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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, 2023

☐ **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 (State or other jurisdiction of incorporation or organization)	**02-0478229** (IRS Employer Identification No.)
5505 Endeavor Lane, Madison, Wisconsin (Address of principal executive offices)	**53719** (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 ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐	Emerging growth company ☐

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

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

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

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

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

The aggregate market value of 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 $16,796,351,138 (based on the closing price of the Registrant's Common Stock on June 30, 2023 of $93.90 per share).

The number of shares outstanding of the Registrant's $0.01 par value Common Stock as of February 20, 2024 was 181,530,967.

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, 2023. 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, 2023

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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; our strategies, positioning, 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 and profitably market our products and services; the acceptance of our products and services by patients and healthcare providers; our ability to meet demand for our products and services; our reliance upon certain suppliers, including suppliers that are the sole source of certain supplies and products used in our tests and operations; 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; recommendations, guidelines and quality metrics issued by various organizations regarding cancer screening or our products and services; our ability to successfully develop and commercialize new products and services and assess potential market opportunities; our ability to effectively enter into and utilize strategic partnerships and acquisitions; our success establishing and maintaining collaborative, licensing and supplier arrangements; our ability to obtain and maintain regulatory approvals and comply with applicable regulations; our ability to protect and enforce our intellectual property; 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; our ability to raise the capital necessary to support our operations or meet our payment obligations under our indebtedness; the potential effects of changing macroeconomic conditions, including the effects of inflation, interest rate and foreign currency exchange rate fluctuations, 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 possibility that costs or difficulties related to the integration of acquired businesses' operations or the divestiture of business operations will be greater than expected and the possibility that integration or divestiture efforts will disrupt our business and strain management time and resources; the outcome of any litigation, government investigations, enforcement actions or other legal proceedings; and our ability to retain and hire key personnel. 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

Exact Sciences Corporation (together with its subsidiaries, "Exact," "we," "us," "our" or the "Company") is a leading, global, advanced cancer diagnostics company. We have developed some of the most impactful tests in cancer screening and diagnostics, and are currently working to develop additional tests, with the goal of bringing new, innovative cancer tests to patients throughout the world.

Our mission at Exact Sciences is to eradicate cancer and the suffering it causes by preventing it, detecting it earlier, and guiding personalized treatment. Our revenues are primarily generated by our laboratory testing services from our Cologuard® colorectal cancer screening test and our Oncotype DX® cancer diagnostic tests and services.

During 2023, we achieved many milestones, including:

- delivering more than 4 million tests to patients, including a record number of Cologuard and Oncotype DX results,
- growing revenues to $2.50 billion for the year ended December 31, 2023, an increase of 20% compared to the year ended December 31, 2022,
- accelerating our path to profitability through prioritization efforts, leading to improved financial results including positive cash provided by operating activities of $156.1 million for the year ended December 31, 2023, an improvement of $379.7 million compared to the year ended December 31, 2022,
- increasing the percentage of healthcare professionals who offer our Cologuard test as a front-line screening test,
- elevating our Cologuard test brand awareness with consumers to 89%, an all-time high,
- expanding the impact of our Oncotype DX Breast Recurrence Score® test by launching in Japan on a reimbursed basis,
- acquiring Resolution Bioscience, Inc. ("Resolution Bioscience") to complement our solid tumor therapy selection capabilities with a high-quality liquid therapy selection platform,
- releasing positive results from our pivotal BLUE-C study to support our next generation Cologuard test and submitting these results for U.S. Food and Drug Administration ("FDA") approval,
- making great progress toward the development of Oncodetect™, our molecular residual disease and recurrence monitoring ("MRD") test, and
- advancing our multi-cancer early detection ("MCED") program.

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 United States ("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 153,000 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. In September 2019, the FDA expanded its indication to include average-risk individuals ages 45-49. Our Cologuard test is now indicated for average risk adults 45 years of age and older.

Our peer-reviewed study, "Multi-target 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 55% 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.

Clinical Genetic Testing

We provide more than 5,000 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 hereditary cancer test, Riskguard™, helps people understand their inherited risk of cancer, arming them with critical information to make better treatment decisions.

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 2024, nearly 311,000 women are expected to be diagnosed with invasive breast cancer in the U.S. according to ACS, and nearly 56,000 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 certain common types 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 globally recognized as standard of care and 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.

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.

Pipeline Research and Development

Our research and development efforts are focused on developing new products and enhancing existing products to address unmet cancer needs and expand the clinical utility and addressable patient populations for our existing tests. We are focused on enhancing our Cologuard test's performance characteristics and developing blood and other liquid-based ("liquid biopsy") tests. These development efforts may lead to a variety of new products, including risk assessment, screening and prevention, early disease diagnosis, adjuvant and/or neoadjuvant disease treatment, metastatic disease treatment selection, and patient monitoring.

Through our collaboration with the Mayo Foundation for Medical Education and Research ("Mayo"), we have successfully performed validation studies involving multiple types of cancer using tissue, blood, and other sample types. In September 2020, Mayo agreed to make available certain personnel to provide us research and development assistance through January 2025. Through recent business development activities, we have also acquired exclusive access to technologies developed by The Johns Hopkins University ("JHU"), Broad Institute, Inc. ("Broad Institute"), Oxford University, and the Ludwig Institute for Cancer Research.

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

- *Colorectal Cancer Screening*. We are seeking to improve our Cologuard test's performance characteristics, focusing on reducing the false positive rate of the test. In June 2023, we and Mayo presented data from the prospective BLUE-C study, the FDA registrational trial for our next-generation Cologuard test, showing overall sensitivity of 94% for colorectal cancer at specificity of 91%. We submitted our next-generation Cologuard test for FDA approval in December 2023. We are also working to develop a blood-based screening test for colorectal cancer as a second-line option for people who haven't been screened with more accurate methods.
- *MCED Test Development.* We are seeking to develop a MCED test, which will be branded as Cancerguard™ to help detect many different types of cancer from a single blood draw. In September 2022, we presented data at the European Society for Medical Oncology ("ESMO") Congress from a biomarker validation study, which demonstrated the ability to detect cancer signals from 15 organ sites with a mean sensitivity of 61% and mean specificity of 98.2%. The multi-biomarker approach detected stage I and stage II cancers with a combined sensitivity of 38.7%. In June 2023, we announced a collaboration with Baylor Scott & White to utilize our Cancerguard test within a subset of their clinics to generate real-world experience and evidence of our MCED approach. A larger case-control study is underway to further validate the results shared at ESMO and to determine the final design of the Cancerguard test. In the future, we plan to begin recruiting patients for the FDA registrational Study of All comeRs ("SOAR") trial, which we expect to be the largest prospective, interventional MCED trial ever conducted in the U.S.
- *MRD Test Development.* We plan to offer our Oncodetect test, a tumor-informed MRD test to help detect small amounts of tumor DNA that may remain in patients' blood after they have undergone initial cancer treatment. This test will help patients and oncologists understand the success of initial treatment, guide further treatment, and monitor for cancer recurrence. Our goal is to support all patients in MRD and recurrence monitoring, whether there is access to tumor tissue to inform patient-specific biomarker targets or no access to tissue and a predefined biomarker panel is used. We recently completed analytical validation of our tumor informed platform utilizing colorectal cancer samples and are currently conducting a clinical validation study for Medicare submission. In June 2023, we entered into a sponsored research agreement and exclusive license agreement with Broad Institute to utilize their Minor Allele Enriched Sequencing Through Recognition Oligonucleotides ("MAESTRO") diagnostic testing technology to further our ability to develop and launch impactful MRD tests.

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

We have one core commercial function with specific teams focused on screening, precision oncology, and international markets.

Cologuard Test Commercial Operations

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

Our sales team actively engages with healthcare providers and their staff 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 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.

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 activities to promote patient adherence including letters, text messages, online chat, emails, and phone calls.

We have undertaken a significant public relations effort to engage patients in the U.S., and launched demographically-targeted, direct-to-patient advertising campaigns in digital, social, print, and other channels. We promote our Cologuard test through a national television advertising campaign, with a majority of placements in national cable and syndicated programming widely viewed by our target patient demographic. During 2023, we continued to deepen our investment in virtual resources, strengthened our digital and television media channels, and explored innovative campaigns to reach 45-49 year old patients.

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, and utilizes medical education and scientific liaisons who target key opinion leaders. We also plan to continue conducting clinical studies with the objective of having results published in peer-reviewed journals. 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 outside the United States 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. We do not offer our Cologuard test outside of the U.S. We are exploring opportunities to make available outside of the U.S. our Cologuard test and other current and future products.

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 became final in May 2021 and after a transition period, 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 the laws of approximately 30 states currently 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 continue to negotiate contracts with 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.

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 Molecular Diagnostic Services Program ("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 an 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 breast cancer test outside of the U.S., including coverage for certain patients in Canada, France, Germany, Ireland, Israel, Italy, Japan, the Netherlands, Saudi Arabia, Spain, Sweden, Switzerland, and the United Kingdom ("U.K.").

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 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 test at two 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 test from third-party suppliers and manufacturers.

Beginning in March 2020, we allocated space at our clinical laboratories in Madison, Wisconsin to process our COVID-19 tests. Throughout 2020 and 2021, we manufactured and assembled our COVID-19 test kits at our manufacturing facilities in Madison, Wisconsin. From 2022 through June 2023, we continued to manufacture COVID-19 reagents out of our manufacturing facilities, and provided all the components for the test kits to a third-party vendor for assembly. We discontinued our COVID-19 testing in the second quarter of 2023.

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. Our liquid therapy selection tests, which were acquired as part of our acquisition of Resolution Bioscience, are currently processed in our CLIA-certified and CAP-accredited clinical reference laboratory facility in Kirkland, Washington.

As part of the acquisition of PreventionGenetics, LLC ("PreventionGenetics") in December 2021, we acquired a CLIA-certified and CAP-accredited DNA testing laboratory in Marshfield, Wisconsin. PreventionGenetics' laboratory provides more than 5,000 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.

We believe that we currently have sufficient capacity to process all of our tests. 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. Certain of these companies have or may be acquired by, or enter into commercial partnerships with, larger companies with greater expertise or resources, which may increase their ability to offer or develop products that compete with ours.

Some of our current and potential competitors may have significant competitive advantage over us, which may make them more attractive to hospitals, clinics, group purchasing organizations and physicians, including:

- technology breakthroughs that we do not have access to;
- entrenched leaders in new areas that we are entering; and
- alternative distribution models that customers prefer.

The U.S. market 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 test faces 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 common screening tests, such as the fecal occult blood test (“FOBT”) and the fecal immunochemical test (“FIT”). Other screening technologies include liquid biopsy tests, such as Epi proColon, which was approved by the FDA in April 2016, pill-based imaging solutions like PillCam COLON, which was cleared by the FDA in February 2014, and C-Scan, which obtained a CE Mark in early 2019. As noted below, a number of companies are developing liquid biopsy tests for colorectal cancer screening, as well as other applications.

We also are aware of at least three companies, Geneoscopy, Mainz Biomed, and Prescient Metabiomics, that are seeking to develop or have developed stool-based colorectal cancer tests in the United States. Geneoscopy conducted a prospective colorectal cancer screening clinical trial for its stool-based colorectal cancer screening test and reported pivotal trial results in October 2023. Geneoscopy filed for FDA approval in January 2023. Our competitors may also be developing additional methods of detecting colorectal cancer and pre-cancer that have not yet been announced.

We believe that our Cologuard test, the first and only sDNA-based non-invasive colorectal cancer screening test on the market today, compares favorably to other available products and services. All other colorectal cancer detection methods in use today are constrained by some combination of poor sensitivity, poor adherence, or high cost. For example, colonoscopy requires advanced dietary restrictions and bowel cleansing, potential time away from work, someone to drive the patient home from the procedure and can also be uncomfortable, time-consuming, hazardous, and expensive. One study showed that 7 out of 10 people age 50 and older who were told they should get a colonoscopy did not do so primarily due to fear. Fecal blood testing, including FIT testing, suffers from poor sensitivity, with only a 74% detection rate for cancer and 24% detection rate for pre-cancer. Additionally, FIT testing suffers from low adherence over time. One study published in the American Journal of Managed Care demonstrated that only 3 out of every 1,000 patients studied adhered to fecal test screening guidelines during a continuous 10-year observation period. There are currently no blood-based DNA tests approved by the FDA and included in USPSTF guidelines, primarily because of their inherent disadvantage of relatively low sensitivity. The only blood-based DNA test with FDA approval is Epigenomics AG Epi proColon test, which has an overall cancer sensitivity rate of 68%, and only 59% for early-stage cancer. In February 2023, Epigenomics AG announced that it would stop the sale of Epi proColon and recall the product.

Our precision oncology products compete against a number of companies that offer products or have conducted research to profile genes and gene expression in breast and colon cancer such as Agendia Inc., Veracyte, Inc., Myriad Genetics, Inc., and Hologic, Inc. Historically, our principal competition for our precision oncology tests has also come from existing diagnostic methods used by pathologists and oncologists which can be difficult to compete with or supplement. Other potential competitors include companies that develop diagnostic tests such as Roche Diagnostics, a division of Roche Holding, Ltd, and Siemens AG, as well as other companies and academic and research institutions.

We believe that our precision oncology tests compete primarily on the basis of the value of the information they provide, the clinical validation of their utility, their level of adoption and reimbursement coverage, and their inclusion in clinical practice guidelines. They are also supported by our ability to commercialize products through our clinical development platform, our collaborations with clinical study groups, the quality of our clinical laboratory, and the level of customer service we provide. While we believe that our precision oncology tests compete favorably with respect to these factors, to continue to do so we must innovate and adopt advanced technology, successfully market, sell and enhance our tests, obtain peer-reviewed publications of our clinical studies in a timely manner, continue to obtain positive reimbursement determinations, continue to expand in countries outside of the U.S., continue to develop our technological and clinical operations, encourage healthcare provider participation in Medicare-required information collection efforts, and successfully expand our reach into additional product markets, including through collaborations with third parties.

In addition to our on-market products, we intend to offer additional liquid biopsy solutions, including tests that screen for colorectal cancer, screen for multiple types of cancers in a single test, provide prognostic information, guide therapy selection, and measure molecular residual disease and cancer recurrence.

We are aware of a large number of companies including Guardant Health, Inc. ("Guardant"), Freenome Inc. ("Freenome"), GRAIL, Inc., and Natera Inc. ("Natera") that have developed, or are developing, liquid biopsy tests for the detection of cancer. These tests could represent significant competition for our current tests and other tests we are currently developing or may develop in the future. Guardant and Freenome are conducting prospective colorectal cancer screening clinical trials for their liquid biopsy tests. Guardant reported pivotal trial results in May 2023, and Freenome is expected to report pivotal trial results in 2024. Guardant made its blood-based colorectal cancer screening test, Shield, available as a laboratory developed test beginning in May 2022 and filed for FDA approval in March 2023.

Guardant and Natera have also developed, and are conducting prospective clinical trials to generate evidence in support of, MRD tests that could represent significant competition for the MRD tests we are currently developing or may develop in the future. Guardant made its MRD test, Reveal, available as a laboratory developed test beginning in February 2021 and has obtained limited commercial coverage and Medicare coverage for the test for certain stages of colorectal cancer in the adjuvant setting. Natera made its MRD test, Signatera, available as a laboratory developed test beginning in 2019 and has obtained limited commercial and Medicare reimbursement for the test across multiple clinical indications, including certain stages of colorectal cancer and breast cancer.

The hereditary cancer testing market is becoming increasingly competitive, and we expect this competition to intensify in the future. We face competition from a variety of sources, including Ambry Genetics, a subsidiary of Konica Minolta Inc.; Myriad Genetics, Inc.; Invitae; Natera; Color Health, Inc.; and Sema4 Genomics; a few large, established general testing companies such as Laboratory Corporation of America Holdings 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.

Competitors may develop their own versions of our tests in countries where we did not apply for patents, where our patents have not issued or where our intellectual property rights are not recognized and compete with us in those countries, including encouraging healthcare providers or patients to use their tests in other countries. We are aware of companies in China that offer or intend to offer tests similar to ours. Competitors also may be able to design around our intellectual property.

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.

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 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 test is regulated by the FDA as a Class III medical device. The FDA granted premarket approval ("PMA") for our Cologuard test in August 2014. The regulations governing our Cologuard test's approval place substantial restrictions on how our Cologuard test is marketed and sold, specifically, by prescription only. In addition, as a condition of our FDA approval, we were required to conduct a post-approval study. The post-approval study concluded in 2020 and final results were submitted to the FDA in late 2020. The FDA notified us in 2023 that our study report fully satisfied our post-approval study requirement and requested that we update the Cologuard labeling, via a PMA supplement to, include the new study information. We have submitted the requested supplement and it is currently under FDA review.

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. In 2017, we recalled one of the components of our Cologuard test kit and circumstances may arise that cause us to recall other products or components used in connection with our Cologuard test.

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 ("LDTs")

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 but has for the most part exercised enforcement discretion and has not required clearance or approval of LDTs prior to marketing.

At various times since 2006, the FDA has issued documents outlining its intent to require varying levels of FDA oversight of many LDTs, including our tests. In October 2023, the FDA published a proposed rule that, if finalized, would regulate LDTs as medical devices under the FDCA. The comment period for the FDA's proposed rule closed in December 2023 and the FDA has indicated its desire to issue a final rule on LDTs in April 2024 or shortly thereafter. Even if the FDA does not finalize its proposed rule, the U.S. Congress may enact statutory changes that could alter or eliminate the FDA's current LDT enforcement policy. It is therefore unclear at this time what form that final regulation may take, or if the FDA will finalize the regulation at all. It is also unclear what additional obligations might be placed on us as we continue to offer LDTs in light of the FDA's renewed interest in greater oversight into this class of tests. Action by the FDA to phase out its current policy of enforcement discretion over LDTs 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 "Self-Referral" and "Anti-Kickback" 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, 2023, and there are no material expenditures planned for such purposes for the year ended December 31, 2024.

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 pertaining to sample type, 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, 2023, we had 208 issued patents in the U.S. and 878 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 2024 and 2043. 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 material data transfer 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 JHU 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 if net sales of a licensed product using JHU proprietary data reach specified 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, 2023, we had approximately 6,600 full-time, part-time and temporary employees, 6,500 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 2023, our voluntary turnover rate was approximately 8%, below the healthcare industry benchmark, which is comprised of certain of our key competitors (Aon, 2023 Salary Increase and Turnover Study — Second Edition, June 2023).

