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, 2020

☐ **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 compan ☐	Emerging growth ☐

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. ☒

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 12,901,152,054 (based on the closing price of the Registrant's Common Stock on June 30, 2020 of $86.94 per share).

The number of shares outstanding of the Registrant's $0.01 par value Common Stock as of February 15, 2021 was 169,093,162.

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, 2020. 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, 2020

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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: uncertainties associated with the coronavirus (COVID-19) pandemic, including its possible effects on our operations, including our supply chain and clinical studies, and the demand for our products and services; our ability to efficiently and flexibly manage our business amid uncertainties related to COVID-19; 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; the willingness of health insurance companies and other payers to cover our products and services and adequately reimburse us for such products and services; 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 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 maintain regulatory approvals and comply with applicable regulations; our ability to manage an international business and our expectations regarding our international expansion and opportunities; the potential effects of foreign currency exchange rate fluctuations and our efforts to hedge such effects; 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 will be greater than expected and the possibility that integration efforts will disrupt our business and strain management time and resources; the outcome of any litigation, government investigations, enforcement actions or other legal proceedings, including in connection with acquisitions; our ability to retain and hire key personnel including employees at businesses we acquire; and the other risks and uncertainties 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 cancer screening and diagnostics company. We have developed some of the most impactful brands in cancer diagnostics, and we are currently working on the development of additional tests, with the goal of bringing new, innovative cancer tests to patients throughout the world.

We are committed to providing earlier answers and life-changing treatment guidance to help people face the most challenging decisions with confidence. From earlier cancer detection to treatment guidance, we seek to help people get the answers they need to make more informed decisions across the cancer continuum. Our revenues are primarily generated by our laboratory testing services, from our Cologuard® colorectal cancer screening test, our Oncotype IQ® cancer diagnostic tests and services, and our COVID-19 test.

We recently executed several significant and transformative projects and acquisitions to enhance shareholder value and bring new, innovative cancer tests to patients.

Significant recent developments include:

- Acquisition of Thrive—In January 2021, we acquired Thrive Earlier Detection Corp. ("Thrive"), a healthcare company dedicated to developing a blood-based, multi-cancer screening test. An early version of Thrive's test achieved promising results with very few false positives in a 10,000-patient, prospective, interventional study detecting 10 different types of cancer, including seven with no recommended screening guidelines.
- Exclusive License of TARDIS Technology —In January 2021, we acquired an exclusive license to The Translational Genomics Research Institute's ("TGen") proprietary Targeted Digital Sequencing ("TARDIS") technology for use in minimal residual disease ("MRD"). We are currently seeking to utilize TARDIS's compelling and technically distinct approach to develop a test to detect small amounts of tumor DNA that may remain in patients' blood after they have undergone initial treatment.
- Acquisition of Base Genomics—In October 2020, we acquired Base Genomics Limited ("Base"), an epigenetics company working to set a new standard in DNA methylation analysis, one of the most promising approaches to detecting cancer in its earliest stages.
- Extension of Mayo Collaboration—In September 2020, we amended and restated our license agreement with Mayo Foundation for Medical Education and Research ("Mayo"), extending our productive collaboration with Mayo through January 2025. Pursuant to the agreement, Mayo dedicates personnel to provide us product development and research and development assistance.
- Launch of Covid-19 Testing—In March 2020, responding to the emergent public health crisis, we began providing Covid-19 testing. Since launch, we have provided more than 2 million results for residents in all 50 states.
- Acquisition of Paradigm—In March 2020, we acquired Paradigm Diagnostics, Inc., a commercial stage cancer diagnostic company. Leveraging Paradigm's technology and laboratory, in October 2020 we launched the Oncotype MAP™ Pan-Cancer Tissue test ("Oncotype MAP" test).
- Acquisition of Viomics—In March 2020, we acquired Viomics, Inc., a development stage company with extensive sequencing capabilities and expertise in identifying unique biomarkers that indicate the presence of cancer in solid tissue and blood.
- Acquisition of Genomic Health—In November 2019, we acquired Genomic Health, Inc., a leading provider of genomic-based tests that help optimize cancer care, and its Oncotype IQ Genomic Intelligence Platform comprised of its flagship line of Oncotype DX® gene expression tests. The Genomic Health acquisition also provided us with a best-in-class international sales infrastructure.

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 tests and precision oncology tests.

Our 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 polyps 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 150,000 new cases of colorectal cancer and approximately 53,000 deaths from colorectal cancer.

Upon approval by the U.S. Food and Drug Administration ("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 our Cologuard test's 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.

An estimated 45 percent 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 nearly 50% 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.

- The U.S. Preventative Services Task Force (“USPSTF”) has given colorectal cancer screening in people ages 50-75 an “A” grade and included our Cologuard test (referred to in their statement as sDNA-FIT) as a recommended screening method for all average-risk patients in that age group. In October 2020, the USPSTF released draft updated recommendation statement that added a “B” grade for colorectal cancer screening for people ages 45-49. We expect that USPSTF will release final updated guidelines in 2021.
- The American Cancer Society 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.

Our Oncotype IQ Tests

With our Oncotype IQ Genomic Intelligence Platform we apply our world-class scientific and commercial expertise and infrastructure to lead the translation of clinical and genomic data into actionable results for treatment planning throughout the cancer patient's journey. We believe our Oncotype IQ tests improve the quality of treatment decisions and the health economics of cancer care.

Our Oncotype IQ Genomic Intelligence Platform is currently comprised of:

- our flagship line of Oncotype DX gene expression tests for breast, prostate and colon cancers,
- Oncotype MAP, a tissue test delivering rapid, comprehensive tumor profiling to aid therapy selection for patients with advanced, metastatic, refractory or recurrent cancer, and
- Oncotype DX AR-V7 Nucleus Detect® test, a liquid-based test for advanced stage prostate cancer.

Oncotype DX Breast Cancer Tests

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. We have delivered more than 1.3 million Oncotype DX Breast Recurrence Score tests to cancer patients since launching the product in 2004.

Among women, breast cancer is the most commonly diagnosed cancer and the leading cause of cancer death. In 2021, more than 281,000 women are expected to be diagnosed with invasive breast cancer in the United States according to ACS, along with more than 49,000 new cases of non-invasive (in situ) breast cancer. Worldwide, it is estimated that there are approximately 2.1 million newly diagnosed cases of breast cancer each year.

The Oncotype DX breast cancer 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 chemotherapy benefit, the Oncotype DX Breast Recurrence Score test is included in all major cancer guidelines worldwide, and is considered a standard of care for women with early-stage breast cancer.

Oncotype DX Breast DCIS Score® Test

Our Oncotype DX DCIS 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 a more informed treatment decisions. The Oncotype DX colon cancer 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.

Oncotype DX Genomic Prostate Score® Test

Worldwide, prostate cancer ranks as the second most frequent cancer and the fifth leading cause of cancer death in men. Our Oncotype DX Genomic Prostate Score (“GPS™”) test helps men newly diagnosed with early-stage prostate cancer to make the most informed treatment decision for their individual disease, including active surveillance. Our prostate needle biopsy-based, multi-gene test has been clinically validated to predict aggressive cancer at the time of diagnosis, helping to identify those men who need immediate surgery or radiation therapy versus those who can confidently choose active surveillance. The result is a more precise and accurate assessment of risk, which helps more men avoid the lifelong complications associated with treatments they do not need, while directing aggressive therapy to those men who require immediate treatment.

