and Supplementary Data" at Item 8 and incorporated herein by reference).

(2) Financial Statement Schedules (Schedules to the Financial Statements have been omitted because the information required to be set forth therein is not applicable or is shown in the accompanying Financial Statements or notes thereto).

(3) Exhibits

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
2.1	Agreement and Plan of Merger, dated July 28, 2019, by and among the Registrant, Spring Acquisition Corp. and Genomic Health, Inc.		8-K (Exhibit 2.1)	7/30/2019	001-35092
2.2	Agreement and Plan of Merger, dated October 26, 2020, by and among the Registrant, certain subsidiaries of the Registrant, Thrive Earlier Detection Corp. and Shareholder Representative Services LLC		8-K (Exhibit 2.1)	10/27/2020	001-35092
2.3	First Amendment to Agreement and Plan of Merger, dated December 23, 2020, by and among the Registrant, certain subsidiaries of the Registrant, Thrive Earlier Detection Corp. and Shareholder Representative Services LLC		8-K (Exhibit 2.1)	1/5/2021	001-35092
2.4	Second Amendment to Agreement and Plan of Merger, dated January 4, 2021, by and among the Registrant, certain subsidiaries of the Registrant, Thrive Earlier Detection Corp. and Shareholder Representative Services LLC		8-K (Exhibit 2.2)	1/5/2021	001-35092
3.1	Sixth Amended and Restated Certificate of Incorporation of the Registrant		S-1 (Exhibit 3.3)	12/4/2000	333-48812
3.2	First Amendment to Sixth Amended and Restated Certificate of Incorporation of the Registrant		8-K (Exhibit 3.1)	7/24/2020	001-35092
3.3	Second Amendment to Sixth Amended and Restated Certificate of Incorporation of the Registrant		8-K (Exhibit 3.1)	6/12/2023	001-35092
3.4	Seventh Amended and Restated By-Laws of the Registrant		8-K (Exhibit 3.2)	6/12/2023	001-35092
4.1	Specimen certificate representing the Registrant's Common Stock		S-1 (Exhibit 4.1)	12/26/2000	333-48812

4.2	Indenture, dated January 17, 2018, by and between the Registrant and U.S. Bank Trust Company, National Association (as successor to U.S. Bank National Association), as Trustee	8-K (Exhibit 4.1)	1/17/2018	001-35092
4.3	Second Supplemental Indenture, dated March 8, 2019, by and between the Registrant and U.S. Bank Trust Company, National Association (as successor to U.S. Bank National Association), as Trustee (including the form of 0.3750% Convertible Senior Notes due 2027)	8-K (Exhibit 4.2)	3/8/2019	001-35092
4.4	Third Supplemental Indenture, dated February 27, 2020, by and between the Registrant and U.S. Bank Trust Company, National Association (as successor to U.S. Bank National Association), as Trustee (including the form of 0.3750% Convertible Senior Notes due 2028)	8-K (Exhibit 4.2)	2/27/2020	001-35092
4.5	Fourth Supplemental Indenture, dated March 1, 2023, by and between the Company and U.S. Bank Trust Company, National Association (as successor in interest to U.S. Bank National Association), as Trustee (including the form of 2.00% Convertible Senior Notes due 2030)	8-K (Exhibit 4.2)	3/1/2023	001-35092
4.6	Fifth Supplemental Indenture, dated April 17, 2024, between the Company and U.S. Bank National Association, as Trustee (including the form of 1.75% Convertible Senior Notes due 2031)	8-K (Exhibit 4.2)	4/17/2024	001-35092
4.7	Description of Common Stock	10-K (Exhibit 4.6)	2/16/2021	001-35092
Lease Agreements				
10.1	Second Amended and Restated Lease Agreement, dated September 28, 2018, by and between University Research Park Incorporated and the Registrant	10-K (Exhibit 10.1)	2/21/2019	001-35092
10.2	Lease Agreement, dated June 25, 2013, by and between Tech Building I, LLC and Exact Sciences Laboratories, Inc.	10-Q (Exhibit 10.2)	8/2/2013	001-35092
10.3	Lease Agreement, dated November 11, 2015, by and between Metropolitan Life Insurance Company and Genomic Health, Inc.	10-K (Exhibit 10.3)	2/21/2020	001-35092
10.4	First Amendment to Lease Agreement, dated October 4, 2019, by and between Metropolitan Life Insurance Company and Genomic Health, Inc.	10-K (Exhibit 10.4)	2/21/2020	001-35092