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 VP of Human Resources, 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 54% of total employees (full-time and part-time), and 49% of management positions. Our eleven-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® in 2023, Forbes' Best-in-State Employer in 2023, and Wisconsin State Journal Top Workplaces in 2023.

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 upon hire and annually thereafter, 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 and podcasts 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 2023 we were able to fill 38% 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 Cologuard 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.
- Failure in our information technology, storage systems, or our clinical laboratory equipment could significantly disrupt our operations and our research and development efforts.
- If the courier delivery services we use in connection with our tests 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 and our ability to foster and maintain an inclusive and collaborative corporate culture.
- 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, 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 may change its position with respect to its regulation of the laboratory developed tests we offer or may seek to offer in the future, causing us to incur substantial costs and time delays and 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 as well as the Foreign Corrupt Practices Act and similar anti-bribery laws.
- 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.
- We expect to rely on third parties to conduct any future studies of our technologies that may be required by the FDA or other U.S. or foreign regulatory bodies, and those third parties may not perform satisfactorily.
- 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 our Cologuard test, our Precision Oncology tests, and any other screening or diagnostic product or service we may offer or develop will depend on the degree of market acceptance by healthcare providers, patients, healthcare payers, 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.
- We expect to continue to make significant investments in our research and development efforts, which may not be successful.
- Our dependence on distributors for sales in many markets outside of the U.S. could limit or prevent us from selling our tests in those markets 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 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.
- 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, 2023, we have accumulated a total deficit of approximately $3.47 billion. Our net loss was $204.1 million, $623.5 million and $595.6 million for the years ended December 31, 2023, December 31, 2022 and December 31, 2021, 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. Although our net losses have diminished considerably over the last several years, 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 Cologuard 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 Cologuard 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 Cologuard 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 Cologuard and precision oncology tests or that we will develop or commercialize any other products or services that will generate significant revenue. The knowledge and experience we have gained commercializing our Cologuard and precision oncology tests may not translate into successful commercialization efforts with respect to new and different products. 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, such as those developed by ACS, USPSTF, American Society of Clinical Oncology, and NCCN, and similar guidelines and recommendations outside the U.S.;
- 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, companies, 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;
- the number of patients screened for colorectal cancer, as well as the number of patients who use our Cologuard test for that purpose;

- the number of women diagnosed with breast cancer;
- 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;
- the ease of use of our ordering process for healthcare providers;
- maintaining and defending patent protection for the intellectual property relevant to our products and services; and
- our ability to establish and maintain adequate commercial manufacturing, distribution, sales and CLIA laboratory testing capabilities.

If we are unable to continue growing sales of our Cologuard 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 Cologuard 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 the outbreak of influenza 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;
- 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, Kirkland, Washington, 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, under the scope of which Oncotype tests could be performed following validation and other required procedures. 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, 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.

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. Our relationships with suppliers may also be negatively affected by general supply chain material shortages worldwide, as suppliers struggle to keep pace with demand and manage their own supply chains.

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 we are not aware of any other platform that we could use in the near future as a commercially viable alternative. Further, Illumina may be the only commercially viable supplier of certain equipment and reagents necessary for some of our current tests and future tests we may develop, including MCED and MRD tests. Since August 2021, Illumina has owned GRAIL, which is commercializing a MCED test against which certain of our planned tests would compete. Illumina's ownership of GRAIL could incentivize Illumina to offer its sequencing products in a manner that advantages GRAIL over us and other competitors, including the potential that Illumina may be unwilling or unable to supply, or commit to supplying, us with sequencing equipment and reagents on commercially acceptable terms, or at all. Illumina has made an irrevocable standing offer to supply any customer with its sequencing products, which we have accepted. However, that offer may not provide pricing or other terms necessary for us or others to successfully compete against GRAIL, including outside of the U.S. On December 17, 2023, Illumina publicly announced its intention to divest GRAIL by the end of the second quarter of 2024, after various regulatory decisions in the U.S. and E.U. questioned whether Illumina's ownership of GRAIL was consistent with antitrust laws. The timing and terms of such divestiture are uncertain and, even if it occurs as

announced, it may not mitigate the risks associated with our use of Illumina's products. Although we expect to continue our efforts to validate alternative sequencing platforms on which we could run our OncoExTra tests or other future tests in a commercially viable manner, we may expend considerable time and efforts, endure delays to our test development and commercialization timelines, and be ultimately unsuccessful in our efforts to validate alternatives. Even if we validate an alternative sequencing platform, we may become substantially dependent on the supplier of that platform.

Similarly, as an additional example, we 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 Hamilton machines and to optimize their use in our tests. We have a long-term supply agreement with Hamilton, which requires our exclusive use of certain Hamilton consumables and components with our Hamilton laboratory equipment. However, it is possible that Hamilton could become unable or unwilling to continue providing us with equipment and supplies on commercially acceptable terms, if at all. If our access to certain Hamilton consumables and components became impacted, we may need to completely replace the Hamilton platform. Validating alternative vendors' offerings could be expensive, time-consuming, and unsuccessful. Further, because our Cologuard test is regulated by the FDA, we may also need FDA clearance or approval to replace certain Hamilton equipment and supplies with another vendor's offerings. FDA approval or clearance may entail extensive new clinical and material costs and delays and may be ultimately unsuccessful.

The loss of a critical supplier, the failure to perform by a critical supplier, the deterioration of our relationship with a critical supplier or any unilateral modification to the contractual terms under which we are supplied certain supplies and/or products 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 supplier.

Failure in our information technology, storage systems, or our clinical laboratory equipment could significantly disrupt our operations and our research and development efforts.

Our ability to execute our business strategy depends, in part, on the continued and uninterrupted performance of our information technology ("IT") systems, which support our operations, including at our clinical laboratories, and our research and development efforts. We depend on our IT systems to receive and process test orders, securely store patient health records and deliver the results of our tests. The integrity and protection of our own data, and that of our customers and employees, is critical to our business. 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. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses, and similar disruptive problems. Cyber-attacks 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 cyber-attacks of our IT systems and networks. To date, none of these attempted cyber-attacks 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 Medicare claims or commercially practicable with regard to commercial claims.

The success of our business substantially depends on the efforts of our senior management team and our qualified personnel and our ability to foster and maintain an inclusive and collaborative corporate culture.

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 for certain highly technical or scientific personnel and experienced salespeople among life science and technology businesses. 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. Because of the competition for their services, we may be unable to hire, partner with or retain additional qualified sales representatives or marketing or medical affairs personnel, either as our employees or independent contractors or through independent sales or other third-party organizations. Market competition for commercial, marketing and medical affairs talent is significant, and we may not be able to hire or retain such talent on commercially reasonable terms, if at all.

All of our employees in the U.S. are at will, which means that either we or the employee may terminate their employment at any time. If we fail to attract and retain necessary personnel or effectively manage leadership changes among key positions in our organization, our business and operating results could be harmed. In addition, recruiting and retaining talented and diverse personnel and fostering an inclusive culture focused on collaboration and partnership across the business are critical to our success. As we grow, we may face challenges in attracting and retaining qualified personnel with diverse backgrounds, experiences and skill sets, which could harm our ability to execute our business strategy.

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 test 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 6,500, as of December 31, 2023. 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 significantly. 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. For example, in September 2023, we acquired Resolution Bioscience, Inc. 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. For example, in August 2022 we completed a divestiture of assets related to our Oncotype DX Genomic Prostate Score test ("GPS test") to MDxHealth SA ("MDxHealth"). 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 test outside of the U.S., we currently commercialize or plan to commercialize our Oncotype DX 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 and regulations, such as tax laws, export and import restrictions, 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;
- limits in our ability to access or penetrate international markets if we are not able to process tests locally;
- lack of intellectual property protection in certain markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, lower margins resulting from smaller scale foreign operations, the impact of local and regional financial crises on demand and payment for our tests, and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, strikes, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade, and other business restrictions;
- staffing difficulties, funding restrictions, and other difficulties facing medical institutions and payers;

- 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 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, and budgeting constraints of governmental entities. Cost inflation, including increases in raw material prices, labor rates, and transportation costs, may continue to 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, 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.

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. Litigation is subject to significant uncertainty and may be expensive, time-consuming, and disruptive to our operations. Although we will vigorously defend 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. 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 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. 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 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. Congress could modify or repeal PAMA in the future or CMS could modify regulations under PAMA, and any such action could have the effect of reducing the CMS reimbursement rate for our tests. Further, it is possible that Medicare or other federal payers that provide reimbursement for our tests may suspend, revoke or discontinue coverage at any time, may require co-payments from patients, or may reduce the reimbursement rates payable to us. Any such action could have a negative impact on our revenues.

Coverage of our Cologuard test 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 test 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 test 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 test.

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 a positive coverage decision and what we believe is an adequate reimbursement rate from CMS for our Cologuard test, 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 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. In 2017, we recalled one of the components of our Cologuard test kit and circumstances may arise that cause us to recall other products or components used in connection with our Cologuard test. Any such recalls could have an adverse effect on our ability to provide the Cologuard test, 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 test is regulated by the FDA as a medical device and we may develop new tests that are deemed medical devices and require FDA clearance or approval. 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 will likely be 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 Cologuard test or future FDA-approved or -cleared tests. For example, our next generation Cologuard test will require FDA approval before it can be marketed and we are in the process of seeking that approval. 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. 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 and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. 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 may change its position with respect to its regulation of the laboratory developed tests we offer or may seek to offer in the future, causing 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 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 FDC Act but has for the most part exercised enforcement discretion and has not required clearance, de novo classification, or approval of LDTs prior to marketing.

At various times since 2006, the FDA has issued documents outlining its intent to require varying levels of FDA oversight of many LDTs, including our tests. In October 2023, the FDA announced a proposed rule seeking to regulate LDTs as medical devices under the FDCA. The comment period for the FDA's proposed rule closed in December 2023 and the FDA has indicated its desire to issue a final rule on LDTs in April 2024 or shortly thereafter. Even if FDA does not finalize its proposed rule, the U.S. Congress may enact statutory changes that could alter or eliminate FDA's current LDT enforcement policy. It is therefore unclear at this time what form that final regulation may take, or if FDA will finalize the regulation at all. It is also unclear what additional obligations might be placed on us as we continue to offer LDTs in light of FDA's renewed interest in greater oversight into this class of tests and the potential for legislative changes. Action by the FDA or Congress to phase out the FDA's current policy of enforcement discretion over LDTs may materially impact our development and commercialization of LDTs, including our Oncotype tests. If pre-market review is required for our current LDTs, the FDA could require that we stop selling our tests pending pre-market clearance or approval and our business could be negatively impacted in the U.S. until such review is completed and clearance or approval is obtained. 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.

If our Oncotype tests are allowed to remain on the market but there is uncertainty about the regulatory status of such tests, if they are labeled investigational by the FDA, or if labeling claims the FDA allows us to make are more limited than the claims we currently make, orders or reimbursement may decline.

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, including the Telephone Consumer Protection Act ("TCPA") and the Controlling the Assault of Non-Solicited Pornography and Marketing Act ("CAN-SPAM 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 included in Item 8 of this Annual Report on Form 10-K, 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.

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, 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.

We expect to rely on third parties to conduct any future studies of our technologies that may be required by the FDA or other U.S. or foreign regulatory bodies, and those third parties may not perform satisfactorily.

We expect to 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 for clinical development activities will reduce our control over these activities. These third parties may not complete activities on schedule or conduct studies in accordance with regulatory requirements or our study design. 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, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, 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.

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 our Cologuard test, our Precision Oncology tests, and any other screening or diagnostic product or service we offer or develop 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, 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;
- 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.

Our assumptions regarding the market opportunity for our products or services may not prove true. For example, we estimate the potential market opportunity for our Cologuard test assuming, among other things, the size of the screening population, the adoption rate in the screening population and a three-year screening interval. Although ACS guidelines and others recommend a three-year screening interval for our Cologuard test and CMS has determined that Medicare will cover the test at this interval, the label for our Cologuard test does not specify a three-year interval and healthcare providers, healthcare payers, the FDA, and other regulators and opinion leaders could recommend a different interval. Further, patients may not adhere to any recommended testing interval.

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 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 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 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 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 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 fails to maintain its current position within any updated USPSTF colorectal cancer screening recommendations, our Cologuard 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. From time to time, we may publicly disclose then-available data from clinical studies before the studies are complete, and the results and related findings and conclusions may be subject to change following the final analysis of the data related to the particular study or trial. As a result, such data should be viewed with caution until the final data are available. Additionally, such data from clinical studies are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment and/or follow-up continues and more patient data become available. 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.

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

As of December 31, 2023, 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 Cologuard test 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 non-invasive 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 test 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 began to expire in 2018. 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 or regulatory agencies 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 co-ownership of such patents with the third party or the unenforceability or invalidity of such patents.

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.

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, 2023, 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.

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 balance sheet includes goodwill and intangible assets that represent 66% of our total assets at December 31, 2023, which are primarily associated with our acquisitions. On at least an annual basis, we assess whether there have been impairments in the carrying value of goodwill. In addition, we review intangible assets for impairment whenever events or changes in circumstances indicate the carrying amount of the asset may 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.

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, 2023, we had total indebtedness of $2.39 billion, including $2.34 billion in aggregate principal and interest due under our convertible senior notes and $50.0 million in borrowings under our Securitization Facility. We also had $4.4 million of letters of credit issued under our Revolver. 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, warranties, affirmative covenants and negative covenants, events of default as well as termination events which would permit the lenders to terminate upon the occurrence of certain specified events, including, among others, failure to pay amounts when due, certain defaults on other material indebtedness, certain judgments, a change of control and bankruptcy and insolvency events. 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 (i) acceleration of the debt outstanding under the agreement 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, policies, and procedures 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 the Company's business. Our AFC regularly discusses with management, Company legal counsel, and the internal audit department the Company's major risk exposures. This includes potential financial impact on the Company and the steps taken to monitor and control those risks. Reviews with management are done annually which includes a summary of legal and regulatory compliance matters and risk management activities, including a review of the Company's 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 the Company's 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 the Company's risks from cybersecurity threats. The CISO has been with the Company for two years and has over 30 years of experience in technology, including 15 years in cybersecurity, and has held the CISO position at prior companies before joining Exact Sciences. The CISO is supported by a cybersecurity team that is staffed with experts in strategy, governance, risk management, compliance, engineering and development, security operations, and incident management.

The CISO provides our AFC with quarterly updates about our cybersecurity program and material risks. This includes updates on cybersecurity practices, programs, and the status of 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 any potential 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. Beginning in 2024, the Cybersecurity Leadership Team, which includes the CISO and executives from all business functions across the organization, meet 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 which are 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 cybersecurity related risks identified 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 from previous cybersecurity incidents, that have materially affected or are reasonably likely to materially affect the Company.

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Item 2. Properties

As of December 31, 2023, 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	1,581,000	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 included in Part II, Item 8, “Consolidated Financial Statements and Supplementary Data” 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 included in Item 8 of this Annual Report on Form 10-K.

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

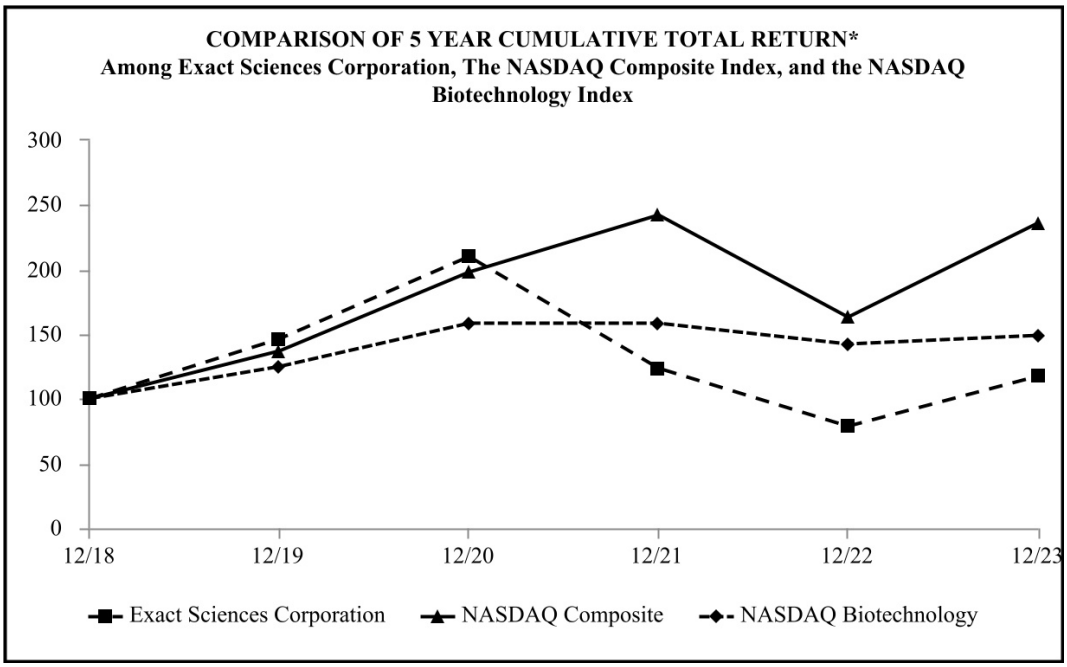
Our common stock is currently listed on the NASDAQ Capital Market under the symbol "EXAS."

As of February 20, 2024, there were 181,530,967 shares of our common stock outstanding held by approximately 179 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, 2023. The graph assumes that the value of the investment in our stock and in each index was $100 on December 31, 2018 and assumes that all dividends were reinvested.



* $100 invested on December 31, 2018 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 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 2021 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, 2022, which was filed with the SEC on February 21, 2023.

Overview

Exact Sciences Corporation is a leading, global, advanced cancer diagnostics company. We have developed some of the most impactful tests in cancer screening and diagnostics, and we are currently working to develop additional tests, with the goal of bringing new, innovative cancer tests to patients throughout the world.

Acquisitions

On September 12, 2023, we 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 a CLIA certified lab based in Kirkland, Washington. The acquisition provides us with a high-quality blood-based therapy selection platform, complementing our comprehensive, tissue-based OncoExTra test.

2024 Priorities

Our top priorities for 2024 are to (1) focus on our people and customers, (2) bring our portfolio to life, and (3) magnify our impact.

Focus on our People and Customers

We want to continue to provide an exceptional experience for our patients and team members. We plan to improve customer relations by delivering simple and smooth workflows, providing communication that is clear and easy to understand, and providing results that are fast and accurate. We will also strive to ensure that Exact Sciences remains a great place to work by taking care of our people.