Oncotype MAP Pan-Cancer Tissue Test

In October 2020 we introduced the Oncotype MAP test. The Oncotype MAP test is a rapid, comprehensive tumor profiling panel that aids therapy selection for patients with advanced, metastatic, refractory, or recurrent cancer. The Oncotype MAP test utilizes next generation sequencing and immunohistochemistry to provide in-depth insights into genomic alterations in hundreds of cancer-related genes. The Oncotype MAP test report supports clinical decision making by showing actionable biomarkers associated with more than 100 evidence-based therapies, over 45 combination therapies, and more than 650 active clinical trial associations. The identification of these biomarkers helps to inform treatment options for a breadth of solid tumor types.

Oncotype DX AR-V7 Nucleus Detect Test

Our Oncotype DX AR-V7 Nucleus Detect test is a blood-based test designed to guide treatment decisions for men with metastatic castration-resistant prostate cancer (“mCRPC”), an advanced stage of the disease in which the cancer continues to grow and spread despite androgen deprivation therapy. mCRPC is often treated with androgen receptor-signaling inhibitor (“ARSI”) therapies. However, one in three patients become resistant to ARSI therapy after two rounds of treatment, leading to poor outcomes and unnecessary treatment costs. Epic Sciences developed and performs the Oncotype DX AR-V7 Nucleus Detect test. We commercialize the test pursuant to an exclusive license and distribution agreement with Epic Sciences.

Covid-19 Testing

In late March 2020, we began providing COVID-19 testing. We have partnered with various customers, including the State of Wisconsin Department of Health, to administer testing. Customers are responsible for employing trained personnel to collect specimens. Specimens are sent to our laboratory in Madison, Wisconsin, where we run the assay in our laboratories and provide test results to ordering providers. In light of the uncertainty surrounding the COVID-19 pandemic, we intend to periodically reassess offering COVID-19 testing.

Pipeline Research and Development

Our research and development efforts are focused on developing new products and enhancing existing products to address new cancer areas 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 fluid-based ("liquid biopsy") tests. These development efforts may lead to a variety of possible 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 Mayo Foundation for Medical Education and Research, we have successfully performed validation studies on multiple types of cancer using tissue, blood, and other samples. In September 2020, Mayo agreed to make available certain personnel to provide us research development assistance through January 2025. Through recent business development activities, we have acquired exclusive access to technologies developed by The Johns Hopkins University, TGen, Oxford University and the Ludwig Institute for Cancer Research.

We expect to advance liquid biopsy through biomarker discovery and validation in tissue, blood, or other fluids and to leverage recent business development activities to accelerate our leadership in earlier cancer detection and treatment guidance. We are pursuing the following opportunities:

- *Colon Cancer Screening.* We are seeking opportunities to improve upon our Cologuard test's performance characteristics. In October 2019, we and Mayo presented at the American College of Gastroenterology's 2019 Annual Scientific Meeting findings from a blinded-case control study showing enhanced colorectal cancer and advanced adenoma detection using newly discovered methylation biomarkers. In October 2020, we acquired Base Genomics, whose methylation analysis technologies promise to build upon other contemplated enhancements to our Cologuard test. To establish the performance of an enhanced multi-target stool DNA test, we expect to enroll more than 10,000 patients 40 years of age and older in our multi-center, prospective BLUE-C study. The timing of any such enhancements to our Cologuard test is unknown and would be subject to FDA approval. We are also working to develop a blood-based screening test for colorectal cancer.
- *Multi-Cancer Screening Test Development.* We are currently seeking to develop a blood-based, multi-cancer screening test. In January 2021, we completed the acquisition of Thrive Earlier Detection Corp., a healthcare company dedicated to developing a blood-based, multi-cancer screening test. An early version of Thrive's test has achieved promising results in a 10,000-patient, prospective, interventional study detecting 10 different types of cancer, including seven with no current recommended screening guidelines, with very few false positives. We are exploring opportunities to incorporate Exact's and Base Genomics' methylation technologies into Thrive's test in order to enhance the test's accuracy and accelerate the widespread adoption of this potentially life-saving advancement.
- *Hepatocellular Carcinoma ("HCC") Test Development.* We are currently seeking to develop a blood-based biomarker test to serve as an alternative to ultrasound and alpha-fetoprotein ("AFP") for use in HCC testing. HCC is the most common type of liver cancer. Our goal is to develop a patient-friendly test that performs better than the current standard of care. In November 2019, we released the results of a 450-patient study which demonstrated 80% overall sensitivity at 90% specificity with a novel combination of six blood-based biomarkers for HCC. The study also showed 71% sensitivity for early stage HCC at 90% specificity. The study compared performance to the AFP test, which demonstrated 45% sensitivity at 90% specificity for early stage HCC.
- *Minimal Residual Disease ("MRD") Test Development.* In January 2021 we acquired an exclusive license to the TGen proprietary TARDIS technology. We are currently seeking to utilize this compelling and technically distinct approach to develop a test to detect small amounts of tumor DNA that may remain in patients' blood after they have undergone initial treatment. In a study published in Science Translational Medicine, TARDIS demonstrated high accuracy in assessing molecular response and residual disease during neoadjuvant therapy to treat breast cancer. TARDIS achieved up to 100-fold improvement beyond the current limit of circulating tumor DNA detection.
- *Development Studies for Oncotype DX Products.* We may also conduct or fund clinical studies that could support additional opportunities for our Oncotype DX products. For example, we are exploring clinical studies to expand the use of genomic testing to address additional populations, including higher-risk patients.

Research and development, which includes our clinical study programs, accounts for a material portion of our operating expenses. As we seek to enhance our current product portfolio and expand our product pipeline by developing additional cancer screening and diagnostic tests, we expect that our research and development expenditures will continue to increase.

Commercial Operations

We operate within a single business segment, with commercial teams focused on screening, precision oncology, and international markets. Beginning in March 2020, the COVID-19 pandemic began to disrupt our commercial operations, including by causing us to suspend face-to-face interactions between sales representatives and healthcare providers. Although a portion of our sales force has no recommenced field-based interactions, access to healthcare providers remains limited.

Cologuard Test Commercial Operations

We promote our Cologuard test through our primary care, gastroenterology, women's health and health systems field sales teams, as well as through an inside sales team. In addition, Pfizer, Inc. ("Pfizer") promotes our Cologuard test and provides certain sales, marketing, analytical and other commercial operations support pursuant to a Promotion Agreement.

Our sales team actively engages with healthcare providers and their staffs 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. 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. This customer-oriented support activity is focused on encouraging and helping patients to complete Cologuard tests that have been ordered for them by their providers. We may undertake several 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 2020, in response to COVID-19, we deepened our investment in virtual resources, including launching a telehealth option for patients which can be found on Cologuard.com. We also built new capabilities to market our Cologuard test to health systems, with a focus on health information technologies. Following the FDA's September 2019 expansion of Cologuard's indication to average-risk individuals ages 45-49, we updated our direct-to-consumer efforts to educate and motivate this younger population to screen with our Cologuard test.

Oncotype IQ Commercial Operations

We promote our Oncotype IQ 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 future success of our Oncotype IQ products. In our domestic sales, marketing and reimbursement efforts, we interact directly with medical, radiation, and surgical oncologists, urologists, pathologists and payers. We employ a direct sales approach that targets oncologists, cancer surgeons and urologists, 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 products and services and the number of favorable reimbursement coverage decisions by third-party payers.