10.5	Lease Agreement, dated September 23, 2005, by and between Metropolitan Life Insurance Company and Genomic Health, Inc.	10-K (Exhibit 10.5)	2/21/2020	001-35092
10.6	First Amendment to Lease Agreement, dated September 5, 2006, by and between Metropolitan Life Insurance Company and Genomic Health, Inc.	10-K (Exhibit 10.6)	2/21/2020	001-35092
10.7	Second Amendment to Lease Agreement, dated November 30, 2010, by and between Metropolitan Life Insurance Company and Genomic Health, Inc.	10-K (Exhibit 10.7)	2/21/2020	001-35092
10.8	Third Amendment to Lease Agreement, dated November 11, 2015, by and between Metropolitan Life Insurance Company and Genomic Health, Inc.	10-K (Exhibit 10.8)	2/21/2020	001-35092
10.9	Fourth Amendment to Lease Agreement, dated October 4, 2019, by and between Metropolitan Life Insurance Company and Genomic Health, Inc.	10-K (Exhibit 10.9)	2/21/2020	001-35092
Agreements with Executive Officers and Directors				
10.10*	Employment Agreement, dated March 18, 2009, by and between Kevin T. Conroy and the Registrant	8-K (Exhibit 10.1)	3/18/2009	000-32179
10.11*	Employment Agreement, dated November 8, 2016, by and between Jeffrey T. Elliott and the Registrant	10-K (Exhibit 10.9)	2/21/2017	001-35092
10.12*	Employment Agreement, dated February 18, 2019, by and between Jacob Orville and the Registrant	10-K (Exhibit 10.17)	2/21/2020	001-35092
10.13*	First Amendment to Employment Agreement, dated July 31, 2024, by and between Jake Orville and the Registrant	10-Q (Exhibit 10.2)	11/5/2024	001-35092
10.14*	Employment Agreement, dated August 22, 2017 by and between Sarah Condella and the Registrant	10-K (Exhibit 10.16)	2/16/2021	001-35092
10.15*	Employment Agreement, dated September 2, 2022, by and between Brian Baranick and the Registrant	10-Q (Exhibit 10.1)	11/3/2022	001-35092
10.16*	First Amendment to Employment Agreement, dated July 31, 2024, by and between Brian Baranick and the Registrant	10-Q (Exhibit 10.3)	11/5/2024	001-35092
10.17*	Employment Agreement, dated April 15, 2024, by and between Aaron Bloomer and the Registrant	10-Q (Exhibit 10.1)	5/8/2024	001-35092
10.18*	First Amendment to Employment Agreement, dated July 31, 2024, by and between Aaron Bloomer and the Registrant	10-Q (Exhibit 10.1)	11/5/2024	001-35092
Equity Compensation Plans and Policies				
10.19*	The Registrant's 2016 Inducement Award Plan	10-Q (Exhibit 10.3)	5/3/2016	001-35092

10.20*	The Registrant's 2016 Inducement Award Plan Form Restricted Stock Unit Award Agreement		S-8 (Exhibit 4.7)	5/3/2016	333-211099
10.21*	The Registrant's 2010 Omnibus Long-Term Incentive Plan (As Amended and Restated Effective July 27, 2017)		10-Q (Exhibit 10.1)	10/30/2017	001-35092
10.22*	The Registrant's Executive Deferred Compensation Plan dated January 1, 2019		10-K (Exhibit 10.22)	2/21/2019	001-35092
10.23*	The Registrant's 2019 Omnibus Long-Term Incentive Plan		S-8 (Exhibit 4.4)	7/31/2019	333-23916
10.24*	The Registrant's 2019 Omnibus Long-Term Incentive Plan Form Stock Option Award Agreement		10-Q (Exhibit 10.2)	8/1/2023	001-35092
10.25*	The Registrant's 2019 Omnibus Long-Term Incentive Plan Form Restricted Stock Unit Award Agreement		10-Q (Exhibit 10.3)	8/1/2023	001-35092
10.26*	The Registrant's 2019 Omnibus Long-Term Incentive Plan Form Restricted Stock Award Agreement		10-Q (Exhibit 10.4)	8/1/2023	001-35092
10.27*	The Registrant's 2019 Omnibus Long-Term Incentive Plan Form Deferred Stock Unit Award Agreement		10-Q (Exhibit 10.5)	8/1/2023	001-35092
10.28*	Genomic Health, Inc. Amended and Restated 2005 Stock Incentive Plan, as amended		S-8 (Exhibit 4.4)	11/8/2019	333-234608
10.29*	Thrive Earlier Detection Corp. 2019 Stock Option and Grant Plan		S-8 (Exhibit 4.6)	1/5/2021	333-251900
10.30*	The Registrant's Non-Employee Director Compensation Policy dated January 29, 2025	X			
10.31*	Amendment No. 1 to the Registrant's 2019 Omnibus Long-Term Incentive Plan		8-K (Exhibit 10.1)	6/9/2022	001-35092
10.32*	Amendment No. 2 to the Registrant's 2019 Omnibus Long-Term Incentive Plan		8-K (Exhibit 10.1)	6/12/2023	001-35092
10.33*	The Registrant's 2010 Employee Stock Purchase Plan (as amended and restated July 31, 2024)		10-Q (Exhibit 10.5)	11/5/2024	001-35092
10.34*	The Registrant's Equity Award, Death, Disability and Retirement Policy		10-K (Exhibit 10.33)	2/21/2024	001-35092
10.35*	The Registrant's Executive Officer Perquisite Policy	X			
Other					
10.36**	Technology License Agreement dated as of October 14, 2009 by and among Hologic, Inc., Third Wave Technologies, Inc., and the Registrant		10-K (Exhibit 10.39)	3/12/2010	000-32179