Bring our Portfolio to Life

We will focus on advancing new tests in our highest priority programs including colorectal cancer screening, MRD, and MCED. We plan to continue investing in our clinical trials to enhance existing products and bring new products to patients and providers, including obtaining FDA approval and securing coverage for our next generation Cologuard test.

Magnify our Impact

We are committed to improving lives through testing more people with our laboratory testing services in 2024 including expanding screening access to underserved populations. By testing more people, we will continue to expand our business in a cost-efficient manner allowing us to generate sustainable profits and increase shareholder value. Generating sustained profits will put the company in a better position to continue investing in life-changing cancer diagnostics to help achieve our mission.

Recent Developments and Trends

We estimate there are up to 60 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 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 are recognizing the opportunity to partner with Exact Sciences to address their screening rates and related quality measures. We aim to partner with them to implement our Cologuard test as an essential part of their screening toolkit and embed it in their workflows. We continue to implement more electronic ordering interfaces connecting health systems to Exact Sciences. Our Cologuard test market share is increasing in larger health systems, helping us screen more Americans.

We have an opportunity to impact even more lives by increasing adoption of Oncotype DX internationally. In 2023, we secured reimbursement for Oncotype DX 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 that more than 100 women a day could learn if their cancer is likely to recur, and potentially be spared of unnecessary chemotherapy.

Results of Operations

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

(Amounts in millions)	2023	2022	Change
Screening	$ 1,864.7	$ 1,424.7	$ 440.0
Precision Oncology	629.1	601.5	27.6
COVID-19 Testing	6.0	58.1	(52.1)
Total	$ 2,499.8	$ 2,084.3	$ 415.5

The increase in Screening revenue was mainly due to an increase in the number of completed Cologuard tests. The increase in completed Cologuard tests for the year ended December 31, 2023 was due to improved sales team productivity, growth across all customer segments, more patients rescreening with our Cologuard test, and improvements in patient adherence. The increase in Precision Oncology revenue was mainly due to an increase in the number of completed Oncotype DX breast cancer tests, both domestically and internationally. The increase in completed Oncotype DX tests was partially offset by a decrease of $19.4 million in revenues from our divested GPS test. 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.

During the years ended December 31, 2023 and 2022, revenue recognized from changes in transaction price was $25.2 million and $20.3 million, respectively. The revenue recognized from changes in transaction price is a result of improvements made in our billing systems and processes, including international contracting and collections.

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 (exclusive of amortization of acquired intangible assets). The increase in cost of sales for the year ended December 31, 2023 was primarily due to an increase in production costs and personnel expenses, which was a result of an increase in completed Cologuard and Oncotype tests and the corresponding increase in headcount to support the increase in tests completed. Cost of sales as a percentage of revenue was 26% and 28% for the years ended December 31, 2023 and 2022, respectively. The decrease in cost of sales as a percentage of revenue was due to improved efficiency in logistical arrangements and personnel as a result of increased volumes. 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)	2023	2022	Change
Production costs	$ 393.4	$ 329.5	$ 63.9
Personnel expenses	182.0	160.1	21.9
Facility and support services	54.4	63.6	(9.2)
Stock-based compensation	20.8	19.2	1.6
Other cost of sales expenses	3.6	2.0	1.6
Total cost of sales expense	$ 654.2	$ 574.4	$ 79.8

Research and development expenses. The increase in research and development expenses for the year ended December 31, 2023 was primarily due to an increase in personnel expenses and facility and support services. These increases were a result of an increase in headcount and other resources needed to support our ongoing clinical trials and other research and development efforts. Our direct research and development costs, which represent a significant portion of our research and development expenses, are primarily related to clinical trial expenses for our BLUE-C clinical study, as well as research related expenses for the development of our MCED and MRD tests. The decrease in direct research and development costs for the year ended December 31, 2023 was primarily due to a reduction in BLUE-C clinical trial related costs as enrollment completed in December 2022. This decrease was offset by an increase in costs related to our MCED and MRD research activities, which increased throughout 2023. We expect that research and development expenses will generally continue to increase in future periods as we continue investing in new tests and enhancing current products.

(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)
Total research and development expenses	$ 425.9	$ 393.4	$ 32.5

Sales and marketing expenses. The decrease in sales and marketing expenses for the year ended December 31, 2023 was primarily due to a decrease in direct marketing costs and professional fees, personnel expenses, and facility and support services. The decrease in direct marketing costs and professional fees was driven by decreases in advertising spend and costs incurred under our promotion agreement with Pfizer Inc., which ended in the third quarter of 2022. The decrease in personnel expenses was due to a realignment of the sales force, which reduced overlap and increased productivity. The decrease in facility and support services was due to fewer costs incurred on commercial related information technology projects. We anticipate sales and marketing expenses will generally increase in future periods while continuing to decrease as a percentage of revenue over time, driven by the growth of Cologuard and Oncotype testing services and the introduction to new tests.

(Amounts in millions)	2023	2022	Change
Personnel expenses	$ 412.9	$ 444.9	$ (32.0)
Direct marketing costs	183.7	237.5	(53.8)
Stock-based compensation	65.6	62.6	3.0
Professional and legal fees	44.7	49.0	(4.3)
Facility and support services	16.9	48.6	(31.7)
Other sales and marketing expenses	3.3	3.4	(0.1)
Total sales and marketing expenses	$ 727.1	$ 846.0	$ (118.9)

General and administrative expenses. The increase in general and administrative expenses for the year ended December 31, 2023 was primarily due to an increase in professional and legal fees, facility and support services, and other general and administrative expenses. We reached settlements with counterparties related to the Medicare Date of Service Rule Investigation and the Federal Anti-Kickback Statute and False Claims Act qui tam lawsuit in 2023, resulting in an expense of $36.2 million included within professional and legal fees for the year ended December 31, 2023, as further described in Note 15 of our consolidated financial statements included in this Annual Report on Form 10-K. The increase in facility and support services was incurred to support the growth in our operations. The increase in other general and administrative expenses was primarily due to a $38.6 million decrease in the gain recorded on our outstanding contingent consideration liabilities as a result of change in fair value, as further described in Note 7 of our consolidated financial statements included in this Annual Report on Form 10-K. We expect general and administrative expenses will generally continue to increase in future periods to support the growth in our existing and pipeline products, but we expect it will decrease as a percentage of revenue over time as we leverage efficiencies in our personnel and information technology systems.

(Amounts in millions)	2023	2022	Change
Personnel expenses	$ 395.6	$ 390.8	$ 4.8
Facility and support services	182.2	136.7	45.5
Professional and legal fees	171.9	116.4	55.5
Stock-based compensation	103.7	91.2	12.5
Other general and administrative	39.8	2.2	37.6
Total general and administrative expenses	$ 893.2	$ 737.3	$ 155.9

Amortization of acquired intangible assets. Amortization of acquired intangible assets decreased to $92.2 million for the year ended December 31, 2023 compared to $97.5 million for the year ended December 31, 2022. This decrease was primarily due to a decrease in amortization on the intangible asset that was disposed of with the sale of the GPS test in August 2022 and the intangible assets that were impaired during the year ended December 31, 2022. This was partially offset by amortization of the intangible assets acquired as part of our acquisition of OmicEra Diagnostics, GmbH in May 2022 and Resolution Bioscience in September 2023.

Impairment of long-lived assets. Impairment of long-lived assets decreased to $0.6 million for the year ended December 31, 2023 compared to $16.0 million for the year ended December 31, 2022. The impairment charges recorded during the year ended December 31, 2023 included impairments to building leases at certain of our domestic locations. The impairment charges recorded during the year ended December 31, 2022 included an impairment to the supply agreement intangible asset acquired as part of the acquisition of Genomic Health, an impairment of the acquired developed technology intangible asset acquired as part of the acquisition of Paradigm Diagnostics, Inc. (“Paradigm”), and building leases at certain of our domestic locations.

Other operating income (loss). Other operating income (loss) increased to a gain of $78.4 million for the year ended December 31, 2023 compared to a loss of $13.2 million for the year ended December 31, 2022. The $78.4 million gain 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 $13.2 million loss for the year ended December 31, 2022 represents the loss on the sale of our GPS test to MDxHealth. The sale of the GPS test is further discussed in Note 18 of our consolidated financial statements included in this Annual Report on Form 10-K.

Investment income (loss), net. Investment income (loss), net increased to net investment income of $32.7 million for the year ended December 31, 2023 compared to a net investment loss of $19.4 million for the year ended December 31, 2022. The net investment loss for the year ended December 31, 2023 was primarily due to gains recorded on our marketable securities and investments in privately held companies. The net investment loss for the year ended December 31, 2022 was primarily due to losses recorded on our investments in privately held companies and marketable securities.

Interest expense. Interest expense decreased to $19.4 million for the year ended December 31, 2023 compared to $19.6 million for the year ended December 31, 2022. 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. Interest expense recorded from our outstanding convertible notes totaled $16.1 million for the year ended December 31, 2022. The convertible notes are further described in Note 10 of our consolidated financial statements included in this Annual Report on Form 10-K.

Income tax benefit (expense). Income tax expense was $2.4 million for the year ended December 31, 2023 compared to a benefit of $9.1 million for the year ended December 31, 2022. Income tax expense for the year ended December 31, 2023 was primarily related to current foreign and state tax expense. The income tax benefit recorded during the year ended December 31, 2022 was primarily related to the future limitations on and expiration of certain Federal and State deferred tax assets, offset by current foreign and state tax expense.

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, 2023, 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, 2023, we had approximately $605.4 million in unrestricted cash and cash equivalents and approximately $172.3 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)	2023	2022
Net cash provided by (used in) operating activities	$ 156.1	$ (223.6)
Net cash provided by investing activities	49.7	74.1
Net cash provided by financing activities	159.8	76.5

Operating activities

The increase in cash provided by operating activities for the year ended December 31, 2023 compared to the year ended December 31, 2022 was primarily due to an increase in revenue, a decrease in operating expenses as a percentage of revenue, and timing of payments on our accounts payable and accrued expenses. The increase in revenue was primarily driven by an increase in the number of completed Cologuard and Oncotype tests. Operating expenses as a percentage of revenue decreased for the year ended December 31, 2023, primarily due to cost saving measures implemented in the second half of 2022.

Investing activities

The decrease in cash provided by investing activities for the year ended December 31, 2023 compared to the year ended December 31, 2022 was due to several factors. Cash provided by sales and maturities of marketable securities decreased by $89.9 million as we invested in more money market accounts due to changes in interest rates and macroeconomic conditions. The decrease was also attributable to a net cash outflow of $52.4 million from the acquisition of Resolution Bioscience in September 2023 compared to payments related to our business combinations of $14.7 million in 2022. The decrease in cash provided by investment activities was offset by a decrease of $90.3 million in purchases of property, plant and equipment due to completion of our clinical lab and warehouse expansions in 2022, and a decrease of $26.3 million in our spend in privately held companies. Additionally, we received $19.8 million in proceeds from maturities and sales of investments in privately held companies for the year ended December 31, 2023, compared to proceeds of $25.0 million from the sale of the GPS test for the year ended December 31, 2022.

Financing activities

The increase in cash provided by financing activities for the year ended December 31, 2023 compared to the year ended December 31, 2022 was primarily due to proceeds of $138.0 million from the issuance of convertible notes in the first quarter of 2023. Cash provided by financing activities for the year ended December 31, 2022 was primarily due to proceeds of $50.0 million from our accounts receivable securitization facility in the second quarter of 2022.

Material Cash Requirements

Convertible Notes

As of December 31, 2023, we had outstanding aggregate principal of $2.34 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”), and March 1, 2030 (the “2030 Notes” and collectively, the “Notes”). The 2025 Notes have an outstanding principal balance of $249.2 million. The 2027 Notes have an outstanding principal balance of $563.8 million. The 2028 Notes have an outstanding principal balance of $949.0 million. The 2030 Notes have an outstanding principal balance of $573.0 million. The 2025 Notes, 2027 Notes, 2028 Notes, and 2030 Notes accrue interest at a fixed rate of 1.0%, 0.375%, 0.375%, and 2.0% per year, respectively, which is payable in cash semi-annually in arrears each year until the maturity date. See Note 10 in the 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. It is our intent and policy to settle all conversions through a combination settlement.

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, 2023, we had minimum operating and finance lease payments of $239.7 million and $13.2 million, respectively. Of the outstanding operating lease obligations, $39.5 million matures in 2024, and the remaining $200.3 million will mature in periods subsequent to 2024. Of the outstanding finance lease obligations, $5.0 million matures in 2024, and the remaining $8.2 million will mature in periods subsequent to 2024. See Note 15 in the 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, multi-cancer early detection test. The projected fiscal year of payment range is from 2028 to 2030. See Note 18 in the Notes to Consolidated Financial Statements 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 18 in the Notes to Consolidated Financial Statements for further information.

As a result of the acquisition of the proprietary Targeted Digital Sequencing ("TARDIS") technology from The Translational Genomics Research Institute ("TGen") in January 2021, an additional $45.0 million would be payable in cash to TGen upon the achievement of cumulative product revenue milestones related to MRD detection and/or treatment. Milestone payments of $10.0 million and $35.0 million would be payable upon achieving $100.0 million and $250.0 million, respectively, in cumulative revenue on or before December 31, 2030. See Note 18 in the 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 in the 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 include the build out of certain lab automation projects at our existing facilities in Madison, WI. These projects are expected to be completed in 2024 and beyond. We also have assets under construction related to leasehold and building improvements, laboratory equipment, and software projects. We expect to incur approximately $150.0 million in capital expenditures in 2024.

Sources of Cash

We have access to a revolving line-of-credit (the "Revolver") of up to $150.0 million, which had its maturity date extended to November 2025 through an amended agreement in October 2022. The Revolver is collateralized by certain marketable securities which must continue to maintain a minimum market value of $150.0 million. PNC Bank, National Association has issued letters of credit totaling $4.4 million, which reduces the amount available for cash advances under the line of credit to $145.6 million. As of December 31, 2023, we had not drawn any funds under the Revolver. In addition to the Revolver, we have access to $150.0 million under an accounts receivable securitization facility (the "Securitization Facility"), which expires in June 2024 at which point we will need to repay the outstanding balance or refinance the Securitization Facility. Any refinancing is subject to market conditions and other factors, including evaluating other financing options available to us. The amount that we may borrow is determined based on the amount of qualifying accounts receivable at a given point in time. The Securitization Facility is collateralized by our accounts receivable. As of December 31, 2023, we had $50.0 million outstanding under the Securitization Facility, which is the minimum amount that we must borrow under the terms of the Securitization Facility. The Revolver and Securitization Facility are further described in Note 9 of our consolidated financial statements included in this Annual Report on Form 10-K.

We believe that our anticipated income from operations, cash and marketable securities on hand, and borrowing capacity under our Revolver and Securitization Facility 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, 2023, we had no off-balance sheet arrangements.

Net Operating Loss Carryforwards

As of December 31, 2023, we had federal, state, and foreign net operating loss ("NOL") carryforwards of approximately $402.9 million, $66.0 million, and $10.4 million, respectively. We also had federal and state research tax credit carryforwards of approximately $70.9 million and $33.0 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, 2023, we had $278.5 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 $17.3 million remaining as of December 31, 2023, 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 in the 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. For the years ended December 31, 2023, 2022, and 2021, we've 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, 2023 would result in an adjustment to revenue of approximately $25.0 million in 2024.

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 $465.8 million and $419.4 million at December 31, 2023 and 2022, 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, 2023, our developed technology intangible assets have a carrying value of $559.2 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 in-process research and development ("IPR&D"). As a result of the acquisition of Thrive, we recorded an IPR&D asset of $1.25 billion. 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.

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. 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 decreased from 6.2% as of December 31, 2022 to 5.8% as of December 31, 2023, and the fair value of the contingent consideration liability was remeasured from $284.1 million as of December 31, 2022 to $270.1 million as of December 31, 2023. 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 impact the estimated fair value as follows:

Assumption	Unit of Measure Change	Fair Value Impact (In Thousands)
Probability of success	5%	$ 15,000
Projected fiscal year of payment	1 Year	14,900
Present-value factor	1%	14,400

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. We also elected to bypass the qualitative assessment and performed a quantitative assessment for our annual IPR&D assessment and concluded that there were no impairments for the year ended December 31, 2023. 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 privately held companies, 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 $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 recorded an impairment charge of $20.2 million during the year ended December 31, 2021 related to the supply agreement intangible asset acquired as part of the combination with Genomic Health. We utilized the income approach to measure the fair value of the acquired developed technology intangible asset, supply agreement intangible asset, and building leases, 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 in the Notes to Consolidated Financial Statements 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, 2023 and December 31, 2022 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, 2023, we had $50.0 million in outstanding variable rate debt. Based on a hypothetical 100 basis point increase in market interest rates, annual interest expense on variable rate debt as of December 31, 2023 would increase by approximately $0.5 million. If we were to draw down additional amounts under either our Revolving Loan or Securitization Facility, the impact of increases in prevailing market interest rates would be even greater. 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, 2023, we had open foreign currency forward contracts with notional amounts of $39.5 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.

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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, 2023 and 2022, 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, 2023, 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, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023 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, 2023, 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, 2023 was $203.6 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 $1,250 million as of December 31, 2023. 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 performed a quantitative assessment as part of its annual IPR&D impairment analysis in the fourth quarter of 2023 under which it determined that the fair value exceeded the carrying value and no impairment loss was recorded. 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.