International Commercial Operations

We now commercialize our Oncotype IQ tests internationally through employees in Canada, Japan and six European countries, as well as through exclusive distribution agreements. We do not offer our Cologuard test outside of the U.S. We have provided our Oncotype IQ tests in more than 90 countries outside of the U.S.

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

We are exploring opportunities to establish local laboratories in certain locations outside of the U.S. Certain countries have severe restrictions on exporting tissue samples. 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 most private payers. As outlined in CMS's National Coverage Determination ("NCD"), Medicare Part B covers our Cologuard test once every three years for beneficiaries who meet all of the following criteria:

- age 50 to 85 years,
- asymptomatic (no signs or symptoms of colorectal disease including, but not limited to, lower gastrointestinal pain, blood in stool, positive guaiac fecal occult blood test or fecal immunochemical test), and
- at average risk for developing colorectal cancer (e.g., no personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease, including Crohn's Disease and ulcerative colitis; no family history of colorectal cancers or adenomatous polyps, familial adenomatous polyposis or hereditary non-polyposis colorectal cancer).

In addition to Medicare reimbursement, 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. Some payers may apply various medical management requirements, including a requirement that they give prior authorization for a Cologuard test before they are willing to pay for it. Other payers may perform post-payment reviews or audits, which could lead to payment recoupments.

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").
- 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.
- We believe the laws of approximately 30 states currently mandate coverage of our Cologuard test by certain health insurance plans.

The federal laws and regulations referenced above currently mandate coverage for individuals beginning at age 50. We believe that if the draft USPSTF colorectal cancer screening guidelines become final as currently written, the ACA mandate would, after a transition period, begin at age 45. While most of the state mandates apply beginning at age 50, we believe some should be interpreted to require coverage beginning at age 45.

Reimbursement for our Oncotype IQ Tests

We depend on government insurance plans, managed care organizations and private insurance plans for reimbursement of our Oncotype IQ tests.

Medicare coverage for our Oncotype IQ 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. To date, Palmetto has determined that our invasive breast and colon cancer tests will be covered, and that our prostate cancer test will be covered for patients with specified risk levels. Coverage determinations for our tests made by Palmetto under the MolDx program have been adopted by Noridian Healthcare Solutions, the MAC that processes Medicare claims submitted by us.

Reimbursement of our Oncotype IQ 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 copayments, where applicable) in accordance with established policy, contract or agreement terms. 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 Oncotype IQ 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, governments are primarily responsible for financing and establishing reimbursement for diagnostic tests. The majority of our international Oncotype IQ test revenues come from reimbursement, payments from our distributors, and patient self-pay. We have obtained coverage for our invasive breast cancer test outside of the U.S., including coverage for certain patients in Canada, France, Spain, Germany, Italy, Ireland, Israel, Saudi Arabia, Switzerland, and the U.K.

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

Reimbursement for Future Products

Successful commercialization of our newly developed products and products in development will also depend on our ability to obtain adequate reimbursement from government insurance plans, managed care organizations and private insurance plans 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 Pathologists ("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. In 2020 we completed the construction of our second manufacturing facility, and we were granted FDA approval for commercial production in July 2020. 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.

We are committed to responding to the challenges posed by the coronavirus ("COVID-19") pandemic. Beginning in March 2020, we allocated space at our clinical laboratories in Madison, Wisconsin to process our COVID-19 tests. We also manufacture and assemble our COVID-19 test kits at our manufacturing facilities in Madison, Wisconsin.

All internally developed Oncotype DX tests for domestic and international patients are currently processed in our clinical reference laboratory facilities in Redwood City, California, which is certified under CLIA and accredited by CAP. Our Oncotype MAP test is processed in our clinical reference laboratory facility in Phoenix, Arizona, which is certified under CLIA and accredited by CAP. The Oncotype DX AR-V7 Nucleus Detect test, which was designed and validated by Epic Sciences, Inc. ("Epic Sciences"), is performed in its CLIA-accredited, CAP-certified clinical reference laboratory facility in San Diego, California.

We believe that we currently have sufficient capacity to process all of our tests. We may require additional facilities in the future as we expand our business and believe that additional space, when needed, will be available on market terms.

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. Some of our current and potential competitors possess greater brand recognition, development capabilities, and financial and other resources than us. We expect to compete with a broad range of organizations in the U.S. and other countries that are engaged in the development, production and commercialization of cancer screening and diagnostic products and services. These competitors include:

- biotechnology, diagnostic and other life science companies,
- academic and scientific institutions,
- governmental agencies, and
- public and private research organizations.

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”), and other screening technologies. Newer screening technologies include liquid biopsy tests, such as Epi proColon, which was approved by the FDA in April 2016, and 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, DiaTech Pharmacogenetics, Prescient Metabiomics, and Geneoscopy, that are seeking to develop stool-based colorectal cancer tests in the United States. Our competitors may also be developing additional methods of detecting colorectal cancer and pre-cancer that have not yet been announced.

Notwithstanding that the market for colorectal cancer screening is highly competitive, we believe that our Cologuard test, as 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, and high cost. For example, colonoscopy requires advance dietary restrictions and bowel cleansing and can be uncomfortable, time-consuming, hazardous, and expensive. Colonoscopy requires sedation, potential lost time from work, and someone to drive the patient home from the procedure. A 2010 study shows 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 percent detection rate for cancer and 24 percent detection rate for pre-cancer. The blood-based DNA tests currently available are also disadvantaged by relatively low sensitivity. Epigenomics AG has reported that the Epi proColon test has an overall cancer sensitivity rate of 68 percent, and only 59 percent for early-stage 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.

Our Oncotype IQ products compete against a number of companies that offer products or have conducted research to profile genes and gene expression in breast, colon, and prostate cancer. These companies include Agendia Inc., BioTheranostics, GenomeDx Biosciences Inc., Guardant Health, Inc., Hologic Inc., Myriad Genetics Inc. (and its Sividon Diagnostics subsidiary), NanoString Technologies Inc., NeoGenomics, Inc., OPKO Health, Inc. (and its Bio-Reference Laboratories, Inc. subsidiary), Pacific Edge Limited, Qiagen N.V. and Veracyte, Inc. Historically, our principal competition for our Oncotype IQ tests has also come from existing diagnostic methods used by pathologists and oncologists, and such traditional diagnostic methods can be difficult to compete with or supplement. Our Oncotype IQ tests also face competition from commercial laboratories with strong distribution networks for diagnostic tests, such as Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated. 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.

For our prostate cancer tests, we face comparatively greater competition than for our breast cancer tests, including competition from products that were on the market prior to our product launch and that are supported by clinical studies and published data. This existing direct and indirect competition for tests and procedures may make it difficult to gain market share, impact our ability to obtain reimbursement or result in a substantial increase in resources necessary to successfully commercialize our Oncotype DX GPS prostate test and the Oncotype DX AR-V7 Nucleus Detect test.

We believe that our Oncotype IQ tests compete primarily on the basis of the value of the quantitative information they provide, the clinical validation of the utility of our tests, the level of adoption and reimbursement coverage for our tests, the inclusion of our tests in clinical practice guidelines, our ability to commercialize products through our clinical development platform, our ability to expand our sales efforts into new areas of medical practice as we launch new products, 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 Oncotype IQ 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 tests that:

- screen for colorectal cancer,
- screen for multiple types of cancers using a single test,
- provide diagnostic information for liver cancer,
- provide prognostic information, guide therapy selection, or measure minimal residual disease or cancer recurrence.