10.37**	Amendment dated December 7, 2012 to Technology License Agreement dated October 14, 2009 by and among Hologic, Inc., Third Wave Technologies, Inc., and the Registrant		10-K (Exhibit 10.37)	3/1/2013	001-35092
10.38**	Second Amended and Restated License Agreement dated effective January 31, 2020, by and between the Registrant and Mayo Foundation for Medical Education and Research		10-Q (Exhibit 10.1)	10/27/2020	001-35092
10.39	Credit Agreement dated as of January 13, 2025 by and among Exact Sciences Corporation, the lenders party thereto, JPMorgan Chase Bank, N.A., as administrative agent, and JPMorgan Chase Bank, N.A., BofA Securities, Inc. and PNC Bank, National Association, as Joint Lead Arrangers and Joint Bookrunners		8-K (Exhibit 10.1)	1/13/2025	001-35092
19	Insider Trading Policy	X			
21	Subsidiaries of the Registrant	X			
23.1	Consent of PricewaterhouseCoopers, LLP	X			
24.1	Power of Attorney (included on signature page)	X			
31.1	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934	X			
31.2	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934	X			
32	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			
97	Incentive-Based Compensation Recovery Policy		10-K (Exhibit 97)	2/21/2024	001-35092
101	The following materials from the Annual Report on Form 10-K of Exact Sciences Corporation for the year ended December 31, 2024 filed with the Securities and Exchange Commission on February 19, 2025, formatted in Inline eXtensible Business Reporting Language ("iXBRL"): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statement of Changes in Stockholders' Equity, (iv) Consolidated Statements of Cash Flows and (v) related notes to these financial statements	X			
104	The cover page from the Annual Report on Form 10-K of Exact Sciences Corporation for the year ended December 31, 2024 filed with the Securities and Exchange Commission on February 19, 2025, formatted in Inline eXtensible Business Reporting Language ("iXBRL")	X			

(*) Indicates a management contract or any compensatory plan, contract or arrangement.

(**) Confidential Treatment requested for certain portions of this Agreement.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

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

EXACT SCIENCES CORPORATION

Date: February 19, 2025

By: /s/ Kevin T. Conroy

Kevin T. Conroy
President & Chief Executive Officer

POWER OF ATTORNEY AND SIGNATURES

We, the undersigned officers and directors of Exact Sciences Corporation, hereby severally constitute and appoint Kevin T. Conroy our true and lawful attorney, with full power to him to sign for us and in our names in the capacities indicated below, any amendments to this Annual Report on Form 10-K, and generally to do all things in our names and on our behalf in such capacities to enable Exact Sciences Corporation to comply with the provisions of the Securities Exchange Act of 1934, as amended, and all the requirements of the Securities Exchange Commission.

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

Name	Title	Date
s/ Kevin T. Conroy Kevin T. Conroy	President and Chief Executive Officer (Principal Executive Officer) and Chairman of the Board	February 19, 2025
/s/ Aaron Bloomer Aaron Bloomer	Executive Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 19, 2025
/s/ Mike Barber Mike Barber	Director	February 19, 2025
/s/ Paul Clancy Paul Clancy	Director	February 19, 2025
/s/ D. Scott Coward D. Scott Coward	Director	February 19, 2025
/s/ James E. Doyle James E. Doyle	Lead Independent Director	February 19, 2025
/s/ Daniel J. Levangie Daniel J. Levangie	Director	February 19, 2025
/s/ Shacey Petrovic Shacey Petrovic	Director	February 19, 2025
/s/ Kim Popovits Kim Popovits	Director	February 19, 2025
/s/ Kathleen Sebelius Kathleen Sebelius	Director	February 19, 2025
/s/ Katherine S. Zanotti Katherine S. Zanotti	Director	February 19, 2025

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