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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 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 asset. These procedures also included, among others (i) testing management's process for developing the fair value estimate of the IPR&D 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 21, 2024

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

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

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 605,378	$ 242,493
Marketable securities	172,266	389,564
Accounts receivable, net	203,623	158,043
Inventory	127,475	118,259
Prepaid expenses and other current assets	85,627	73,898
Total current assets	1,194,369	982,257
Long-term assets:		
Property, plant and equipment, net	698,354	684,756
Operating lease right-of-use assets	143,708	167,003
Goodwill	2,367,120	2,346,040
Intangible assets, net	1,890,396	1,956,240
Other long-term assets, net	177,387	90,577
Total assets	$ 6,471,334	$ 6,226,873
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 78,816	$ 74,916
Accrued liabilities	341,683	299,216
Operating lease liabilities, current portion	29,379	28,366
Debt, current portion	50,000	—
Other current liabilities	14,823	10,249
Total current liabilities	514,701	412,747
Long-term liabilities:		
Convertible notes, net	2,314,276	2,186,106
Long-term debt, less current portion	—	50,000
Other long-term liabilities	335,982	352,459
Operating lease liabilities, less current portion	161,070	182,399
Total liabilities	3,326,029	3,183,711
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, 2023 and December 31, 2022	—	—
Common stock, $0.01 par value Authorized—400,000,000 shares issued and outstanding—181,364,180 and 177,925,631 shares at December 31, 2023 and December 31, 2022	1,815	1,780
Additional paid-in capital	6,611,237	6,311,644
Accumulated other comprehensive income (loss)	1,428	(5,236)
Accumulated deficit	(3,469,175)	(3,265,026)
Total stockholders' equity	3,145,305	3,043,162
Total liabilities and stockholders' equity	$ 6,471,334	$ 6,226,873

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

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

	Year Ended December 31,		
	2023	2022	2021
Revenue	$ 2,499,766	$ 2,084,279	$ 1,767,087
Operating expenses:			
Cost of sales (exclusive of amortization of acquired intangible assets)	654,248	574,394	458,757
Research and development	425,882	393,418	385,646
Sales and marketing	727,090	846,011	861,889
General and administrative	893,204	737,304	801,262
Amortization of acquired intangible assets	92,160	97,450	95,001
Impairment of long-lived assets	621	15,969	20,210
Total operating expenses	2,793,205	2,664,546	2,622,765
Other operating income (loss)	78,427	(13,244)	—
Loss from operations	(215,012)	(593,511)	(855,678)
Other income (expense)			
Investment income (loss), net	32,713	(19,425)	31,778
Interest expense	(19,447)	(19,634)	(18,606)
Total other income (expense)	13,266	(39,059)	13,172
Net loss before tax	(201,746)	(632,570)	(842,506)
Income tax benefit (expense)	(2,403)	9,064	246,881
Net loss	$ (204,149)	$ (623,506)	$ (595,625)
Net loss per share—basic and diluted	$ (1.13)	$ (3.54)	$ (3.48)
Weighted average common shares outstanding—basic and diluted	180,144	176,351	171,348

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

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

	Year Ended December 31,		
	2023	2022	2021
Net loss	$ (204,149)	$ (623,506)	$ (595,625)
Other comprehensive loss, before tax:			
Unrealized gain (loss) on available-for-sale investments	5,343	(3,823)	(2,162)
Foreign currency adjustment	1,321	30	23
Comprehensive loss, before tax	(197,485)	(627,299)	(597,764)
Income tax benefit related to items of other comprehensive loss	—	—	170
Comprehensive loss, net of tax	$ (197,485)	$ (627,299)	$ (597,594)

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

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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, January 1, 2021	159,423,410	$ 1,595	$ 4,279,327	$ 526	$ (2,045,895)	$ 2,235,553
Conversion of convertible notes, net of tax	580	—	43	—	—	43
Exercise of common stock options	1,295,104	13	14,424	—	—	14,437
Issuance of common stock to fund the Company's 2020 401(k) match	162,606	2	22,932	—	—	22,934
Compensation expense related to issuance of stock options and restricted stock awards	1,879,169	19	334,004	—	—	334,023
Purchase of employee stock purchase plan shares	331,769	3	23,067	—	—	23,070
Issuance of common stock for business combinations	10,581,429	106	1,355,064	—	—	1,355,170
Net loss	—	—	—	—	(595,625)	(595,625)
Other comprehensive loss	—	—	—	(1,969)	—	(1,969)
Balance, December 31, 2021	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
Compensation expense related to issuance of stock options and restricted stock awards	2,220,510	22	206,801	—	—	206,823
Purchase of employee stock purchase plan shares	668,605	7	25,484	—	—	25,491
Issuance of common stock for business combinations	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
Compensation expense related to issuance of stock options and restricted stock awards	1,801,954	18	231,294	—	—	231,312
Purchase of employee stock purchase plan shares	924,448	10	28,334	—	—	28,344
Replaced restricted stock awards for business combinations	—	—	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

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

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

	Year Ended December 31,		
	2023	2022	2021
Cash flows from operating activities:			
Net loss	$ (204,149)	$ (623,506)	$ (595,625)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation	114,448	100,108	85,345
(Gain) loss on non-marketable and marketable equity investments	(4,098)	21,774	(29,008)
Deferred tax benefit	(955)	(11,901)	(253,169)
Stock-based compensation	231,312	206,823	253,063
Post-combination expense for acceleration of unvested equity	—	—	80,960
Gain on settlement of convertible notes	(10,324)	—	—
Amortization of acquired intangible assets	92,160	97,450	95,001
Asset acquisition IPR&D expense	500	—	85,337
Loss on sale of asset	—	13,244	—
Impairment of long-lived assets	621	15,969	20,210
Gain on contingent consideration from sale of asset	(73,300)	—	—
Remeasurement of contingent consideration liabilities	(18,044)	(56,617)	6,360
Non-cash lease expense	27,891	28,639	25,825
Other	399	10,835	12,356
Changes in assets and liabilities, net of effects of acquisition:			
Accounts receivable, net	(43,416)	61,088	25,150
Inventory, net	(7,690)	(13,231)	(9,221)
Operating lease liabilities	(26,701)	(20,646)	(16,685)
Accounts payable and accrued liabilities	82,750	(52,180)	169,800
Other assets	(11,618)	(84)	(24,672)
Other liabilities	6,333	(1,324)	(33,263)
Net cash provided by (used in) operating activities	156,119	(223,559)	(102,236)
Cash flows from investing activities:			
Purchases of marketable securities	(139,854)	(131,486)	(1,164,050)
Maturities and sales of marketable securities	363,156	453,072	794,322
Purchases of property, plant and equipment	(124,190)	(214,462)	(135,766)
Proceeds from sale of asset	—	25,000	—
Maturities and sales of investments in privately held companies	19,794	—	—
Investments in privately held companies	(16,564)	(42,823)	(18,044)
Business combination, net of cash acquired and issuance costs	(52,413)	(14,686)	(499,730)
Asset acquisitions, net of cash acquired	(500)	—	(58,073)
Other investing activities	250	(549)	(744)
Net cash provided by (used in) investing activities	49,679	74,066	(1,082,085)
Cash flows from financing activities:			
Proceeds from accounts receivable securitization facility	—	50,000	—
Proceeds from exercise of common stock options	3,197	6,524	14,437
Proceeds in connection with the Company's employee stock purchase plan	28,344	25,491	23,070
Payments on construction loan	—	—	(23,749)
Proceeds from issuance of convertible notes	137,976	—	—
Other financing activities	(9,751)	(5,530)	(5,286)
Net cash provided by financing activities	159,766	76,485	8,472
Effects of exchange rate changes on cash and cash equivalents	1,321	30	23
Net increase (decrease) in cash, cash equivalents and restricted cash	366,885	(72,978)	(1,175,826)
Cash, cash equivalents and restricted cash at the beginning of period	242,790	315,768	1,491,594
Cash, cash equivalents and restricted cash at the end of period	$ 609,675	$ 242,790	$ 315,768

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

	Year Ended December 31,		
	2023	2022	2021
Supplemental disclosure of non-cash investing and financing activities:			
Property, plant and equipment acquired but not paid	$ 18,505	$ 15,943	$ 33,177
Business acquisition contingent consideration liability	$ —	$ 4,600	$ 350,348
Supplemental disclosure of cash flow information:			
Interest paid	$ 18,776	$ 11,519	$ 10,735
Reconciliation of cash, cash equivalents and restricted cash:			
Cash and cash equivalents	$ 605,378	$ 242,493	$ 315,471
Restricted cash — included in other long-term assets, net as of December 31, 2023 and 2021, and prepaid expenses and other current assets as of December 31, 2022	4,297	297	297
Total cash, cash equivalents and restricted cash	$ 609,675	$ 242,790	$ 315,768

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. Exact is a leading, global advanced cancer diagnostics company. It has developed some of the most impactful tests in cancer screening and diagnostics, including Cologuard® and Oncotype DX®. Exact is currently working to develop additional tests, with the goal of bringing new, innovative cancer tests to patients throughout the world.

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, 2023 and 2022, the allowance for doubtful accounts recorded was not significant to the Company's consolidated balance sheets. For the years ended December 31, 2023, 2022 and 2021, 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.

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 Privately Held Companies

The Company determines whether its investments in privately held companies 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 privately held companies 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 privately held companies 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, 2023, 2022 and 2021 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, finite-lived intangible assets, and investments in privately held companies, 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)	**2023**	**2022**	**2021**
Shares issuable upon conversion of convertible notes	23,231	20,309	20,309
Shares issuable upon the release of restricted stock awards	6,273	5,255	4,321
Shares issuable upon the release of performance share units	1,598	968	878
Shares issuable upon exercise of stock options	1,286	1,518	2,284
Shares issuable in connection with acquisitions	—	—	45
	32,388	28,050	27,837

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

The Company expenses the costs of media advertising at the time the advertising takes place. The Company expensed approximately $137.9 million, $170.3 million, and $144.0 million of media advertising during the years ended December 31, 2023, 2022, and 2021, 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. The Company calculates its incremental borrowing rates for specific lease terms, used to discount future lease payments, as a function of the United States ("U.S.") Treasury rate and an indicative Moody's rating for operating leases or finance leases.

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.

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, and allocated overhead such as rent, information technology costs, equipment depreciation and utilities. 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 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, 2023, 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 $529.0 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, 2023, 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	**2023**	**2022**	**2021**	**2023**	**2022**	**2021**
Centers for Medicare and Medicaid Services	17%	14%	20%	10%	14%	11%
UnitedHealthcare	12%	12%	11%	10%	9%	8%
State of Wisconsin	—%	3%	8%	—%	5%	9%

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, 2023 and 2022 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, 2023 and 2022.

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In July 2023, the FASB issued Accounting Standards Update ("ASU") No. 2023-03, *Presentation of Financial Statement (Topic 205), Income Statement - Reporting Comprehensive Income (Topic 220), Distinguishing Liabilities from Equity (Topic 480), Equity (Topic 505), and Compensation - Stock Compensation (Topic 718)*. This update amends various Securities and Exchange Commission ("SEC") paragraphs in the Accounting Standards Codification to reflect the issuance of SEC Staff Accounting Bulletin No. 120, among other things. The Company adopted this conforming guidance upon issuance during the third quarter of fiscal year 2023. 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 Accounting Standards Codification to conform with certain 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 November 2023, the FASB issued 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 31, 2023 and interim periods within fiscal years beginning after December 31, 2024. Early adoption is permitted. 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): Improvement 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.

(2) REVENUE

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

	Year Ended December 31,		
(In thousands)	**2023**	**2022**	**2021**
Screening			
Medicare Parts B & C	$ 701,400	$ 545,458	$ 438,646
Commercial	992,244	743,238	569,944
Other	171,057	136,007	53,718
Total Screening	1,864,701	1,424,703	1,062,308
Precision Oncology			
Medicare Parts B & C	$ 188,689	$ 197,327	$ 197,394
Commercial	181,318	177,518	180,177
International	153,277	117,738	109,913
Other	105,826	108,905	74,192
Total Precision Oncology	629,110	601,488	561,676
COVID-19 Testing	$ 5,955	$ 58,088	$ 143,103
Total	$ 2,499,766	$ 2,084,279	$ 1,767,087

Screening revenue primarily includes laboratory service revenue from Cologuard and PreventionGenetics tests while Precision Oncology revenue includes laboratory service revenue from global Oncotype DX and therapy selection tests.

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. The Company recognized revenue from a change in transaction price of $25.2 million and $20.3 million for the years ended December 31, 2023 and 2022, respectively. The Company recorded a downward adjustment to revenue from a change in transaction price of $11.8 million for the year ended December 31, 2021.

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, 2023 and 2022.

Revenue recognized for the year ended December 31, 2023 and 2022, 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, 2023 and 2022:

	December 31,	
(In thousands)	**2023**	**2022**
Cash and cash equivalents		
Cash and money market	$ 530,100	$ 178,168
Cash equivalents	75,278	64,325
Total cash and cash equivalents	605,378	242,493
Marketable securities		
Available-for-sale debt securities	$ 168,425	$ 384,415
Equity securities	3,841	5,149
Total marketable securities	172,266	389,564
Total cash, cash equivalents, and marketable securities	$ 777,644	$ 632,057

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.

Available-for-sale debt securities, including the classification within the consolidated balance sheet at December 31, 2022, consisted of the following:

(In thousands)	Amortized Cost	Gains in AOCI (1)	Losses in AOCI (1)	Estimated Fair Value
Cash equivalents				
Commercial paper	$ 63,021	$ —	$ —	$ 63,021
U.S. government agency securities	1,304	—	—	1,304
Total cash equivalents	64,325	—	—	64,325
Marketable securities				
U.S. government agency securities	$ 228,012	$ —	$ (2,789)	$ 225,223
Corporate bonds	116,318	20	(1,667)	114,671
Asset backed securities	45,374	2	(855)	44,521
Total marketable securities	389,704	22	(5,311)	384,415
Total available-for-sale debt securities	$ 454,029	$ 22	$ (5,311)	$ 448,740

(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, 2023:

	Due one year or less		Due after one year through five years	
(In thousands)	Cost	Fair Value	Cost	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				
Corporate bonds	$ 33,518	$ 33,474	$ 22,194	$ 22,354
U.S. government agency securities	33,407	33,403	23,187	23,313
Commercial paper	20,984	20,984	—	—
Asset backed securities	—	—	35,081	34,897
Total marketable securities	87,909	87,861	80,462	80,564
Total available-for-sale securities	$ 163,187	$ 163,139	$ 80,462	$ 80,564

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 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, 2022, 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	$ 37,458	$ (337)	$ 187,766	$ (2,452)	$ 225,224	$ (2,789)
Corporate bonds	35,055	(575)	73,702	(1,092)	108,757	(1,667)
Asset backed securities	27,984	(735)	15,536	(120)	43,520	(855)
Total available-for-sale securities	$ 100,497	$ (1,647)	$ 277,004	$ (3,664)	$ 377,501	$ (5,311)

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, 2023 and 2022 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, 2023, 2022, and 2021.

(4) INVENTORY

Inventory consisted of the following:

	December 31,	
(In thousands)	2023	2022
Raw materials	$ 58,593	$ 61,207
Semi-finished and finished goods	68,882	57,052
Total inventory	$ 127,475	$ 118,259

(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, 2023	December 31, 2022
Property, plant and equipment			
Land	n/a	$ 4,716	$ 4,716
Leasehold and building improvements	(1)	214,562	200,588
Land improvements	15 years	6,729	6,417
Buildings	30 - 40 years	290,777	288,941
Computer equipment and computer software	3 years	168,131	142,896
Machinery and equipment	3 - 10 years	290,294	246,344
Furniture and fixtures	3 - 10 years	35,756	34,047
Assets under construction	n/a	104,592	68,398
Property, plant and equipment, at cost		1,115,557	992,347
Accumulated depreciation		(417,203)	(307,591)
Property, plant and equipment, net		$ 698,354	$ 684,756

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

At December 31, 2023, the Company had $104.6 million of assets under construction, which consisted of $53.2 million in machinery and equipment, $29.1 million of capitalized costs related to software projects, $15.7 million in leasehold and building improvements, and $6.6 million related to buildings. 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, 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

The following table summarizes the net-book-value and estimated remaining life of the Company's intangible assets as of December 31, 2022:

(In thousands)	Weighted Average Remaining Life (Years)	Cost	Accumulated Amortization	Net Balance at December 31, 2022
Finite-lived intangible assets				
Trade name	12.5	$ 104,000	$ (20,653)	$ 83,347
Customer relationships	8.0	4,000	(444)	3,556
Patents and licenses	4.2	11,542	(8,152)	3,390
Acquired developed technology (1)	7.8	861,474	(245,527)	615,947
Total finite-lived intangible assets		981,016	(274,776)	706,240
In-process research and development	n/a	1,250,000	—	1,250,000
Total intangible assets		$ 2,231,016	$ (274,776)	$ 1,956,240

(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"), whose functional currency is also its local currency. Intangible asset balances are translated into U.S. dollars using exchange rates in effect at period end, and adjustments related to foreign currency translation are included in other comprehensive income.

As of December 31, 2023, 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)	
2024	$ 92,908
2025	91,860
2026	90,800
2027	90,800
2028	90,800
Thereafter	183,228
Total	$ 640,396

There were no impairment losses recorded on finite-lived intangible assets during the year ended December 31, 2023.

The Company recorded an IPR&D asset of $1.25 billion related to a project associated with the development of a U.S. Food and Drug Administration ("FDA") approved, blood-based, multi-cancer early detection ("MCED") test as part of the acquisition of Thrive Earlier Detection Corporation ("Thrive") in January 2021. The Company performed a quantitative assessment as part of its annual IPR&D impairment analysis in the fourth quarter of 2023 under which it determined that the fair value exceeded the carrying value and no impairment loss was recorded.

On August 2, 2022, the Company completed a sale of the developed technology intangible asset related to the Oncotype DX Genomic Prostate Score 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 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 assets in the Company's consolidated statement of operations.

Goodwill

The change in the carrying amount of goodwill for the years ended December 31, 2023 and 2022 is as follows:

(In thousands)	
Balance, January 1, 2022	$ 2,335,172
OmicEra acquisition	10,809
PreventionGenetics acquisition adjustment	(58)
Effects of changes in foreign currency exchange rates (1)	117
Balance, December 31, 2022	2,346,040
Resolution Bioscience acquisition (2)	20,692
Effects of changes in foreign currency exchange rates (1)	388
Balance December 31, 2023	$ 2,367,120

(1) Represents the impact of foreign currency translation related to the goodwill acquired as a result of the acquisition of OmicEra. Goodwill balances are translated into U.S. dollars using exchange rates in effect at period end, and adjustments related to foreign currency translation are included in other comprehensive income.

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

There were no impairment losses recorded on goodwill for the years ended December 31, 2023, 2022, and 2021.

(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, 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)

The following table presents the Company's fair value measurements as of December 31, 2022 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, 2022	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	$ 178,168	$ 178,168	$ —	$ —
Commercial paper	63,021	—	63,021	—
U.S. government agency securities	1,304	—	1,304	—
Restricted cash (1)	297	297	—	—
Marketable securities				
U.S. government agency securities	$ 225,223	$ —	$ 225,223	$ —
Corporate bonds	114,671	—	114,671	—
Asset backed securities	44,521	—	44,521	—
Equity securities (2)	5,149	5,149	—	—
Non-marketable securities	$ 10,065	$ —	$ —	$ 10,065
Liabilities				
Contingent consideration	$ (306,927)	$ —	$ —	$ (306,927)
Total	$ 335,492	$ 183,614	$ 448,740	$ (296,862)

(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.