We are aware of a number of companies — including Bioprognos, Bluestar Genomics, Burning Rock, Caris Life Sciences, CellMax, Inc., Clinical Genomics, DiaCarta, EarlyDx, Epigenomics AG, Foundation Medicine, Freenome Inc., Glycotest, GRAIL, Inc., Guardant Health, Inc., Helio Health, Immunovia AB, Inivata, Invitae, JBS Science, Natera Inc., Nucleix Ltd., Singlera Genomics, Sysmex Ignostics, and Tempus — that have developed, or are developing, liquid biopsy tests for the detection of cancer, based on the detection of proteins, tumor cells, nucleic acids, epigenetic markers, or other biomarkers. These tests could represent significant competition for our current tests, including our Cologuard and Oncotype IQ tests, as well as other tests we may develop. Guardant Health, Inc. and Freenome Inc. are conducting prospective colorectal cancer screening clinical trials intended to support FDA approval, and other companies may do so in the future.

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 at least one company that is offering or intends to offer in China a test that appears similar to our Cologuard test. 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 may have more expertise, experience, financial resources, or stronger business relationships. These competitors may have broader product lines and greater name recognition than we do. Furthermore, even if we do develop new marketable products or services, our current and future competitors may develop products and services that are more 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 provider activity, including for example influenza outbreaks that may reduce the percentage of patients that can be seen, 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 sanctions, including withdrawal of products from the market, recalls, refusal to authorize government contracts, product seizures, exclusion from participation in federal and state healthcare programs, civil money penalties, injunctions, and criminal prosecution.

U.S. Food and Drug Administration

Devices subject to FDA regulation must undergo premarket review prior to commercialization unless the device is exempt from such review. The FDA granted premarket approval ("PMA") for our Cologuard test in August 2014. The regulations governing Cologuard'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. There can be no assurance that the results of this study will be satisfactory and will not cause the FDA to modify or withdraw our approval for the Cologuard test.

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. The regulatory review and approval process for medical devices can be costly, timely, and uncertain. This process may involve, among other things, successfully completing additional clinical trials and submitting a premarket clearance notice or filing a premarket approval application with the FDA. If premarket review is required by the FDA, there can be no assurance that our tests will be cleared or approved on a timely basis, if at all. In addition, there can be no 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 products. Ongoing compliance with FDA regulations could increase the cost of conducting our business, subject us to FDA inspections and other regulatory actions, and potentially subject us to penalties in the event we fail to comply with such requirements.

Laboratory Developed Tests ("LDTs")

Our Oncotype IQ tests 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. Historically, LDTs have been regulated under CLIA while the FDA has exercised enforcement discretion and not required approvals or clearances for many LDTs performed by CLIA-certified laboratories. The FDA has traditionally chosen not to exercise its authority to regulate LDTs because LDTs were limited in number, were relatively simple tests, and were typically used to diagnose rare diseases and uncommon conditions.

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. The FDA has yet to implement any form of oversight requirements with respect to LDTs, and it is unclear at this time if or when the FDA ends enforcement discretion for LDTs. It is also unclear whether the FDA may decide to regulate certain LDTs on a case-by-case basis at any time. Action by the FDA to exercise enforcement discretion over LDTs may materially impact our development and commercialization of LDTs, including without limitation our Oncotype IQ 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, including those of California, New York, Maryland, Pennsylvania, Rhode Island and Florida, 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. If we fail to meet any applicable requirements of CLIA or state law, that failure could adversely affect any future CMS consideration of our technologies, prevent their approval entirely, and/or interrupt the commercial sale of any products and services and otherwise cause us to incur significant expense.

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, which protects personal information other than health information covered by HIPAA and allows certain data access and erasure rights to California consumers. Further, we are required to comply with international personal data protection laws and regulations, including the European Union's General Data Protection Regulation ("GDPR"). The GDPR is a prescriptive, detailed regulation that provides extensive powers to public authorities to sanction and stop use of personal data. While companies are afforded some flexibility in determining how to comply with the GDPR's various requirements, the GDPR has 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. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain stool, tissue, blood, and other patient samples and associated patient information could significantly impact our business and our future business plans, including potentially a temporary inability to provide tests to patients in the European Union.

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.

We may be subject to substantial penalties for violations of anti-fraud and abuse laws, including denial of payment and refunds or recoupments, suspension of payments from Medicare, Medicaid or other federal healthcare programs, and exclusion from participation in federal and state healthcare programs, as well as civil monetary and criminal penalties and imprisonment. 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

If we or our operations are found to be in violation of applicable laws and regulations prohibiting improper referrals for healthcare services or products, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U.S. federal or state healthcare programs, and the curtailment or restructuring of our operations.

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 to the Anti-Kickback Statute, in October 2018, Congress enacted the Eliminating Kickbacks in Recovery Act of 2018 ("EKRA") as a component of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. EKRA is an anti-kickback law similar to the federal Anti-Kickback Statute that, subject to several exceptions, makes it a criminal offense to pay any remuneration to induce referrals to, or in exchange for, patients using the services of a recovery home, a substance use clinical treatment facility, or laboratory. 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. That said, an interpretation of EKRA that prohibits certain incentive compensation payments to sales employees or other forms of remuneration that would otherwise be permissible under a safe harbor to the federal Anti-Kickback Statute would directly conflict with the intent of the federal Anti-Kickback Statute and regulations and would prohibit a number of practices that are common throughout the industry. Significantly, EKRA permits the U.S. Department of Justice ("DOJ") to issue regulations clarifying EKRA's exceptions or adding additional exceptions, but no such regulations or applicable guidance have yet been issued.

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.

Any action against us for violation of these or similar foreign laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

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. Our failure to comply with any applicable transparency reporting requirements may subject us to substantial penalties.

International

When marketing our tests outside of the U.S., we are subject to foreign 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. 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-kickback 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 that is reimbursable under any national healthcare program. 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 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, 2020, and there are no material expenditures planned for such purposes for the year ended December 31, 2021.

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. As of December 31, 2020, we had 130 issued patents in the U.S. and 733 issued patents outside of the U.S., which includes validated patents issued by the European Patent Office in key European Union countries, covering genes and methods that are components of the Cologuard test, Oncotype DX breast, colon and prostate cancer tests, pipeline technologies or research methods and platform technologies. In addition, we have a number of pending patent applications in the U.S. and in other countries, including provisional and non-provisional filings. Our issued U.S. patents expire at various times between 2022 and 2038. 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. In these patent applications, we have either sole or joint ownership positions. 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 patent applications. Under some 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. Generally, the license agreements require us to pay royalties based on certain net revenues received, and may require minimum royalty amounts, milestone payments, and maintenance fees.

Mayo

In June 2009, we entered into a license agreement with Mayo, which was most recently amended in September 2020. Under the license agreement, 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.

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, 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 various low single-digit royalty rates on net sales of current and future products using the licensed Mayo intellectual property during the term of the Mayo agreement.

In addition to the royalties described above, we are also required to pay Mayo cash of $0.2 million, $0.8 million, and $2.0 million upon each product using the licensed Mayo intellectual property reaching $5.0 million, $20.0 million, and $50.0 million in cumulative net sales, respectively.

As part of the September 2020 amendment, we agreed to pay Mayo an additional $6.3 million, payable in five annual installments, through 2024. The Company paid Mayo the first annual installment of $1.3 million in the third quarter of 2020 and will make subsequent annual payments in the first quarter of each year beginning in January 2021.

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 2038 (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 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.

Hologic

In October 2009, we entered into a technology license agreement with Hologic, Inc. (“Hologic”). Under the license agreement, Hologic granted us an exclusive, worldwide license within the field of human stool based colorectal cancer and pre-cancer detection or identification with regard to certain Hologic patents, patent applications and improvements, including Hologic’s Invader detection chemistry (the “Covered Hologic IP”). The licensed patents and patent applications contain both method and composition-of-matter claims. The jurisdictions covered by these patents and patent applications include the U.S., Australia, Canada, China, the European Union, Japan, and Korea. The license agreement also provided us with non-exclusive, worldwide licenses to the Covered Hologic IP within a field covering clinical diagnostic purposes relating to colorectal cancer (including cancer diagnosis, treatment, monitoring, or staging) and the field of detection or identification of colorectal cancer and pre-cancer through means other than human stool samples. In December 2012, we entered into an amendment to this license agreement with Hologic pursuant to which Hologic granted us a non-exclusive worldwide license to the Covered Hologic IP within the field of any disease or condition within, related to or affecting the gastrointestinal tract and/or appended mucosal surfaces.

We are required to pay Hologic a low single-digit royalty on our net sales of products using the Covered Hologic IP.

Unless earlier terminated in accordance with the agreement, the license agreement will remain in effect until the last of the licensed patents expires in 2029. The agreement contains customary termination provisions which, among other things, permit termination in the event of material uncured breaches.

Human Capital

Our vision to pursue smarter solutions that 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, 2020, we had approximately 5,000 full-time, part-time and temporary employees, 4,800 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 2020, our voluntary turnover rate was less than 9%, below the healthcare industry benchmark, which is comprised of certain of our key competitors (Aon, 2020 Salary Increase and Turnover Study — Second Edition, September 2020).

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 equal 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, gender identity, genetic information, veteran status, or any other basis prohibited by applicable law.

Our Senior VP of Human Resources is part of the executive leadership team and has direct responsibility for our diversity and inclusion program. 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 competitive benefits, women make up approximately 55% of total employees (full-time and part-time), and 50% of management positions. Our board of directors includes four female members to support diversity of opinion and perspective at the board level as well. In addition, we have been awarded with a Great Place to Work® Certification™ in 2020, Fortune's Best Workplaces in Health Care & Biopharma™ in 2020, and Fortune's Best Workplaces for Millennials™ in 2020.

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. We offer the following benefits, among others, to 100% of our U.S. employees, including part-time employees (subject, in certain cases, to minimum tenure or number of hours worked thresholds): medical, dental, and vision care coverage for all employees and their dependents; life, disability, and accident insurance and critical illness benefits; health care and dependent care flexible spending account programs; employer contributions to health savings accounts (for specific medical plans); 401(k) with employer matching; retirement planning resources; employee stock purchase plan; equity awards upon hire and annually thereafter; annual cash bonus program; parental leave program.

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, governed by the Exact Sciences' Employee Training Policy. The program applies to all our employees, including full-time, part-time, and temporary employees. Senior leadership, in conjunction with Human Resources, is responsible for ensuring that all personnel, including contractors and consultants, have the appropriate education, training, competency, and credentials.

Our organizational development team and functional training teams create opportunities for personal growth, professional growth, and career mobility. From facilitated workshops and podcasts to eLearning modules and succession planning, we have invested in internal capabilities to meet our employees at any stage of their career growth and development. We have also created a variety of tools to facilitate developmental feedback. Thanks, in large part, to our training and development investments, in 2020 we were able to fill 35% of our open positions with internal candidates.

Financial Information

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

Available Information

We were incorporated in the State of Delaware on February 10, 1995. Our corporate headquarters are located at 5505 Endeavor Lane, Madison, Wisconsin 53719. Our telephone number is 608-284-5700. Our Internet website address is *www.exactsciences.com*. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge through the investor relations page of our Internet website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. 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.
- We may need additional capital to execute our business plan.
- Our success depends heavily on our Cologuard and Oncotype IQ tests.
- Our operating results could be subject to significant fluctuation, which could increase the volatility of our stock price.
- Other companies or institutions may develop and market novel or improved technologies, which may make our technologies less competitive or obsolete.
- 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 rely upon single-source suppliers and loss or interruption of supply 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.
- 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 prohibitively expensive, customer satisfaction and our business could be negatively impacted.
- The success of our business is substantially dependent upon the efforts of our senior management team and our ability to attract and retain personnel.
- Our business and reputation will suffer if we are unable to establish and comply with stringent quality standards to assure that the highest level of quality is observed in the performance of our tests.
- Product and professional liability suits against us could result in expensive and time-consuming litigation, payment of substantial damages and increases in our insurance rates.
- Our inability to manage growth could harm our business.
- We may engage in acquisitions that are not successful and which could disrupt our business, cause dilution to our stockholders and reduce our financial resources.
- International expansion of our business exposes us to business, regulatory, political, operational, financial, compliance and economic risks associated with doing business outside of the U.S.
- The COVID-19 outbreak has and may further materially and adversely affect our business and financial results.
- We currently offer COVID-19 testing, but there can be no assurance that we will continue to be able to successfully offer, perform or generate revenues from the test.

Risks Relating to Governmental Regulation and Reimbursement

- We face uncertainty related to healthcare reform, pricing, coverage and reimbursement.
- If third-party payers, including managed care organizations, do not approve and maintain reimbursement for our Cologuard and Oncotype IQ tests at adequate reimbursement rates, our commercial success could be compromised.
- Because of Medicare billing rules or changes in Medicare billing rules and processes, we may not receive reimbursement for all tests provided to Medicare patients or may experience delays in receiving payments.
- If we are unable to obtain or maintain adequate reimbursement for our Oncotype IQ tests outside of the U.S., our ability to expand internationally will be compromised.
- If we fail to meet any applicable requirements of CLIA or similar state laws, that failure could adversely affect any future payer consideration of our technologies, prevent their approval entirely, and/or interrupt the commercial sale and/or marketing of any products and services and otherwise cause us to incur significant expense.
- Failure to maintain compliance with FDA requirements may prevent or delay the development, marketing or manufacturing of our Cologuard test, or future improvements to that test.
- Delays in obtaining regulatory clearances or approvals for new medical devices, or improvements to or expanded indications for our current offerings, could prevent, delay or adversely impact future product commercialization.
- If the FDA were to change its position with respect to its regulation of the laboratory developed tests we offer or plan to offer, we could incur substantial costs and time delays and decreased demand for or reimbursement of our tests.
- If we were required to conduct additional clinical trials, those trials could result in delays or failure to obtain necessary regulatory approvals or clearances, which could harm our business.
- 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 clinical diagnostics. We could be subject to significant fines and penalties if we or our partners fail to comply with these laws and regulations.
- Due to billing complexities in the diagnostic and laboratory service industry, we may not be able to collect payment for the tests we perform.
- 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.
- Compliance with the HIPAA security, privacy and breach notification regulations may increase our costs.
- We expect to rely on third parties to conduct any future studies of our technologies that may be required by the FDA or other US or foreign regulatory bodies, and those third parties may not perform satisfactorily.
- We are subject to increasingly complex taxation rules and practices.
- Our business is subject to complex and evolving laws, as well as customer and patient expectations, regarding data privacy, protection and security.