(2) Inclusive of the American Depository Shares of MDxHealth received as part of the sale of the Company's GPS test, which are restricted to a holding period of six months after the date of the sale of August 2, 2022. The shares had a fair value of $4.6 million as of December 31, 2022.

There have been no changes in valuation techniques or transfers between fair value measurement levels during the year ended December 31, 2023. 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
Beginning balance, January 1, 2022	$ 3,090
Purchase of non-marketable securities	10,000
Change in fair value	1,038
Conversion of non-marketable securities	(4,063)
Balance, December 31, 2022	10,065
Purchases of non-marketable securities	6,957
Changes in fair value	1,127
Settlement of non-marketable securities	(10,499)
Ending balance, December 31, 2023	$ 7,650

Contingent Consideration Liabilities

The fair value of the contingent consideration liabilities was $288.7 million and $306.9 million as of December 31, 2023 and 2022, respectively, which was included in other long-term liabilities in the consolidated balance sheets.

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

(In thousands)	Contingent Consideration
Balance, January 1, 2022 (1)	$ 359,021
Purchase price contingent consideration (2)	4,600
Changes in fair value	(56,617)
Payments	(77)
Balance, December 31, 2022	306,927
Changes in fair value	(18,044)
Payments	(226)
Balance, December 31, 2023	$ 288,657

(1) The change in fair value of the contingent consideration liability during the year ended December 31, 2021 was not significant.

(2) 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.

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 $288.7 million and $306.8 million as of December 31, 2023 and 2022, respectively. The Company evaluates the fair value of the expected contingent consideration and the corresponding 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 expected 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 89% and 91% as of December 31, 2023 and 2022, respectively, and a weighted average present-value factor of 5.8% and 6.2% as of December 31, 2023 and 2022, respectively. The projected fiscal year of payment range is from 2025 to 2030. Unobservable inputs were weighted by the relative fair value of the contingent consideration liability.

The fair value of the contingent consideration liability related to certain revenue milestones associated with the Biomatrica, Inc. acquisition was not significant as of December 31, 2022, and the revenue milestone period ended September 30, 2023. 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 Investments

Non-marketable equity securities without readily determinable fair values, which are classified as a component of other long-term assets, net, had the following aggregate carrying amounts and downward and upward adjustments as of and for the years ended December 31, 2023 and 2022:

	Year ended December 31,	
(In thousands)	**2023**	**2022**
Upward adjustments (1)	$ 4,314	$ 779
Downward adjustments and impairments (2)	(4,250)	(10,821)
Aggregate carrying value	45,968	39,842

(1) Cumulative upward adjustments on non-marketable equity securities held as of December 31, 2023 was $5.1 million. The upward adjustments recorded were due to increases in the valuation of the underlying investee as determined by the value of the follow-on rounds of investment by other third-party investors. There were no upward adjustments recorded during the year ended December 31, 2021.

(2) Cumulative downward adjustments and impairments on non-marketable equity securities held as of December 31, 2023 was $15.1 million. The adjustments recorded were due to adverse changes in the market and the investees' ability to continue as a going concern. There were no downward adjustments recorded during the year ended December 31, 2021.

The Company recorded a realized gain of $5.4 million, a realized loss of $10.0 million, and a realized gain of $30.5 million on non-marketable securities for the years ended December 31, 2023, 2022, and 2021, respectively.

The Company has committed capital to venture capital investment funds (the "Funds") of $17.5 million, of which $12.1 million remained callable through 2033 as of December 31, 2023. The aggregate carrying amount of the Funds, which are classified as a component of other long-term assets, net in the Company's consolidated balance sheets, were $5.2 million and $3.9 million as of December 31, 2023 and 2022, respectively. Gains and losses recorded on the Company's investments in the Funds were not significant for the years ended December 31, 2023, 2022, and 2021.

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, 2023 and 2022, the Company had open foreign currency forward contracts with notional amounts of $39.5 million and $22.3 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, 2023 and 2022, and there were no gains or losses recorded to adjust the fair value of the open foreign currency contract held as of December 31, 2023. 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, 2023 and 2022.

(8) ACCRUED LIABILITIES

Accrued liabilities at December 31, 2023 and 2022 consisted of the following:

	December 31,	
(In thousands)	2023	2022
Compensation	$ 247,619	$ 201,252
Professional fees	45,405	43,715
Other	17,274	22,329
Research and trial related expenses	14,219	17,455
Assets under construction	11,210	10,462
Licenses	5,956	4,003
Total	$ 341,683	$ 299,216

(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 provides 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 fluctuates over time based on the total amount of eligible customer accounts receivable generated by the Company during the normal course of operations. The Securitization Facility requires the Company to maintain minimum borrowings under the facility of $50.0 million. The debt issuance costs incurred related to the Securitization Facility were not significant and are being 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 are 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 sell all of their right, title and interest in their accounts receivables to Exact Receivables. The receivables are used to collateralize borrowings made under the Securitization Facility. The Company retains the responsibility of servicing the accounts receivable balances pledged as collateral under the Securitization Facility and provides a performance guaranty.

As of December 31, 2023, the eligible borrowing base under the Securitization Facility was $108.5 million of which the Company elected to collateralize $50.0 million. As of December 31, 2023 and December 31, 2022, the Company had an outstanding balance of $50.0 million, which is included in debt, current portion and long-term debt, less current portion, respectively, on the Company's consolidated balance sheets. The outstanding balance accrues interest at a rate equal to a daily secured overnight financing rate ("SOFR") rate plus a SOFR adjustment and an applicable margin. The interest rate was 6.89% at December 31, 2023.

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. There were no other amendments to the Revolver.

The Company has agreed to various financial covenants under the Revolving Loan Agreement, and as of December 31, 2023, the Company is 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, 2023 and December 31, 2022, respectively. As of December 31, 2023, the Company has not drawn funds from, nor are any amounts outstanding under, the Revolving Loan Agreement.

Construction Loan Agreement

During December 2017, the Company entered into a loan agreement with Fifth Third Bank (the "Construction Loan Agreement"), which provided the Company with a non-revolving construction loan (the "Construction Loan") of $25.6 million- with a maturity date of December 10, 2022. The Company used the Construction Loan proceeds to finance the construction of an additional clinical laboratory and related facilities in Madison, Wisconsin. The Construction Loan was collateralized by the additional clinical laboratory and related facilities.

The Construction Loan Agreement bore interest at a rate equal to the sum of the 1-month LIBOR rate plus 2.25%. The interest incurred on the Construction Loan was not significant and was capitalized to the construction project. The Company also incurred minimal debt issuance costs which were recorded as a direct deduction from the liability, and amortized over the life of the Construction Loan.

As part of the Revolving Loan Agreement discussed above, the Company agreed to repay in full all outstanding debt owed to Fifth Third Bank under the Construction Loan Agreement, and as of December 31, 2021, the remaining outstanding balance had been fully repaid in connection with the termination of the Construction Loan Agreement. Any unamortized issuance costs at the time or repayment were recorded as a loss.

(10) CONVERTIBLE NOTES

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

Convertible note obligations included in the consolidated balance sheet consisted of the following as of December 31, 2022:

				Fair Value (1)	
(In thousands)	Principal Amount	Unamortized Debt Discount and Issuance Costs	Net Carrying Amount	Amount	Leveling
2028 Convertible Notes - 0.375%	$ 1,150,000	$ (15,775)	$ 1,134,225	$ 908,500	2
2027 Convertible Notes - 0.375%	747,500	(9,445)	738,055	612,950	2
2025 Convertible Notes - 1.000%	315,005	(1,179)	313,826	326,808	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.

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 (collectively, the “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, which is reflected in interest expense in the Company's consolidated statement of operations. The loss represents the difference between (i) the fair value of the consideration transferred and (ii) the carrying value of the debt at the time of repurchase.

In February 2020, the Company issued and sold $1.15 billion in aggregate principal amount of 0.375% Convertible Notes (the "2028 Notes" and, collectively with the 2025 Notes and the 2027 Notes, the "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, which is recorded in interest expense in the Company's consolidated statement of operations. The loss represents the difference between (i) the fair value of the consideration transferred and (ii) the carrying value of the debt at the time of repurchase.

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. The gain represents the difference between (i) the fair value of the consideration transferred and (ii) the carrying value of the debt at the time of exchange.

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 loss represents the difference between (i) the fair value of the consideration transferred and (ii) the carrying value of the debt at the time of exchange.

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.

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 convert such Notes at any time. 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.

It is the Company's intent and policy to settle all conversions through combination settlement. The initial conversion rate is 13.26, 8.96, 8.21, and 12.37 shares of common stock per $1,000 principal amount for the 2025 Notes, 2027 Notes, 2028 Notes, and 2030 Notes, respectively, which is equivalent to an initial conversion price of approximately $75.43, $111.66, $121.84, and $80.83 per share of the Company's common stock for the 2025 Notes, 2027 Notes, 2028 Notes, and 2030 Notes, respectively. The 2025 Notes, 2027 Notes, 2028 Notes, and 2030 Notes are potentially convertible into up to 3.3 million, 5.0 million, 7.8 million, and 7.1 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 $73.98 on December 31, 2023, 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)	
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)	2023	2022	2021
Debt issuance costs amortization	$ 5,350	$ 5,727	$ 5,727
Debt discount amortization	106	147	147
Gain on settlement of convertible notes	(10,324)	—	—
Coupon interest expense	18,072	10,266	10,266
Total interest expense on convertible notes	$ 13,204	$ 16,140	$ 16,140

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

	Year Ended December 31,		
	2023	2022	2021
2030 Convertible Notes	2.09 %	— %	— %
2028 Convertible Notes	0.63 %	0.64 %	0.64 %
2027 Convertible Notes	0.67 %	0.68 %	0.68 %
2025 Convertible Notes	1.17 %	1.18 %	1.18 %

The remaining period over which the unamortized debt discount will be recognized as non-cash interest expense is 1.04 years, 3.21 years, 4.17 years, and 6.17 years for the 2025 Notes, 2027 Notes, 2028 Notes, and 2030 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 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, 2023, 2022, and 2021, 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 proprietary data 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 if net sales of a licensed product using JHU proprietary data reach specified levels. The Company will record the sales-based royalties and sales-based milestones once achievement is deemed probable. The Company has not incurred charges related to the achievement of any sales-based royalties or sales-based milestones as of December 31, 2023.

Targeted Digital Sequencing ("TARDIS") License Agreement

In January 2021, the Company entered into an exclusive, worldwide license to the proprietary TARDIS technology, which the Company intends to develop and commercialize as a molecular residual disease ("MRD") test, from The Translational Genomics Research Institute ("TGen"), an affiliate of City of Hope. Under the agreement, the Company acquired a royalty-free, worldwide exclusive license to proprietary TARDIS patents and know-how. The Company accounted for this transaction as an asset acquisition. In connection with the asset acquisition, the Company paid upfront fair value consideration of $52.3 million comprised of $25.0 million in cash and issuance of 191,336 shares of common stock valued at $27.3 million based on the average of the high and low market price of the Company's shares on the acquisition date. In addition, the Company is obligated to make milestone payments to TGen of up to $45.0 million in sales-based milestone payments upon cumulative net sales related to MRD detection and/or treatment reaching specified levels. These payments are contingent upon achievement of these cumulative revenues on or before December 31, 2030. The upfront consideration was recorded to research and development expense in the consolidated statement of operations immediately after acquisition as the asset was deemed to be incomplete and had no alternative future use at the time of acquisition. The Company will record the sales milestones once achievement is deemed probable. No acquisition related costs were incurred in this asset acquisition during the year ended December 31, 2021.

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 any charges related to the achievement of development milestones or sales milestones as of December 31, 2023.

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.

(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, and $81.3 million for the service fee during the years ended December 31, 2022 and 2021, respectively. The Company incurred charges of $85.8 million, and $121.0 million for promotion, sales and marketing services performed by Pfizer on behalf of the Company during the years ended December 31, 2022 and 2021, respectively. 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 year ended December 31, 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, 2023, 2022 and 2021 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
PreventionGenetics	December 2021	1,070,410	84,252
Ashion	April 2021	125,444	16,224
Thrive	January 2021	9,323,266	1,191,420
TARDIS license	January 2021	191,335	27,263

Changes in Accumulated Other Comprehensive Income (Loss)

The amount recognized in AOCI for the years ended December 31, 2023, 2022 and 2021 were as follows:

(In thousands)	Cumulative Translation Adjustment	Unrealized Gain (Loss) on Securities (1)	AOCI
Balance at January 1, 2021	$ —	$ 526	$ 526
Other comprehensive income (loss) before reclassifications	23	(1,648)	(1,625)
Amounts reclassified from accumulated other comprehensive income (loss)	—	(514)	(514)
Net current period change in accumulated other comprehensive loss	23	(2,162)	(2,139)
Income tax benefit related to items of other comprehensive loss	—	170	170
Balance at December 31, 2021	$ 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 income (loss)	1,321	5,343	6,664
Balance at December 31, 2023	$ 1,374	$ 54	$ 1,428

(1) There was no tax impact from the amounts recognized in AOCI for the years ended December 31, 2023 and 2022.

Amounts reclassified from AOCI for the years ended December 31, 2023, 2022 and 2021 were as follows:

		Year Ended December 31,		
Details about AOCI Components (In thousands)	Affected Line Item in the Statements of Operations	2023	2022	2021
Change in value of available-for-sale investments				
Sales and maturities of available-for-sale investments	Investment income (loss)	$ 3,927	$ 226	$ (514)
Total reclassifications		$ 3,927	$ 226	$ (514)

(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 2023: 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, 2023, options to purchase 404,833 shares were outstanding under the 2019 Stock Plan and 7,867,224 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, 2023, there were 16,046,161 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, 2023, options to purchase 881,340 shares were outstanding under the 2010 Stock Plan and 3,340 shares of restricted stock and restricted stock units were outstanding. At December 31, 2023, 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, 2023, there were 1,834,193 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, 2023, there were 3,965,807 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 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, 2023, 2022, and 2021 is as follows:

(In thousands)	Year Ended December 31, 2023	2022	2021
Cost of sales	$ 20,761	$ 19,218	$ 16,835
Research and development	41,242	33,825	49,723
Sales and marketing	65,552	62,568	55,716
General and administrative	103,757	91,212	216,952
Total stock-based compensation	$ 231,312	$ 206,823	$ 339,226

As of December 31, 2023, there was approximately $354.8 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 2.42 years.

In connection with the acquisition of Thrive, the Company accelerated the vesting of shares of previously unvested stock options and restricted stock units for employees with qualifying termination events. During the year ended December 31, 2021, the Company accelerated 139,096 shares of previously unvested stock options and 58,171 shares of previously unvested restricted stock awards and restricted stock units and recorded $19.0 million of non-cash stock-based compensation for the accelerated awards. As further discussed in Note 18, the Company also recorded $86.2 million in stock-based compensation related to accelerated vesting of awards held by Thrive employees in connection with the acquisition.

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, 2023, 2022 and 2021.

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, 2023	1,517,876	$ 44.82	4.7	
Exercised	(194,629)	16.44		
Forfeited	(37,074)	95.02		
Outstanding, December 31, 2023	1,286,173	$ 47.67	3.8	$ 42,878
Vested and expected to vest, December 31, 2023	1,286,173	$ 47.67	3.8	$ 42,878
Exercisable, December 31, 2023	1,228,594	$ 45.32	3.7	$ 42,878

(1) The total intrinsic value of options exercised during the years ended December 31, 2023, 2022, and 2021 was $11.7 million, $36.4 million, and $155.8 million, respectively, determined as of the date of exercise.

The Company received approximately $3.2 million, $6.5 million, and $14.4 million from stock option exercises during the years ended December 31, 2023, 2022 and 2021, respectively.

Restricted Stock and Restricted Stock Units

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

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

	Restricted Shares	Weighted Average Grant Date Fair Value (1)
Outstanding, January 1, 2023	5,254,709	$ 85.87
Granted	3,510,373	62.36
Released (2)	(1,797,915)	88.28
Forfeited	(694,404)	73.54
Outstanding, December 31, 2023	6,272,763	$ 73.39

(1) The weighted average grant date fair value of the restricted stock units granted during the years ended December 31, 2022 and 2021 was $68.18 and $129.16, respectively.

(2) The fair value of restricted stock units vested and converted to shares of the Company's common stock was $158.2 million, $117.6 million, and $219.4 million for the years ended December 31, 2023, 2022, and 2021, 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 performance share unit activity is as follows:

	Performance Share Units (1)	Weighted Average Grant Date Fair Value (2)
Outstanding, January 1, 2023	967,846	$ 102.58
Granted	782,966	80.50
Released (3)	(12,284)	78.32
Forfeited	(140,727)	93.73
Outstanding, December 31, 2023	1,597,801	$ 92.73

(1) The performance share units 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 performance share units as of December 31, 2023 was 772,906.

(2) The weighted average grant date fair value of the performance share units granted during the years ended December 31, 2022 and 2021 was $89.43 and $138.09, respectively.

(3) The fair value of performance share units vested and converted to shares of the Company's common stock was $1.0 million and $27.2 million for the years ended December 31, 2023 and 2022, respectively. There were no performance share units vested and converted to shares of the Company's common stock during the year ended December 31, 2021.