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

- We have finite resources, which may restrict our success in commercializing our products, and we may be unsuccessful in entering into or maintaining third-party arrangements to support our internal efforts.
- If we are unable to deploy and maintain effective sales, marketing and medical affairs capabilities, we will have difficulty achieving market awareness and selling our products and services.
- The success of our Cologuard test, our Oncotype IQ 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, our products.
- We expect to make significant investments to research and develop new cancer tests, which may not be successful.
- Our dependence on distributors for sales outside of the U.S. could limit or prevent us from selling our tests in foreign markets and impact our revenue.
- If we or Pfizer fail to adequately perform under our Cologuard Promotion Agreement, or if the Promotion Agreement is terminated prior to its full term, our business, prospects, financial condition and results of operations could be adversely affected.
- Our research and development efforts will be hindered if we are not able to obtain samples, contract with third parties for access to samples or complete timely enrollment in future clinical trials.

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.

Risks Relating to our Securities

- We are required to assess our internal control over financial reporting on an annual basis and any future adverse results from such assessment could result in a loss of investor confidence and an adverse effect on our stock price.
- We face risks associated with currency exchange rate fluctuations, which could adversely affect our operating results.
- Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations.
- 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 management has broad discretion over the use of our available cash and marketable securities and might not spend available cash and marketable securities in ways that increase the value of your investment.
- Our indebtedness could adversely affect our business, financial condition and results of operations.
- Servicing our debt will require a significant amount of cash, and we may not have sufficient cash flow from our business to pay amounts due under our indebtedness, including the convertible notes.

Risks Related to our Business and Business Strategy

We may never become profitable.

We have incurred losses since we were formed. From our date of inception on February 10, 1995 through December 31, 2020, we have accumulated a total deficit of approximately $1.97 billion. We expect to continue investing significantly toward development and commercialization of our colorectal cancer screening technology, our Oncotype IQ tests, our blood-based multi-cancer screening test and other products and services. If our revenue does not grow significantly, we will not be 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 business plan.

Although we believe that we have sufficient capital to fund our operations for at least the next twelve months, we may require additional capital to fully fund our current strategic plan, which includes successfully commercializing our Cologuard and Oncotype IQ 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, 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 stockholders' 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 or 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 colorectal cancer screening test and our Oncotype DX breast cancer test.

For at least the next 12 months, our ability to generate revenues will depend very substantially on the commercial success of our Cologuard and Oncotype DX breast cancer tests. There can be no assurance that we will develop or commercialize any other products or services that will generate significant revenue. The commercial success of our tests 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 United States;
- 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 sales, 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 third-party payers within and outside the U.S.
- the existence of federal or state laws that mandate coverage for colorectal cancer screening, the extent to which those laws mandate coverage of our Cologuard test 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 to grow sales of our Cologuard and Oncotype DX breast cancer tests or if we are delayed or limited in doing so, 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 stockholders.

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

- the impact of the COVID-19 pandemic on our business and operations;
- our success in marketing and selling, and changes in demand for, our Cologuard and Oncotype IQ tests, and the level of reimbursement and collection obtained for such tests;
- seasonal variations 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 for diagnostic tests and preventive services;
- our success in collecting payments from third-party 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 of costly clinical trials.

Other companies or institutions may develop and market novel or improved technologies, which may make our technologies less competitive or obsolete.

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 possess greater brand recognition, financial and other resources and development capabilities than us. As more information regarding cancer genomics becomes available to the public, we anticipate that competition will further increase. We expect to compete with a broad range of organizations in the U.S. and other countries that are engaged in the development, production and commercialization of cancer screening and diagnostic products and services. These competitors include:

- biotechnology, diagnostic and other life science companies;
- academic and scientific institutions;
- governmental agencies; and
- public and private research organizations.

The U.S. market for colorectal cancer and pre-cancer screening is large, consisting of nearly 110 million 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, and “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 and the fecal immunochemical test, and newer screening technologies. Newer screening technologies include liquid biopsy tests, such as Epi proColon, approved by the FDA in April 2016, and pill-based imaging solutions like PillCam COLON, cleared by the FDA in February 2014, and C-Scan, which obtained a CE Mark in early 2019. 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, DiaTech Pharmacogenetics, Prescient Metabiomics, and Geneoscopy, that are seeking to develop, stool-based colorectal cancer tests in the U.S. Our competitors may also be developing additional methods of detecting colorectal cancer and pre-cancer that have not yet been announced.

Similarly our Oncotype IQ products compete against a number of companies that offer products or have conducted research to profile genes and gene expression in breast, colon and prostate cancer. These companies include Agendia Inc., BioTheranostics, GenomeDx Biosciences Inc., Guardant Health, Inc., Hologic Inc., Myriad Genetics Inc. (and its Sividon Diagnostics subsidiary), NanoString Technologies Inc., NeoGenomics, Inc., OPKO Health, Inc. (and its Bio-Reference Laboratories, Inc. subsidiary), Pacific Edge Limited, Qiagen N.V. and Veracyte, Inc. Historically, our principal competition for our Oncotype IQ tests has also come from existing diagnostic methods used by pathologists and oncologists, and such traditional diagnostic methods can be difficult to change or supplement. Our Oncotype IQ tests also face competition from commercial laboratories with strong distribution networks for diagnostic tests, such as Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated. 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.

For our prostate cancer tests, we face comparatively greater competition than for our breast cancer tests, including competition from products which were on the market prior to our product launch and which are supported by clinical studies and published data. This existing direct and indirect competition for tests and procedures may make it difficult to gain market share, impact our ability to obtain reimbursement or result in a substantial increase in resources necessary for us to successfully continue to commercialize our Oncotype DX GPS prostate test and the Oncotype DX AR-V7 Nucleus Detect test.

We believe that our Oncotype IQ tests compete primarily on the basis of the value of the quantitative information they provide, the clinical validation of the utility of our tests, the level of adoption and reimbursement coverage for our tests, the inclusion of our tests in clinical practice guidelines, our ability to commercialize products through our clinical development platform, our ability to expand our sales efforts into new areas of medical practice as we launch new products, 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 Oncotype IQ 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 tests that:

- screen for colorectal cancer,
- screen for multiple types of cancers using a single test,
- surveil for liver cancer,
- provide prognostic information, guide therapy selection, or measure minimal residual disease or cancer recurrence.

We are aware of a number of companies — including Bioprognos, Bluestar Genomics, Burning Rock, Caris Life Sciences, CellMax, Inc., Clinical Genomics, DiaCarta, EarlyDx, Epigenomics AG, Foundation Medicine, Freenome Inc., Glycotest, GRAIL, Inc., Guardant Health, Inc., Helio Health, Immunovia AB, Inivata, Invitae, JBS Science, Natera Inc., Nucleix Ltd., Singlera Genomics, Sysmex Ignostics, and Tempus — that have developed, or are developing, liquid biopsy tests for the detection of cancer, based on the detection of proteins, tumor cells, nucleic acids, epigenetic markers, or other biomarkers. These tests could represent significant competition for our current tests, including our Cologuard and Oncotype IQ tests, as well as other tests we may develop. Guardant Health, Inc. and Freenome Inc. are conducting prospective colorectal cancer screening clinical trials intended to support FDA approval, and other companies may do so in the future.

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 the use of their test by healthcare providers or patients in other countries.

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 commercializing competing products and services. These competitors may have broader product lines and greater name recognition than we do. Furthermore, even if we do develop new marketable products or services, our current and future competitors may develop products and services that are more 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.

We currently perform our Cologuard test in two laboratory facilities in Madison, Wisconsin. We manufacture the Cologuard test in a single facility in Madison, Wisconsin. Our headquarters are also located in Madison, Wisconsin.

As we expand the commercialization of products and services and increase the number of tests processed by our laboratory facilities, we believe it may be necessary to both expand our existing laboratory facilities and to add one or more new manufacturing and laboratory facilities in order to increase our manufacturing and processing capacity to meet anticipated demand. During 2018 we expanded the capacity at our first laboratory facility in Madison, Wisconsin to approximately three million Cologuard tests per year. In 2019, we began performing the Cologuard test out of a second laboratory facility in Madison, Wisconsin. We estimate our current annual capacity to perform the Cologuard test at approximately seven million tests per year. In early 2020, we also completed construction of an additional manufacturing facility, warehouse, and office space in Madison, Wisconsin. Finally, our financial condition will be adversely affected if demand for our products and services does not materialize in line with our current expectations and if, as a result, we end up building excess capacity that does not yield a reasonable return on our investment.

We perform our Oncotype DX tests out of our clinical laboratory facilities in Redwood City, California. Redwood City is situated near active earthquake fault lines and we do not have a redundant facility where we can perform our Oncotype DX tests. 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 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.

In order to rely on a third party to perform certain of our tests, we could only use another facility with established state licensure and CLIA accreditation under the scope of which Oncotype DX tests could be performed following validation and other required procedures. We cannot assure you that we would be able to find another CLIA 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. In order to establish a redundant clinical reference laboratory outside of our Redwood City, California facilities, we would have to spend considerable time and money securing adequate space, constructing the facility, recruiting and training employees, and establishing the additional operational and administrative infrastructure necessary to support a second facility. We may not be able, or it may take considerable time, to replicate our testing processes or results in a new facility. Additionally, any new clinical reference laboratory facility opened by us 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 rely upon certain single-source suppliers and loss or interruption of supply from single-source suppliers could have a disruptive effect on our business.

We purchase certain supplies from third-party suppliers and manufacturers. In some cases, due to the unique attributes of products that are incorporated into our tests, we maintain a single-source supplier relationship. 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 perform their obligations in a timely and cost-effective manner and they may be unwilling to increase production capacity commensurate with demand for our tests or future products or services. Moreover, we may become dependent on other single-source suppliers as we expand and develop our product and service pipeline. The loss of a single-source supplier, the failure to perform by a single-source supplier, the deterioration of our relationship with a single-source supplier or any unilateral modification to the contractual terms under which we are supplied materials by a single-source supplier could have a disruptive effect on our business, and could adversely affect our results of operations.

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 are dependent 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. The regulatory environment governing information, security and privacy laws is increasingly demanding and continues to evolve. 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.

High-profile security breaches at other companies and in government agencies have increased in recent years, and security industry experts and government officials have warned about the risks of hackers and cyber-attacks targeting businesses such as ours. Cyber-attacks are becoming more sophisticated and frequent, and in some cases have caused significant harm. Computer hackers and others routinely attempt to breach the security of technology products, services and systems, and to fraudulently induce employees, customers, or others to disclosure information or unwittingly provide access to systems or data.

We have experienced and expect to continue to experience attempted cyber-attacks of our IT systems or 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
- and manage the administrative aspects of our business and damage our reputation.

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, including the California Consumer Privacy Act, the E.U. General Data Protection Regulation, or GDPR, and other regulations, the breach of which could result in significant penalties.

In addition, the interpretation and application of consumer, health related and data protection laws in the U.S., Europe and elsewhere are often uncertain, contradictory and in flux, such as in the area of international transfers of personal data. Genomic Health self-certified with the Department of Commerce for compliance with the U.S.-E.U. Privacy Shield in August 2016, and Exact Sciences self-certified in November 2019 and added Genomic Health, Inc. as a covered subsidiary in July 2020. The Privacy Shield was invalidated by the E.U. Court of Justice in July 2020 in Data Protection Commissioner v. Facebook Ireland decision (*"Schrems II"*), requiring Exact Sciences and all organizations exporting personal data from the E.U. to the U.S. to implement other measures to permit that transfer. European data protection authorities' and Exact Sciences customers have not consistently interpreted *Schrems II* so far, and an ultimate interpretation could significantly restrict performance of laboratory tests in the U.S. for persons in the E.U. More generally as well, authorities could interpret or apply European data protection law in a manner that is inconsistent with our practices. If so, this could result in prohibitions on processing of data required to perform our tests in Europe or government-imposed fines, or both, which could adversely affect our business. In addition, complying with these various laws, and satisfying healthcare providers' and patients' evolving expectations with respect to data protection, could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

System upgrades and enhancements require significant expenditures and allocation of valuable employee resources. We deployed SAP SE and Epic Systems Corporation ("Epic") software in our Madison, Wisconsin based operations in 2019. Since implementation, there have been significant software upgrades and roll-outs that have gone live and we expect this to continue over the next 12 months and beyond. Epic's software handles multiple components of our information technology system, from order entry all the way through revenue cycle and customer care. Differences in software and systems across our operations may create complexity and compatibility problems. As we complete acquisitions, it is necessary for us to integrate the acquired company's information technology systems into our existing systems. Delays in integration or disruptions to our business from implementation of new or upgraded systems could have a material adverse impact 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, integrating new systems, protecting confidential patient information, and improving service levels will not be delayed or that additional systems issues will not arise in the future. Failure to adequately protect and maintain the integrity of our information systems issues and data may result in 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 prohibitively 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 DX testing to our laboratory facilities in Redwood City, California 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.

If we use hazardous materials in a manner that causes injury, we could be liable for damages.

Our activities currently require the use of hazardous materials and medical specimens. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials or specimens. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products, as well as regulations relating to the safety and health of laboratory employees. The cost of compliance with these laws and regulations may become significant and could negatively affect our operating results.

The success of our business is substantially dependent upon the efforts of our senior management team and our ability to attract and retain personnel.

Our success depends largely on the skills, experience and performance of key members of our senior management team. Our executives are critical to directing and managing our growth and development in the future. Our success is substantially dependent upon our senior management's ability to lead our company, implement successful corporate strategies and initiatives, develop key relationships, including relationships with collaborators and business partners, and successfully commercialize products and services. If we were to lose any of our senior management team, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies.

Competition for desirable personnel is intense, and there can be no assurance that we will be able to attract and retain the necessary staff. Our research and development programs, commercial laboratory operations and information technology infrastructure depend on our ability to attract and retain highly skilled personnel. We may not be able to attract or retain qualified talent due to the competition for qualified personnel among life science and technology businesses, particularly in the San Francisco Bay Area. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. In addition, our success depends on our ability to attract and retain salespeople with extensive experience in primary care, oncology, gastroenterology and urology and close relationships with healthcare providers and other hospital personnel. 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 are not able to attract and retain the necessary personnel, our business and operating results could be harmed.

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 cancer 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.

Product and professional liability suits against us could result in expensive and time-consuming litigation, payment of substantial damages and increases in our insurance rates.

The sale and use of our tests could lead to product or professional liability claims. We may also be subject to liability for errors in the test results we provide to healthcare providers or for a misunderstanding of, or inappropriate reliance upon, the information we provide. Claims could also arise out of clinical studies we may conduct or any of our other activities. A product or professional liability claim could result in substantial damages, be costly and time consuming to defend, and cause material harm to our business, reputation or financial condition. We cannot assure you that our liability insurance would protect our assets from the financial impact of defending a product or professional liability claim. 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.

Our inability to manage growth could harm our business.