Employee Stock Purchase Plan ("ESPP")

A summary of ESPP activity is as follows:

(in thousands, except share and per share amounts)	Year Ended December 31, 2023	2022	2021
Shares issued under the 2010 Purchase Plan	924,448	668,605	331,769
Cash received under the 2010 Purchase Plan	$ 28,344	$ 25,491	$ 23,070
Weighted average fair value per share of stock purchase rights granted during the period	$ 16.32	$ 17.52	$ 34.93

The 924,448 shares issued during the year ended December 31, 2023 were as follows:

Offering period ended	Number of Shares	Weighted Average price per Share
April 30, 2023	544,453	$ 30.02
October 31, 2023	379,995	$ 31.57

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

	Year Ended December 31, 2023	2022	2021
Risk-free interest rates	4.68% - 4.71%	1.49% - 4.71%	0.04% - 0.16%
Expected term (in years)	1.25	0.5 - 2	0.5 - 2
Expected volatility	63.13% - 67.30%	50.94% - 63.13%	43.00% - 68.51%
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, 2023, as follows:

Shares reserved for issuance	
2019 Stock Plan	16,046,161
2010 Purchase Plan	1,834,193
	17,880,354

(15) COMMITMENTS AND CONTINGENCIES

Leases

The components of lease expense were as follows:

(In thousands)	Year Ended December 31, 2023	2022	2021
Finance lease cost			
Amortization of right-of-use assets	$ 3,845	$ 4,612	$ 5,731
Interest on lease liabilities	800	808	1,018
Operating lease cost	36,576	36,291	31,730
Short-term lease cost	750	476	628
Variable lease cost	8,449	7,985	5,212
Total lease Cost	$ 50,420	$ 50,172	$ 44,319

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

(In thousands)	Year Ended December 31, 2023	2022	2021
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows from operating leases	$ 39,301	$ 33,448	$ 27,461
Operating cash flows from finance leases	783	699	938
Finance cash flows from finance leases	3,569	4,345	5,290
Non-cash investing and financing activities:			
Right-of-use assets obtained in exchange for new operating lease liabilities (1)	4,986	24,572	74,369
Right-of-use assets obtained in exchange for new finance lease liabilities	5,443	11,276	5,460
Weighted-average remaining lease term - operating leases (in years)	6.87	7.43	8.33
Weighted-average remaining lease term - finance leases (in years)	2.80	3.27	2.95
Weighted-average discount rate - operating leases	6.59 %	6.37 %	6.11 %
Weighted-average discount rate - finance leases	7.43 %	6.60 %	5.36 %

(1) This includes an insignificant amount of right-of-use assets acquired as part of the business combinations described in Note 18 for the years ended December 31, 2023 and 2022, and $39.6 million for the year ended December 31, 2021.

As of December 31, 2023 and 2022, the Company’s right-of-use assets from operating leases are $143.7 million and $167.0 million, respectively, which are reported in operating lease right-of-use assets in the Company’s consolidated balance sheets. As of December 31, 2023, the Company has 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. As of December 31, 2022, the Company had outstanding operating lease obligations of $210.8 million, of which $28.4 million is reported in operating lease liabilities, current portion and $182.4 million is reported in operating lease liabilities, less current portion in the Company’s consolidated balance sheets.

As of December 31, 2023 and 2022, the Company's right-of-use assets from finance leases are $11.3 million and $10.2 million, respectively, which are reported in other long-term assets, net in the Company's consolidated balance sheets. As of December 31, 2023, the Company has 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. As of December 31, 2022, the Company had outstanding finance lease obligations of $10.6 million, of which $3.2 million is reported in other current liabilities and $7.4 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, 2023 were as follows:

(In thousands)	
2024	$ 39,476
2025	36,660
2026	34,851
2027	34,226
2028	27,901
Thereafter	66,634
Total minimum lease payments	239,748
Imputed interest	(49,299)
Total	$ 190,449

Maturities of finance lease liabilities on an annual basis as of December 31, 2023 were as follows (amounts in thousands):

(In thousands)	
2024	$ 5,044
2025	4,552
2026	2,797
2027	827
2028	—
Thereafter	—
Total minimum lease payments	13,220
Imputed interest	(1,279)
Total	$ 11,941

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.

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, 2023, 2022, and 2021 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 $40.6 million, $36.5 million, and $30.0 million, respectively, in the statements of operations for the years ended December 31, 2023, 2022, and 2021.

(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 $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 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 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, 2023, the Company has earned $11.0 million of the refundable tax credits under the Amended WEDC Agreement. The unpaid portion is $9.3 million, of which $3.8 million is reported in prepaid expenses and other current assets and $5.5 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, 2023, 2022, and 2021, 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	$ 14,663
Developed technology	26,000
Total identifiable assets acquired	40,663
Net operating liabilities	(7,152)
Net identifiable assets acquired	33,511
Goodwill	20,691
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 total purchase price allocation is preliminary and based upon estimates and assumptions that are subject to change within the measurement period as additional information for the estimates is obtained. The measurement period remains open pending the completion of valuation procedures related to the acquired assets and assumed liabilities, including in connection with the developed technology intangible asset.

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 requires 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. 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 are described in Note 7.

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	$	2,586
Developed technology		10,000
Total identifiable assets acquired		12,586
Net operating liabilities		(3,987)
Net identifiable assets acquired		8,599
Goodwill		10,809
Net assets acquired	$	19,408

The Company recorded $10.0 million of identifiable intangible assets related to the developed technology associated with OmicEra's proteome analysis platform. Developed technology represents purchased technology that had reached technological feasibility and for which OmicEra had substantially completed development as of the date of acquisition. The fair value of the developed technology has been determined using the income approach multi-period excess earnings method, which involves significant unobservable inputs (Level 3 inputs). These inputs include projected sales, margin, obsolescence factor, required rate of return, and tax rate. Cash flows were discounted to their present value as of the closing date. The developed technology intangible asset is amortized on a straight-line basis over its estimated useful life of 16 years.

The calculation of the excess 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, the potential to enhance the capabilities of current and future products, and expected research and development synergies. The total goodwill related to this acquisition is deductible for tax purposes.

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.

PreventionGenetics, LLC

On December 31, 2021, the Company completed the acquisition (the "PreventionGenetics Acquisition") of all of the outstanding equity interests of PreventionGenetics, LLC. The PreventionGenetics Acquisition provided the Company a CLIA certified and College of American Pathologist ("CAP") accredited sequencing lab based in Marshfield, Wisconsin. PreventionGenetics provides more than 5,000 predefined genetic tests for nearly all clinically relevant genes, additional custom panels, and comprehensive germline, whole exome ("PGxome®"), and whole genome ("PGnome®") sequencing tests. The Company has included the financial results of PreventionGenetics in the consolidated financial statements from the date of the acquisition.

The acquisition date fair value of the consideration transferred for PreventionGenetics was approximately $185.4 million, which consisted of the following:

(In thousands)		
Cash	$	101,129
Common stock issued		84,252
Total purchase price	$	185,381

The fair value of the 1,070,410 common shares issued as part of 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 $78.71.

Of the total $101.1 million of consideration settled through the payment of cash, $85.8 million was paid as of December 31, 2021. The remaining $15.3 million represented withheld cash consideration used to cover working capital adjustments or seller claims that arose following the completion of the acquisition. The withheld cash consideration was settled during the year ended December 31, 2022, and there is no remaining liability on the consolidated balance sheet.

Acquisition-related costs were not significant and were recorded in 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.

Ashion Analytics, LLC

On April 14, 2021, the Company completed the acquisition ("Ashion Acquisition") of all of the outstanding equity interests of Ashion Analytics, LLC from PMed Management, LLC ("PMed"), which is a subsidiary of The Translational Genomics Research Institute. The Ashion Acquisition provided the Company a CLIA-certified and CAP-accredited sequencing lab based in Phoenix, Arizona. Ashion developed GEM ExTra®, a comprehensive genomic cancer test, and provides access to whole exome, matched germline, and transcriptome sequencing capabilities. The Company has included the financial results of Ashion in the consolidated financial statements from the date of the acquisition.

The acquisition date fair value of the consideration transferred for Ashion was approximately $110.0 million, which consisted of the following:

(In thousands)		
Cash	$	74,775
Common stock issued		16,224
Contingent consideration		19,000
Total purchase price	$	109,999

The fair value of the 125,444 common shares issued as part of 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 $129.33.

The contingent consideration arrangement requires the Company to pay $20.0 million of additional cash consideration to PMed upon the Company's commercial launch, on or before the tenth anniversary of the Ashion Acquisition, of a test for MRD detection and/or treatment (the "Commercial Launch Milestone"). The fair value of the Commercial Launch Milestone at the acquisition date was $19.0 million. The contingent consideration arrangement also requires the Company to pay $30.0 million of additional cash upon the Company's achievement, on or before the fifth anniversary of the Ashion Acquisition, of cumulative revenues from MRD products of $500.0 million (the "MRD Product Revenue Milestone"). No value was ascribed to the MRD Product Revenue Milestone based on probability assessments as of the acquisition date. The fair value of the Commercial Launch Milestone and MRD Product Revenue Milestone 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 are described in Note 7.

Acquisition-related costs were not significant and were recorded in 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.

Thrive Earlier Detection Corporation

On January 5, 2021, the Company completed the acquisition ("Thrive Merger") of all of the outstanding capital stock of Thrive Earlier Detection Corporation. Thrive, headquartered in Cambridge, Massachusetts, is a healthcare company dedicated to incorporating earlier cancer detection into routine medical care. The Company expects that combining Thrive's early-stage MCED test with the Company's scientific platform, clinical organization, and commercial infrastructure will bring an accurate blood-based, MCED test to patients faster. The Company has included the financial results of Thrive in the consolidated financial statements from the date of the acquisition.

The acquisition date fair value of the consideration transferred for Thrive was approximately $2.19 billion, which consisted of the following:

(In thousands)		
Common stock issued	$	1,175,431
Cash		584,996
Contingent consideration		331,348
Fair value of replaced equity awards		52,245
Previously held equity investment fair value		43,034
Total purchase price	$	2,187,054

The Company issued 9,323,266 common shares that had a fair value of $1.19 billion based on the average of the high and low market price of the Company's shares on the acquisition date, which was $127.79. Of the total consideration for common stock issued, $1.18 billion was allocated to the purchase consideration and $16.0 million was recorded as compensation within general and administrative expenses in the consolidated statement of operations on the acquisition date due to accelerated vesting of legacy Thrive restricted stock awards ("RSA") and RSU awards in connection with the acquisition.

The Company paid $590.2 million in cash on the acquisition date. Of the total consideration for cash, $585.0 million was allocated to the purchase consideration and $5.2 million was recorded as compensation within general and administrative expenses on the acquisition date due to accelerated vesting of legacy Thrive RSU and RSAs that were cash-settled in connection with the acquisition.

The contingent consideration arrangement requires the Company to pay up to $450.0 million of additional cash consideration to Thrive's former shareholders upon the achievement of two discrete events, FDA approval and CMS coverage, for $150.0 million and up to $300.0 million, respectively. The fair value of the contingent consideration arrangement at the acquisition date was $352.0 million. 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 are described in Note 7. Of the total fair value of the contingent consideration, $331.3 million was allocated to the consideration transferred, $6.4 million was allocated to the Company's previous ownership interest in Thrive, and $14.3 million was deemed compensatory as participation is dependent on replaced unvested equity awards vesting which requires future service. Compensation expense related to the milestones could be up to $18.2 million undiscounted and will be recognized in the future once probable and payable.

The Company replaced unvested stock options, RSUs, and RSAs and vested stock options with an acquisition-date fair value of $197.0 million. Of the total consideration for replaced equity awards, $52.2 million was allocated to the consideration transferred and $144.8 million was deemed compensatory as it was attributable to post acquisition vesting. Of the total compensation related to replaced awards, $65.0 million was expensed on the acquisition date due to accelerated vesting of stock options in connection with the acquisition and $79.8 million relates to future services and will be expensed over the remaining service periods of the unvested stock options, RSUs, and RSAs on a straight-line basis. Including expense recognized for accelerated vesting of RSUs and RSAs described above, total expected stock-based compensation expense is $166.0 million, of which $86.2 million was recognized immediately to general and administrative expenses in the consolidated statement of operations due to accelerated vesting.

The fair value of the stock options assumed by the Company was determined using the Black-Scholes option pricing model. The fair value of the RSA and RSUs assumed by the Company was determined based on the average of the high and low market price of the Company's shares on the acquisition date. The share conversion ratio of 0.06216 was applied to convert Thrive's outstanding equity awards for Thrive's common stock into equity awards for shares of the Company's common stock.

The fair value of options assumed were based on the assumptions in the following table:

Option Plan Shares Assumed	
Risk-free interest rates	0.11% - 0.12%
Expected term (in years)	1.26 - 1.57
Expected volatility	65.54% - 71.00%
Dividend yield	0%
Weighted average fair value per share of options assumed	$109.74 - $124.89

The Company previously held a preferred stock investment of $12.5 million in Thrive and recognized a gain of approximately $30.5 million on the transaction within investment income (expense), net on the Company's consolidated statement of operations, which represented the adjustment of the Company's historical investment to the acquisition date fair value. The fair value of the Company's previous ownership in Thrive was determined based on the pro-rata share payout applied to the Company's interest combined with the fair value of the Company's share of the contingent consideration arrangement, as discussed above.

The net loss before tax of Thrive included in the Company's consolidated statement of operations from the acquisition date of January 5, 2021 to December 31, 2022 was $255.0 million.

The following unaudited pro forma financial information summarizes the combined results of operations for the Company and Thrive, as though the companies were combined as of the beginning of January 1, 2020.

(In thousands)	Year Ended December 31, 2021	Year Ended December 31, 2020
Total revenues	$ 2,084,279	$ 1,767,087
Net loss before tax	(761,337)	(1,014,352)

The unaudited pro forma financial information for all periods presented above has been calculated after adjusting the results of Thrive to reflect the business combination accounting effects resulting from this acquisition. The Company incurred $86.2 million of stock-based compensation expense related to accelerated vesting in connection with the acquisition, $13.5 million of stock-based compensation expense related to accelerated vesting for employees with qualifying termination events, and $10.3 million of transaction costs incurred to execute the acquisition during the first quarter of 2021. These expenses are included in general and administrative expenses on the consolidated statement of operations for the year ended December 31, 2021 and are reflected in pro forma earnings for the year ended December 31, 2020 in the table above. The Company recorded a realized gain of $30.5 million during the first quarter of 2021 in investment income (expense), net on the Company's consolidated statement of operations relating to the Company's pre-acquisition investment in Thrive. This gain has been reduced to $7.6 million due to the Company's smaller ownership interest in Thrive on January 1, 2020, and is reflected in pro forma earnings for the year ended December 31, 2020 in the table above. The Company recorded a remeasurement of contingent consideration of $7.2 million related to Thrive in general and administrative expenses in the consolidated statement of operations for the year ended December 31, 2021. This expense is reflected in the year ended December 31, 2020 in the table above. The historical consolidated financial statements have been adjusted in the unaudited pro forma combined financial information to give effect to pro forma events that are directly attributable to the business combination and factually supportable. The unaudited pro forma financial information is for informational purposes only and is not indicative of the results of operations that would have been achieved if the acquisition had taken place as of January 1, 2020.

During the year ended December 31, 2021, the Company incurred $10.3 million of acquisition-related costs recorded in 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.

In connection with acquisition-related severances, the Company recorded $19.0 million of expense related to vesting of previously unvested equity awards and $3.9 million of additional benefit charges for the year ended December 31, 2021.

Asset Acquisitions

PFS Genomics Inc.

On May 3, 2021, the Company acquired 90% of the outstanding capital stock of PFS Genomics Inc. ("PFS"). On June 23, 2021, the Company completed the acquisition of the remaining 10% interest in PFS. The Company paid cash of $33.6 million for 100% of the outstanding capital stock in PFS. PFS is a healthcare company focused on personalizing treatment for breast cancer patients to improve outcomes and reduce unnecessary treatment. The Company expects this acquisition to expand its ability to help guide early-stage breast cancer treatment through individualized radiotherapy treatment decisions.

The transaction was treated as an asset acquisition under GAAP because substantially all of the fair value of the gross assets acquired were deemed to be associated with the acquired technology.

Acquisition related costs were not significant in this asset acquisition.

Divestitures

Oncotype DX Genomic Prostate Score Test

On August 2, 2022, pursuant to an asset purchase agreement ("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 ("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 $73.3 million during the year ended December 31, 2023, which is included in other operating income (loss) in the consolidated statement of operations. The gain was estimated using historical GPS test revenues by MDxHealth under the most likely amount method.

As of December 31, 2023, a portion of the contingent consideration is classified as a contract asset. The contract asset was $41.7 million and zero as of December 31, 2023 and 2022, respectively. The remaining balance of $31.6 million, which represents the amount earned during the 2023 earnout year, is classified as a receivable as of December 31, 2023. The contract asset and receivable are 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 functions as a single 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, its President and Chief Executive Officer, to monitor the Company's operating performance and support decisions regarding allocation of resources to its operations. Performance is continuously monitored at the consolidated level to timely identify deviations from expected results.

The following table summarizes total revenue from customers by geographic region. Product revenues are attributed to countries based on ship-to location.

	Year Ended December 31,		
(In thousands)	2023	2022	2021
United States	$ 2,346,489	$ 1,966,541	$ 1,657,174
Outside of United States	153,277	117,738	109,913
Total revenues	$ 2,499,766	$ 2,084,279	$ 1,767,087

Long-lived assets located in countries outside of the U.S. are not significant.

(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, 2023, the Company had federal net operating loss, state net operating loss, and foreign net operating loss carryforwards of approximately $402.9 million, $66.0 million, and $10.4 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, 2023 the Company has $278.5 million of federal net operating loss carryovers incurred after December 31, 2017 with an unlimited carryover period and $124.4 million of federal net operating loss carryovers expiring at various dates through 2037. State and foreign net operating loss carryovers expire at various dates through 2043. 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 $70.9 million and $33.0 million, respectively, which may be used to offset future income tax liability. The federal credit carryforwards expire at various dates through 2043 and are subject to review and possible adjustment by the Internal Revenue Service. The state credit carryforwards expire at various dates through 2038 with the exception of $19.7 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)	2023	2022	2021
Loss before income taxes:			
Domestic	$ (204,128)	$ (617,240)	$ (801,536)
Foreign	2,382	(15,330)	(40,970)
Total loss before income taxes	$ (201,746)	$ (632,570)	$ (842,506)

The expense (benefit) for income taxes consists of:

(In thousands)	Year Ended December 31, 2023	2022	2021
Current expense (benefit):			
Federal	$ —	$ —	$ —
State	2,266	2,170	1,388
Foreign	2,561	1,131	4,898
Deferred tax expense (benefit):			
Federal	2,395	(3,292)	(222,693)
State	(1,829)	(8,926)	(30,528)
Foreign	(2,990)	(147)	54
Total income tax expense (benefit)	$ 2,403	$ (9,064)	$ (246,881)

The Company recorded income tax expense for the year ended December 31, 2023 of $2.4 million primarily related to current foreign and state tax expense.

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, 2023	2022
Deferred tax assets:		
Operating loss carryforwards	$ 477,420	$ 553,320
Tax credit carryforwards	104,580	87,579
Compensation related differences	85,007	67,976
Lease liabilities	47,118	51,560
Capitalized research and development	191,468	108,117
Other temporary differences	10,275	19,353
Tax assets before valuation allowance	915,868	887,905
Less - Valuation allowance	(465,832)	(419,356)
Total deferred tax assets	450,036	468,549
Deferred tax liabilities		
Amortization	$ (415,064)	$ (435,991)
Property, plant and equipment	(9,465)	(4,653)
Lease assets	(35,786)	(40,674)
Other temporary differences	(7,010)	(6,944)
Total deferred tax liabilities	(467,325)	(488,262)
Net deferred tax liabilities	$ (17,289)	$ (19,713)

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 $465.8 million and $419.4 million at December 31, 2023 and 2022, 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 $17.3 million remaining as of December 31, 2023, which is included in other long-term liabilities on the Company's consolidated balance sheet. The overall change in valuation allowance for December 31, 2023 and 2022 was an increase of $46.5 million and an increase of $157.1 million, respectively.

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

	December 31,		
(In thousands)	2023	2022	2021
Balance as of January 1,	$ (419,356)	$ (262,238)	$ (293,397)
Valuation allowances established	(44,759)	(159,919)	(206,574)
Changes to existing valuation allowances	(1,242)	2,780	(1,500)
Acquisition and purchase accounting	(475)	21	239,233
Balance as of December 31,	$ (465,832)	$ (419,356)	$ (262,238)

During the year ended December 31, 2023, the Company recorded an increase to the valuation allowance of $44.8 million primarily related to losses from continuing operations.

During the year ended December 31, 2022, the Company recorded an increase to the valuation allowance of $159.9 million primarily related to losses from continuing operations.

During the year ended December 31, 2021, the Company recorded an increase to the valuation allowance of $206.6 million primarily related to losses from continuing operations. Offsetting the increase, the Company recorded a decrease to the valuation allowance of $239.2 million related to the Thrive Merger offset against goodwill.

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

	December 31,		
	2023	2022	2021
U.S. Federal statutory rate	21.0 %	21.0 %	21.0 %
State taxes	3.9	3.9	3.6
Federal and state tax rate changes	1.1	(0.2)	(0.3)
Foreign tax rate differential	—	(0.1)	(0.6)
Acquired IPR&D asset expense	—	—	(0.8)
Research and development tax credits	7.6	2.3	0.7
Stock-based compensation expense	(4.4)	(2.0)	1.1
Non-deductible executive compensation	(3.5)	(0.4)	(0.2)
Transaction costs	—	—	(0.1)
Loss on extinguishment - convertible debt	(0.7)	—	—
Other adjustments	(2.5)	1.2	1.2
Valuation allowance	(23.7)	(24.4)	3.7
Effective tax rate	(1.2)%	1.3 %	29.3 %

For the year ended December 31, 2023, the Company recognized a 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.

For the year ended December 31, 2021, the Company recognized an income tax benefit, representing an effective tax rate of 29.3%. The difference between the expected statutory federal tax rate of 21.0% and the effective tax rate of 29.3% for the year ended December 31, 2021, was primarily attributable to an income tax benefit of $239.2 million recorded as a result of a change in the deferred tax asset valuation allowance resulting from the Thrive Merger.

The Company had unrecognized tax benefits related to federal and state research and development tax credits of $36.4 million, $28.3 million, and $21.8 million as of December 31, 2023, 2022, and 2021, 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)	2023	2022	2021
January 1,	$ 28,270	$ 21,780	$ 16,629
Increase due to current year tax positions	7,447	5,861	5,363
Increase due to prior year tax positions	1,108	629	—
Decrease due to prior year tax positions	(426)	—	(212)
Settlements	—	—	—
December 31,	$ 36,399	$ 28,270	$ 21,780

As of December 31, 2023, 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 2000 through 2023, and to state income tax examinations for the tax years 2000 through 2023. 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, 2023, 2022 and 2021.

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, 2023 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, 2023, 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, 2023. 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, 2023, 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, 2023 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 fiscal quarter ended December 31, 2023, 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 6, 2023, Daniel J. Levangie, a member of our board of directors, adopted a Rule 10b5-1 trading arrangement for the sale of 5,000 shares of our common stock. The arrangement's expiration date is March 15, 2024, subject to early termination for certain specified events set forth in the arrangement.

On November 13, 2023, James Doyle, a member of our board of directors, adopted a Rule 10b5-1 trading arrangement for the sale of 4,900 shares of our common stock. The arrangement's expiration date is August 30, 2024, subject to early termination for certain specified events set forth in the arrangement.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item will be included in the Company's definitive proxy statement to be filed with the SEC within 120 days after December 31, 2023, in connection with the solicitation of proxies for the Company's 2024 Annual Meeting of Shareholders (the "2024 Proxy Statement"), and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this Item will be included in the 2024 Proxy Statement, and is incorporated herein by reference.

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

The information required by this Item will be included in the 2024 Proxy Statement, and is incorporated herein by reference.

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

The information required by this Item will be included in the 2024 Proxy Statement, and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by this Item will be included in the 2024 Proxy Statement, and is incorporated herein by reference.

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	First Supplemental 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 (including the form of 1.0% Convertible Senior Notes due 2025)	8-K (Exhibit 4.2)	1/17/2018	001-35092
4.4	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
4.5	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
4.6	Fourth Supplemental Indenture, dated March 1, 2023, 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
4.7	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*	Employment Agreement, dated August 22, 2017, by and between Sarah Condella and the Registrant	10-K (Exhibit 10.16)	2/16/2021	001-35092
10.14*	Employment Agreement, dated November 11, 2021, by and between Everett Cunningham and the Registrant	10-K (Exhibit 10.15)	2/22/2022	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*	Consulting Agreement, dated December 31, 2022, by and between Scott Coward and the Registrant	10-K (Exhibit 10.17)	2/21/2023	001-35092
Equity Compensation Plans and Policies				
10.17*	The Registrant's 2016 Inducement Award Plan	10-Q (Exhibit 10.3)	5/3/2016	001-35092
10.18*	The Registrant's 2016 Inducement Award Plan Form Restricted Stock Unit Award Agreement	S-8 (Exhibit 4.7)	5/3/2016	333-211099
10.19*	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

10.20*	The Registrant's Executive Deferred Compensation Plan dated January 1, 2019		10-K (Exhibit 10.22)	2/21/2019	001-35092
10.21*	Third Amendment to the Registrant's 2010 Employee Stock Purchase Plan		10-Q (Exhibit 10.1)	7/30/2019	001-35092
10.22*	The Registrant's 2019 Omnibus Long-Term Incentive Plan		S-8 (Exhibit 4.4)	7/31/2019	333-23916
10.23*	The Registrant's 2019 Omnibus Long-Term Incentive Plan Form Stock Option Award Agreement		10-Q (Exhibit 10.2)	8/1/2023	001-35092
10.24*	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
10.25*	The Registrant's 2019 Omnibus Long-Term Incentive Plan Form Restricted Stock Award Agreement		10-Q (Exhibit 10.4)	8/1/2023	001-35092
10.26*	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
10.27*	Genomic Health, Inc. Amended and Restated 2005 Stock Incentive Plan, as amended		S-8 (Exhibit 4.4)	11/8/2019	333-234608
10.28*	Thrive Earlier Detection Corp. 2019 Stock Option and Grant Plan		S-8 (Exhibit 4.6)	1/5/2021	333-251900
10.29*	The Registrant's Non-Employee Director Compensation Policy dated January 24, 2023		10-Q (Exhibit 10.3)	5/9/2023	001-35092
10.30*	Amendment No. 1 to the Registrant's 2019 Omnibus Long-Term Incentive Plan		8-K (Exhibit 10.1)	6/9/2022	001-35092
10.31*	Amendment No. 2 to the Registrant's 2019 Omnibus Long-Term Incentive Plan		8-K (Exhibit 10.1)	6/12/2023	001-35092
10.32*	The Registrant's 2010 Employee Stock Purchase Plan (as amended and restated March 22, 2023)		10-Q (Exhibit 10.2)	5/9/2023	001-35092
10.33*	The Registrant's Equity Award, Death, Disability and Retirement Policy	X			
Other					
10.34**	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
10.35**	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

10.36**	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
10.37+	Receivables Financing Agreement dated as of June 29, 2022 by and among Exact Receivables LLC, as borrower, the persons from time to time party thereto as lenders and group agents, PNC Bank, National Association, as administrative agent, Exact Sciences Laboratories, LLC, as initial servicer, and PNC Capital Markets, LLC, as structuring agent		8-K (Exhibit 10.1)	6/30/2022	001-35092
10.38+	Receivables Purchase Agreement dated as of June 29, 2022 by and among Exact Sciences Corporation, as seller, Exact Sciences Laboratories, LLC, as initial servicer, and Exact Receivables LLC, as buyer		8-K (Exhibit 10.2)	6/30/2022	001-35092
10.39+	Receivables Purchase Agreement dated as of June 29, 2022 by and among the entities from time to time party thereto as originators, Exact Sciences Laboratories, LLC, as initial servicer, and Exact Sciences Corporation, as buyer		8-K (Exhibit 10.3)	6/30/2022	001-35092
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	X			
101	The following materials from the Annual Report on Form 10-K of Exact Sciences Corporation for the year ended December 31, 2023 filed with the Securities and Exchange Commission on February 21, 2024, 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			

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104	The cover page from the Annual Report on Form 10-K of Exact Sciences Corporation for the year ended December 31, 2023 filed with the Securities and Exchange Commission on February 21, 2024, 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.

(+) Certain information has been omitted from this exhibit pursuant to Item 601 of Regulation S-K.

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 21, 2024

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 21, 2024
/s/ Jeffrey T. Elliott Jeffrey T. Elliott	Executive Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 21, 2024
/s/ Paul Clancy Paul Clancy	Director	February 21, 2024
/s/ D. Scott Coward D. Scott Coward	Director	February 21, 2024
/s/ James E. Doyle James E. Doyle	Lead Independent Director	February 21, 2024
/s/ Freda Lewis-Hall Freda Lewis-Hall	Director	February 21, 2024
/s/ Pierre Jacquet Pierre Jacquet	Director	February 21, 2024
/s/ Daniel J. Levangie Daniel J. Levangie	Director	February 21, 2024
/s/ Shacey Petrovic Shacey Petrovic	Director	February 21, 2024
/s/ Tim Scannell Tim Scannell	Director	February 21, 2024
/s/ Kathleen Sebelius Kathleen Sebelius	Director	February 21, 2024
/s/ Katherine S. Zanotti Katherine S. Zanotti	Director	February 21, 2024

EXHIBIT 10.33

EXACT SCIENCES CORPORATION

EQUITY AWARD DEATH, DISABILITY AND RETIREMENT POLICY

1. **Introduction**. This Equity Award Death, Disability and Retirement Policy, as amended (the "**Policy**"), specifies the treatment of each outstanding equity award (an "**Equity Award**") granted by Exact Sciences Corporation, a Delaware corporation (including any successor thereto, the "**Company**"), in the event of the Death, Disability or Retirement (each as defined below) of the original grantee of such Equity Award (the "**Grantee**"). This Policy does not apply to (a) an Equity Award granted to an individual or entity in such individual's or entity's capacity as a non-employee service provider of the Company or a Subsidiary (as defined below), (b) an Equity Award held by an individual or entity other than the Grantee, or (c) an Equity Award granted under the Exact Sciences Corporation 2010 Employee Stock Purchase Plan, as may be amended or replaced ("**ESPP**"), regardless of whether such Equity Award was granted under the component of the ESPP intended to constitute an "employee stock purchase plan" under Section 423 of the Code (as defined below) or under the component of the ESPP that does not qualify as an "employee stock purchase plan" under Section 423 of the Code.

2. **Effectiveness; Amendment; Termination**. This Policy initially became effective on February 17, 2023 (the "**Effective Date**") and was amended on October 25, 2023, and, as amended, applies to Equity Awards granted before, on or after such amendment date. The Company's Board of Directors (or a duly delegated committee thereof) may, at any time and from time to time, amend, suspend, or terminate the Policy. Upon termination, the Policy will continue to apply to Equity Awards granted prior to such termination. No amendment, suspension, or termination of the Policy will, without the consent of a Grantee, materially impair the rights of, or obligations to, such Grantee with respect to an Equity Award granted prior to such amendment, suspension or termination. This Policy will be binding upon the Company's successors and assigns.

3. **Definitions**. For purposes of this Policy:

    a. "**Code**" means the Internal Revenue Code of 1986, as now in effect or as hereafter amended.

    b. "**Death**" means the termination of a Grantee's Service as a result of such Grantee's death, as established by such Grantee's death certificate.

    c. "**Disability**" means a termination of a Grantee's Service by the Company or a Subsidiary (i) as a result of such Grantee's "disability," if such term or term of similar import is defined in the applicable Grantee's then-effective employment agreement or offer letter, and for all other Grantees, (ii) as a result of a determination by the Company's group long-term disability plan carrier that the applicable Grantee has incurred a "disability," as such term or term of similar import is defined in the Company's group long-term disability plan, as may be amended from time to time, or (iii) for Grantees who are non-employee Service Providers at the time of such termination, following a determination by the Social Security Administration that such person has incurred a "disability," provided that such non-employee Service Provider provides proof of such determination in a form satisfactory to the Company. Notwithstanding the foregoing, for Grantees whose primary work location is outside the United States, "disability" means a termination of such Grantee's Service by the Company or a Subsidiary if: (i) at the time of termination, such Grantee is receiving disability benefits for a complete disability or such Grantee has been expressly determined to be completely disabled and eligible to receive benefits for a complete disability under applicable law, and (ii) the termination was a result of the complete disability.

    d. **"Equity Award"** means a grant of an option, stock appreciation right, restricted stock, restricted stock unit, or other stock-based award.

    e. "**Retirement**" means a termination of a Grantee's Service voluntarily by the Grantee if such termination becomes effective on or after the date:

i. For a Grantee who holds a title of Vice President or below at the time of such resignation (as determined by the Company in its sole discretion), such Grantee attains age 55 and completes of 15 Years of Service (as defined below); and

ii. For a Grantee who holds a title above Vice President at the time of such resignation (as determined by the Company in its sole discretion), the Grantee: (1) attains age 55 and completes of 15 Years of Service or (2) attains age 60 and completes 10 Years of Service.

f. "**Service**" means service as a Service Provider to the Company or a Subsidiary. Unless otherwise stated in the award agreement corresponding to an Equity Award, then, with respect to such Equity Award, the corresponding Grantee's change in position or duties will not result in terminated Service for purposes of determining Years of Service hereunder, so long as such Grantee continues to be a Service Provider to the Company or a Subsidiary following such change.

g. "**Service Provider**" means an employee, consultant or advisor of the Company or a Subsidiary, or a non-employee member of the Company's Board of Directors, in each case who is paid compensation for such service directly by the Company or a Subsidiary.

h. "**Subsidiary**" means any "subsidiary corporation" of the Company within the meaning of Section 424(f) of the Code.

i. "**Years of Service**" means the total number of whole years of Service (rounded down) since a Grantee's original date of Service with the Company or its Subsidiaries (as determined by the Company in its sole discretion and excluding Service prior to becoming an employee of the Company or its Subsidiaries). For this purpose, if such Grantee's Service with the Company and its Subsidiaries previously terminated and such Grantee recommenced Service with the Company or its Subsidiaries more than one year after the termination date, the period of such previous Service will not count as Years of Service. If such Grantee's Service with the Company and its Subsidiaries previously terminated and such Grantee recommenced Service with the Company or its Subsidiaries within one year or less of the termination date, the period of such previous Service will count as Years of Service. For Subsidiaries acquired by the Company, only employees of such Subsidiary who were employed on the date of the closing of the acquisition of such Subsidiary will be given credit for Years of Service with such Subsidiary prior to the date of such closing.

4. **Retirement Benefits**.

a. Advance Notice; Application. A Grantee will incur a Retirement for purposes of this Policy only if such Grantee delivers to the Company advance written notice of such Grantee's voluntary termination of Service giving rise to such Retirement in accordance with this Section 4(a). For a Grantee who holds a title below Vice President at the time such notice is delivered to the Company, such notice must be delivered to the Company at least 2 months before such termination of Service. For a Grantee who holds a title of Vice President or above at the time such notice is delivered to the Company, such notice must be delivered to the Company at least 6 months before such termination of Service. The Retirement benefits under this Policy will apply to an Equity Award only if such Equity Award is granted at least 6 months prior to the date the notice described in this Section 4(a) is delivered to the Company. Notice may be provided in advance of the Retirement eligibility date, as long as the Grantee reaches Retirement eligibility by the termination date provided in the notice. For purposes of Sections 4(b) through (d) and Sections (5)(a) through (c), if, at the time of the termination of a Grantee's Service, such Grantee is a non-employee member of the Company's Board of Directors, such Grantee's position shall be considered the equivalent of Executive Vice President.

b. Time-Based Equity Awards. With respect to an Equity Award held by a Grantee for which vesting is not contingent on the achievement of one or more performance goals (a "**Time-Based Equity Award**"), upon the Retirement of such Grantee:

i. If such Grantee holds a title below Vice President at such time (as determined by the Company in its sole discretion), the portion of such Equity Award scheduled to vest during the 2-year period following such Retirement will: (1) if such Equity Award is granted prior to the Effective Date, continue to vest as if such Grantee had not Retired and (2) if such Equity Award is granted on or after the Effective Date, become fully vested;

ii. If such Grantee holds the title of Vice President at such time (as determined by the Company in its sole discretion), such Equity Award will continue to vest for 2 years following the date of such Retirement as if such Grantee had not Retired;

iii. If such Grantee holds the title of Senior Vice President at such time (as determined by the Company in its sole discretion), such Equity Award will continue to vest for 3 years following the date of such Retirement as if such Grantee had not Retired; and

iv. If such Grantee holds the title of Executive Vice President or the equivalent or above at such time (as determined by the Company in its sole discretion), such Equity Award will continue to vest for 4 years following the date of such Retirement as if such Grantee had not Retired (or, if earlier, through the last vesting date of such Equity Award).

c. Performance-Based Equity Awards. With respect to an Equity Award held by a Grantee for which vesting is contingent on the achievement of continued service and one or more performance goals (a "**Performance-Based Equity Award**"), upon the Retirement of such Grantee, provided that at least 2/3rd of the performance period applicable to such Performance-Based Equity Award have elapsed on or prior to such Retirement, such Equity Award will remain outstanding and: (1) the performance goal(s) applicable to such Equity Award will be measured, and such Equity Award will correspondingly be determined performance-vested, if at all, based on such measurements, as if such Retirement had not occurred and (2) a prorated portion of such Equity Award that becomes performance-vested pursuant to the preceding clause (1) will, following such measurement and determination, immediately time-vest and accordingly become fully vested. Such proration will be based on the number of whole calendar days, rounded down, that elapsed in the performance period corresponding to such Equity Award through the date of such Retirement, divided by the number of calendar days in such performance period. With respect to a Performance-Based Equity Award held by a Grantee, if, on or prior to the Retirement of such Grantee, at least 2/3rd of the performance period applicable to such Performance-Based Equity Award has not elapsed, such Equity Award will be forfeited immediately upon such Retirement.

d. Stock Options.

i. With respect only to a stock option Equity Award granted on or after the Effective Date, upon the Retirement of the Grantee holding such Equity Award, if such Grantee holds the title of Vice President or below at such time (as determined by the Company in its sole discretion), the post-termination exercise period relating to such Retirement will be 1 year after the last vesting date applicable to such Equity Award, or, if earlier, the original expiration date of such Equity Award; and

ii. With respect only to a stock option Equity Award granted on or after the Effective Date, upon the Retirement of the Grantee holding such Equity Award, if such Grantee holds the title of Senior Vice President or above at such time (as determined by the Company in its sole discretion), the post-termination exercise period relating to such Retirement will be 2 years after the last vesting date applicable to such Equity Award, or, if earlier, the original expiration date of such Equity Award.

e. Restrictive Covenants. The Retirement benefits set forth above for an Equity Award will be contingent on the compliance, by the Grantee holding such Equity Award, with any confidentiality, non-competition, non-solicitation or similar obligations in favor of the Company or its Subsidiaries.

5. **Death and Disability Benefits**.

a. Time-Based Equity Awards.

i. With respect to a Time-Based Equity Award held by a Grantee, upon the Death of such Grantee, or upon the death of such Grantee following Retirement, such Equity Award will become fully vested.

ii. With respect to a Time-Based Equity Award held by a Grantee, upon the Disability of such Grantee, if such Grantee holds the title of Executive Vice President or the equivalent or above at such time (as determined by the Company in its sole discretion), such Equity Award will become fully vested.

iii. With respect to a Time-Based Equity Award held by a Grantee, upon the Disability of such Grantee, if such Grantee holds a title below Executive Vice President or the equivalent at such time (as determined by the Company in its sole discretion) such Equity Award will: (1) if such Equity Award is granted prior to the Effective Date, continue to vest as if such Grantee had not become Disabled and (2) if such Equity Award is granted on or after the Effective Date, become fully vested.

b. Performance-Based Equity Awards.

i. With respect to a Performance-Based Equity Award held by a Grantee, upon the Death, Disability, or death following the Retirement of such Grantee who holds the title of Executive Vice President or the equivalent or below at such time (as determined by the Company in its sole discretion), such Equity Award will remain outstanding and: (1) the performance goal(s) applicable to such Equity Award will be measured, and such Equity Award will correspondingly be determined performance-vested, if at all, based on such measurements, as if such Death, Disability or death had not occurred and (2) a prorated portion of such Equity Award that becomes performance-vested pursuant to the preceding clause (1) will, following such measurement and determination, immediately time-vest and accordingly become fully vested. Such proration will be based on the number of whole calendar days, rounded down, that elapsed in the performance period corresponding to such Equity Award through the date of such Death, Disability or death, divided by the number of calendar days in such performance period.

ii. With respect to a Performance-Based Equity Award held by the Grantee who is the Chief Executive Officer of the Company at the time of his or her Death, Disability or death following his or her Retirement, upon such Death, Disability or death, such Equity Award will remain outstanding and: (1) the performance goal(s) applicable to such Equity Award will be measured, and such Equity Award will correspondingly be determined performance-vested, if at all, based on such measurements, as if such Death, Disability or death had not occurred and (2) the portion of such Equity Award that becomes performance-vested pursuant to the preceding clause (1) will, following such measurement and determination, immediately time-vest and accordingly become fully vested.

c. Stock Options.

i. With respect only to a stock option Equity Award granted on or after the Effective Date, upon the Death or Disability of the Grantee holding such Equity Award, if such Grantee holds the

title of Vice President or below at such time (as determined by the Company in its sole discretion), the post-termination exercise period relating to such Death or Disability will be 1 year after the last vesting date applicable to such Equity Award, or, if earlier, the original expiration date of such Equity Award; and

ii. With respect only to a stock option Equity Award granted on or after the Effective Date, upon the Death or Disability of the Grantee holding such Equity Award, if such Grantee holds the title above Vice President at such time (as determined by the Company in its sole discretion), the post-termination exercise period relating to such Death or Disability will be 2 years after the last vesting date applicable to such Equity Award, or, if earlier, the original expiration date of such Equity Award).

6. **Section 409A**.

a. If Section 409A of the Code ("**Section 409A**"), is applicable to an Equity Award, the treatment of such Equity Award under this Policy is intended to comply with Section 409A. Without limiting the generality of the foregoing, if Section 409A is applicable to an Equity Award: (1) any payment provided under this Policy to the Grantee of such Equity Award as a result of such Grantee's termination of employment will, if such Grantee is a "specified employee" within the meaning of Section 409A at the time of such termination, be delayed until the first business day after the 6-month period following such termination (or, if earlier, until Death), to the extent necessary to comply with Section 409A; (2) any payment or benefit subject to such Grantee's execution and non-revocation of a release of claims, if such execution and non-revocation could be made in more than one taxable year of such Grantee, will be made in the later taxable year; and (3) all references herein to "termination date" or "termination of employment" or any term of such import will mean "separation from service" within the meaning of Section 409A(a)(2)(A)(i). For purposes of Section 409A, any right to a series of payments under this Policy will be treated as a right to a series of separate payments. Notwithstanding Section 2, this Policy may be amended from time, without Grantee consent, as the Company may determine to be necessary or appropriate in order to be exempt from the application of, or to comply with, Section 409A. The Company makes no representation or warranty regarding the treatment of this Plan or the benefits payable under this Plan or any Award Agreement under federal, state or local income tax laws, including Section 409A.

7. **No Change to Existing Terms and Conditions**. Except as otherwise expressly provided in this Policy, the terms and conditions applicable to an Equity Award outside of this Policy, including the terms and conditions of the equity plan governing such Equity Award, the award agreement evidencing such Equity Award, and a Grantee's employment agreement or offer letter, will continue to apply to such Equity Award, provided that in the event of any conflict between this Policy and such terms and conditions, this Policy will govern to the extent it provides for more favorable treatment to the Grantee with respect to the Grantee's Equity Awards upon the Grantee's Death, Disability or Retirement. This Policy may not be construed to prevent the forfeiture or divestiture of any Equity Award if otherwise contemplated under the terms and conditions applicable to such Equity Award, including under any restrictive covenant agreement or clawback policy applicable to such Equity Award.

8. **Payroll Taxes**. In the event the Company or a Subsidiary is required to withhold any federal, state, or local employment taxes, payroll taxes or other similar withholding amounts prior to the settlement of an Equity Award that is subject to Section 409A of the Code, then the person holding such award may not elect the method by which the Company or such Subsidiary implements such withholding.

9. **Governing Law**. This Policy will be governed by and construed in accordance with the laws of the State of Wisconsin without giving effect to the principles of conflicts of law, provided that the provisions set forth herein that are required to be governed by the Delaware General Corporation Law will be governed by such law.

EXHIBIT 21

SUBSIDIARIES OF EXACT SCIENCES CORPORATION

Registrant's consolidated subsidiaries are shown below, together with the state or jurisdiction of organization of each subsidiary and the percentage of voting securities that Registrant owns in each subsidiary.

Name of Subsidiary	Jurisdiction of Incorporation or Organization	Percent of Outstanding Voting Securities Owned as of December 31, 2023
Genomic Health, Inc.	Delaware	100 %
Exact Sciences Laboratories, LLC	Delaware	100 %
Exact Sciences Thrive, LLC	Delaware	100 %

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-190350; No. 333-207703; No. 333-211099; No. 333-212730; No. 333-219553; No. 333-229780; No. 333-232916; No. 333-219553; No. 333-234608; No. 333-251900; No. 333-266471 and No. 333-273572) and Form S-3 (No. 333-238845 and No. 333-272196) of Exact Sciences Corporation of our report dated February 21, 2024 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Chicago, Illinois
February 21, 2024

EXHIBIT 31.1

CERTIFICATION

I, Kevin T. Conroy, certify that:

1. I have reviewed this annual report on Form 10-K of Exact Sciences Corporation (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: February 21, 2024

/s/ Kevin T. Conroy

Name: Kevin T. Conroy

Title: President and Chief Executive Officer

(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Jeffrey T. Elliott, certify that:

1. I have reviewed this annual report on Form 10-K of Exact Sciences Corporation (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting

Dated: February 21, 2024

/s/ Jeffrey T. Elliott

Name: Jeffrey T. Elliott

Title: Executive Vice President and Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 32

CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Exact Sciences Corporation (the "Company") for the year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Kevin T. Conroy, President and Chief Executive Officer of the Company and Jeffrey T. Elliott, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to our knowledge that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 21, 2024

/s/ Kevin T. Conroy

Name: Kevin T. Conroy
Title: President and Chief Executive Officer
(Principal Executive Officer)

Dated: February 21, 2024

/s/ Jeffrey T. Elliott

Name: Jeffrey T. Elliott
Title: Executive Vice President and Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 97

EXACT SCIENCES CORPORATION

INCENTIVE-BASED COMPENSATION RECOVERY POLICY

1. Policy Purpose Generally. The purpose of this Exact Sciences Corporation (the "Company") Incentive-Based Compensation Recovery Policy (this "Policy") is to enable the Company to recover erroneously awarded compensation, including in the event that the Company is required to prepare an Accounting Restatement. This Policy is intended to comply with the requirements set forth in Listing Rule 5608 of the corporate governance rules of The NASDAQ Stock Market (the "Listing Rule"), and to provide the Company certain additional recovery rights, and shall be construed and interpreted in accordance with such intent. Unless otherwise defined in this Policy, capitalized terms shall have the meaning ascribed to such terms in Section 10. This Policy shall become effective on December 1, 2023, and, at such time, shall supersede the Company's Incentive Compensation Recoupment Policy. Where the context requires, reference to the Company shall include the Company's subsidiaries and affiliates (as determined by the Committee in its discretion).

2. Policy Administration Generally. This Policy shall be administered by the Human Capital Committee of the Board (the "Committee") unless the Board determines to administer this Policy itself. The Committee has full and final authority to make all determinations under this Policy. All determinations and decisions made by the Committee pursuant to the provisions of this Policy shall be final, conclusive and binding on all persons, including the Company, its affiliates, its stockholders and covered persons. Any action or inaction by the Committee with respect to a covered person under this Policy in no way limits the Committee's actions or decisions not to act with respect to any other covered person under this Policy or under any similar policy, agreement or arrangement, nor shall any such action or inaction serve as a waiver of any rights the Company may have against any covered person other than as set forth in this Policy.

3. Recovery of Incentive Compensation.

    a. Mandatory Recovery in connection with Accounting Restatement.

        i. This Section 3(a) applies to all Incentive-Based Compensation received by a person: (a) on or after October 2, 2023, and beginning service as an Executive Officer; (b) who served as an Executive Officer at any time during the performance period for such Incentive-Based Compensation; (c) while the Company had a class of securities listed on a national securities exchange or a national securities association; and (d) during the three completed fiscal years immediately preceding the Accounting Restatement Date. In addition to such last three completed fiscal years, the immediately preceding clause (d) includes any transition period that results from a change in the Company's fiscal year within or immediately following such three completed fiscal years; provided, however, that a transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year that comprises a period of nine to twelve months shall be deemed a completed fiscal year. For purposes of this Section 3(a), Incentive-Based Compensation is deemed received in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if the payment or grant of the Incentive-Based Compensation occurs after the end of that period. For the avoidance of doubt, Incentive-Based Compensation that is subject to both a Financial Reporting Measure vesting condition and a service-based vesting condition shall be considered received when the relevant Financial Reporting Measure is achieved, even if the Incentive-Based Compensation continues to be subject to the service-based vesting condition.

ii. In the event of an Accounting Restatement, the Company must recover, reasonably promptly, Erroneously Awarded Compensation, in amounts determined pursuant to this Policy. The Company's obligation to recover Erroneously Awarded Compensation is not dependent on if or when the Company files restated financial statements. Recovery under this Policy with respect to an Executive Officer shall not require the finding of any misconduct by such Executive Officer or such Executive Officer being found responsible for the accounting error leading to an Accounting Restatement. In the event of an Accounting Restatement, the Company shall satisfy the Company's obligations under this Policy to recover any amount owed from any applicable Executive Officer by exercising its sole and absolute discretion in how to accomplish such recovery. The Company's recovery obligation pursuant to this Section 3(a) shall not apply to the extent that the Committee, or in the absence of the Committee, a majority of the independent directors serving on the Board, determines that such recovery would be impracticable and:

1. The direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered. Before concluding that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on expense of enforcement, the Company must make a reasonable attempt to recover such Erroneously Awarded Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Stock Exchange; or

2. Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the registrant, to fail to meet the requirements of Section 401(a)(13) or Section 411(a) of the Code.

iii. The Company shall not indemnify any Executive Officer or former Executive Officer against the loss of Erroneously Awarded Compensation. Further, the Company shall not pay or reimburse an Executive Officer for purchasing insurance to cover any such loss.

b. Recovery in connection with Detrimental Conduct. In addition to the Company's mandatory recovery obligations in connection with an Accounting Restatement as set forth in Section 3(a), in the event that an employee of the Company at the level of Vice President or above engages in fraud or misconduct that, in the sole discretion of the Committee, is likely to cause or has caused material financial, operational, or reputational harm to the Company ("Detrimental Conduct"), the Committee may, in its sole discretion, recover incentive compensation (including Incentive-Based Compensation) received by such person during and after the period in which such Detrimental Conduct occurred. Detrimental Conduct subject to this Section 3(b) must have occurred within the three years preceding the date on which the Committee determines that such Detrimental Conduct has occurred. For purposes of this Section 3(b), incentive compensation is deemed received in the Company's fiscal period during which the performance goal specified in the incentive compensation award is attained, even if the payment or grant of the incentive compensation occurs after the end of that period. For the avoidance of doubt, incentive compensation that is subject to both a performance vesting condition and a service-based vesting condition shall be considered received when the relevant performance condition is achieved, even if the incentive compensation continues to be subject to the service-based vesting condition. The Committee shall determine the amount of incentive compensation to be recovered in its sole discretion based upon the relevant covered person's relative degree of fault or involvement, the impact of the conduct on the Company, the magnitude of any loss caused and other relevant facts and circumstances. The Committee may effect recoupment in any manner consistent with applicable law.

4. Committee Indemnification. Any members of the Committee, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be fully indemnified by the Company to the fullest extent under applicable law

and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

5. Severability. The provisions in this Policy are intended to be applied to the fullest extent of the law. To the extent that any provision of this Policy is found to be unenforceable or invalid under any applicable law, such provision shall be applied to the maximum extent permitted, and shall automatically be deemed amended in a manner consistent with its objectives to the extent necessary to conform to any limitations required under applicable law.

6. Amendment; Termination. The Board may amend this Policy from time to time in its sole and absolute discretion and shall amend this Policy as it deems necessary to reflect the Listing Rule. The Board may terminate this Policy at any time.

7. Other Recovery Obligations; General Rights. To the extent that the application of this Policy would provide for recovery of Incentive-Based Compensation that the Company recovers pursuant to Section 304 of the Sarbanes-Oxley Act or other recovery obligations, the amount the relevant individual has already reimbursed the Company shall be credited to the required recovery under this Policy. This Policy shall not limit the rights of the Company to take any other actions or pursue other remedies that the Company may deem appropriate under the circumstances and under applicable law. To the maximum extent permitted under the Listing Rule, this Policy shall be administered in compliance with (or pursuant to an exemption from the application of) Section 409A of the Code.

8. Successors. This Policy is binding and enforceable against all covered persons and their beneficiaries, heirs, executors, administrators or other legal representatives.

9. Governing Law; Venue. This Policy and all rights and obligations hereunder are governed by and construed in accordance with the internal laws of the State of Delaware, excluding any choice of law rules or principles that may direct the application of the laws of another jurisdiction. All actions arising out of or relating to this Policy shall be heard and determined exclusively in the Court of Chancery of the State of Delaware or, if such court declines to exercise jurisdiction or if subject matter jurisdiction over the matter that is the subject of any such legal action or proceeding is vested exclusively in the U.S. Federal courts, the U.S. District Court for the District of Delaware.

10. Definitions.

    a. "Accounting Restatement" means an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

    b. "Accounting Restatement Date" means the earlier to occur of: (i) the date the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if the Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement; and (ii) the date a court, regulator, or other legally authorized body directs the Company to prepare an Accounting Restatement.

    c. "Board" means the board of directors of the Company.

    d. "Code" means the U.S. Internal Revenue Code of 1986, as amended. Any reference to a section of the Code or regulation thereunder includes such section or regulation, any valid regulation or other official guidance promulgated under such section, and any comparable provision of any future legislation or regulation amending, supplementing, or superseding such section or regulation.

    e. "Erroneously Awarded Compensation" means, in the event of an Accounting Restatement, the amount of Incentive-Based Compensation previously received that exceeds the amount of Incentive-

Based Compensation that otherwise would have been received had it been determined based on the restated amounts in such Accounting Restatement, and must be computed without regard to any taxes incurred or paid by the relevant Executive Officer; provided, however, that for Incentive-Based Compensation based on stock price or total stockholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement: (i) the amount of Erroneously Awarded Compensation must be based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or total stockholder return upon which the Incentive-Based Compensation was received; and (ii) the Company must maintain documentation of the determination of that reasonable estimate and provide such documentation to the Stock Exchange.

f. "Executive Officer" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. An executive officer of the Company's parent or subsidiary is deemed an "Executive Officer" if the executive officer performs such policy making functions for the Company. For the avoidance of doubt, "Executive Officer" includes, but is not limited to, any person identified as an executive officer pursuant to Item 401(b) of Regulation S-K under the U.S. Securities Act of 1933, as amended.

g. "Financial Reporting Measure" means any measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measure that is derived wholly or in part from such measure; provided, however, that a Financial Reporting Measure is not required to be presented within the Company's financial statements or included in a filing with the U.S. Securities and Exchange Commission to qualify as a "Financial Reporting Measure." For purposes of this Policy, "Financial Reporting Measure" includes, but is not limited to, stock price and total stockholder return.

h. "Incentive-Based Compensation" means any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

i. "Stock Exchange" means the national stock exchange on which the Company's common stock is listed.