In connection with the commercialization of our tests, we have added, and expect to continue to add personnel in the areas of sales and marketing, laboratory operations, billing and collections, quality assurance and compliance. Our number of full-time employees has increased from 1,977, as of December 31, 2018, to 4,110, as of December 31, 2019 and to 4,833, as of December 31, 2020. Further, as we build our commercialization efforts and expand research and development activities for new products and services, the scope and complexity of our operations is increasing significantly. As a result of our growth, our operating expenses and capital requirements have also increased, 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 move forward in commercializing our tests, we will also need to effectively manage our growing manufacturing, laboratory operations and sales and marketing needs. We are continuing to expand our current facilities and add new facilities to support anticipated demand for our tests and anticipated growth in our personnel. 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 that are not successful and which could disrupt our business, cause dilution to our stockholders and reduce our financial resources.

We undertake acquisition activities from time to time. In November 2019 we completed the acquisition of Genomic Health, Inc., in March 2020 we completed the acquisitions of Paradigm Diagnostics, Inc. and Viomics, Inc., in October 2020 we completed the acquisitions of Base Genomics Limited and in January 2021 we completed the acquisition of Thrive Earlier Detection Corporation. Certain risks may exist as a result of these and other acquisition activities, including, among others, that:

- we may encounter potential unknown liabilities and unforeseen increased expenses, delays or unfavorable conditions in connection with the integration of the acquired businesses into our business;
- we may be unable to successfully integrate the acquired businesses into our business;
- we may lose key employees;
- we may encounter potential unknown liabilities and unforeseen risks associated with contracts containing consent and/or other provisions that may be triggered by the acquisitions;
- we may be unable to realize the anticipated benefits of the acquisitions or do so within the anticipated timeframe;
- our future results will suffer 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. Because we have only made a limited number of acquisitions to date, our ability to do so successfully is unproven. If we do identify suitable candidates, 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. In addition to the risks outlined above, we may decide to incur debt in connection with an acquisition or issue our common stock or other securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results.

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

Our business strategy incorporates 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, data protection laws, regulatory requirements and other governmental approvals, permits and licenses;
- significant competition from local and regional product offerings;
- difficulties in complying with unclear product regulations in various jurisdictions, including the changing regulation in Europe with regard to medical device and in vitro diagnostic ("IVD") regulations;

- 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;
- complexities associated with managing multiple payer reimbursement regimes, public payers or patient self-pay systems;
- logistics and regulations associated with shipping tissue samples 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, 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, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- regulatory and compliance risks that relate to maintaining accurate information and control over the activities of our salesforce and distributors that may fall within the purview of the U.S. 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;
- complexity of compliance with local standard contractual requirements to access public customers and payers.

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

The COVID-19 outbreak has and may further materially and adversely affect our business and financial results.

The COVID-19 outbreak, which the World Health Organization has classified as a pandemic, together with related precautionary measures, began to materially disrupt our business in March 2020 and may continue to disrupt our business for an unknown period of time. The territories in which we market, sell, distribute and perform our tests are attempting to address the COVID-19 pandemic in varying ways, including stay-at-home orders, temporarily closing businesses, restricting gatherings, restricting travel, and mandating social distancing and face coverings. Certain jurisdictions have begun re-opening only to return to restrictions due to increases in new COVID-19 cases. Even in areas where “stay-at-home” restrictions have been lifted and the number of cases of COVID-19 has declined, many individuals remain cautious about resuming activities such as preventive-care medical visits. Medical practices continue to be cautious about allowing individuals, such as sales representatives, into their offices. Many individuals continue to work from home rather from an office setting. The level and nature of the disruption caused by COVID-19 is unpredictable, may be cyclical and long-lasting and may vary from location to location. As a result, COVID-19 has significantly impacted, and may continue to significantly impact, our operating results including our revenues, margins, and cash utilization, among other measures.

Beginning in March 2020, we undertook temporary precautionary measures intended to help minimize the risk of the virus to our employees, including requiring most employees to work remotely; suspending field-based, face-to-face interactions by our sales force; requiring on-site employees to undergo COVID-19 testing, wear personal protective equipment (including face masks or shields) and maintain social distancing; pausing all non-essential travel worldwide for our employees; and limiting employee attendance at industry events and in-person work-related meetings, to the extent those events and meetings are continuing. Our commercial partner for our Cologuard test, Pfizer, took similar precautions, including suspending face-to-face interactions between sales representatives and healthcare providers.

We expect to adjust our precautionary measures at our various locations based on local recovery levels and applicable governmental regulations. For example, a portion of the Company’s and Pfizer’s sales force has recommenced field-based interactions, although access to healthcare providers remains limited and the resumption of normal activities is expected to be gradual. Our business could be negatively affected if we take excessive, ineffective or inadequate precautions.

The COVID-19 pandemic has materially impacted our business, and may continue to impact our business for an unknown period of time. Such impacts may include the following:

- Both our and Pfizer's sales teams have been, and for an extended period of time may continue to be, limited in their in-person interactions with healthcare providers, and therefore, also limited in their ability to engage in various types of healthcare provider education activities as contemplated by our and Pfizer's Cologuard promotion agreement; while we amended and restated our promotion agreement with Pfizer to, among other things, address changes to the operational landscape resulting from the COVID-19 pandemic, our expectations regarding the duration, severity and effects of the pandemic may prove inaccurate, and we may not realize the expected benefits from this agreement;
- Healthcare providers or patients have canceled or delayed scheduling, and for an extended period of time may continue to cancel or delay scheduling, standard wellness visits and other non-emergency appointments and procedures (including mammograms and prostate cancer screenings), contributing to a decline in orders for our products or services;
- Restrictions on travel, commerce and shipping may prevent patients and pathologists from shipping samples to our clinical laboratories;
- Illnesses, quarantines, financial hardships, restrictions on travel, commerce and shipping, or other consequences of the pandemic, may disrupt our supply chain or other business relationships, and we or other parties may assert rights under force majeure clauses to excuse performance;
- We have experienced, and for an extended period of time may continue to experience, reduced volumes at our clinical laboratories and we may need to suspend operations at some or all of our clinical laboratories;
- We have taken, and may take additional, cost cutting measures, which may hinder our efforts to commercialize our products or delay the development of future products and services but we might not realize all of the cost savings we expect to achieve as a result of those efforts;
- We and our partners have postponed or cancelled clinical studies, which may delay or prevent our launch of future products and services;
- Our workforce, much of which has been asked to work remotely in an effort to reduce the spread of COVID-19, may be infected by the virus or otherwise distracted;
- A combination of factors, including infection from the virus, supply shortfalls, and inability to obtain or maintain equipment, could adversely affect our lab capacity and our ability to meet the demand for our testing services. In March of 2020 we began offering a COVID-19 test and by devoting lab capacity and supplies to that test, we may experience capacity limitations and supply shortfalls that adversely affect our ability to provide our Cologuard test and other tests that may generate more revenue and higher profits; and
- We may inaccurately estimate the duration or severity of the COVID-19 pandemic, which could cause us to misalign our staffing, spending, activities and precautionary measures with market current or future market conditions.

Despite our efforts, the ultimate impact of COVID-19 depends on factors beyond our knowledge or control, including the duration and severity of the outbreak, third-party actions taken to contain its spread and mitigate its public health effects and short- and long-term changes in the behaviors of medical professionals and patients resulting from the pandemic.

We currently offer COVID-19 testing, but there can be no assurance that we will continue to be able to successfully offer, perform or generate revenues from the test.

In late March 2020, we began providing COVID-19 testing. While we have entered into a limited number of contracts to provide COVID-19 testing and expect to pursue additional contracts, there can be no assurance that our efforts to offer and perform COVID-19 testing will be successful. The success of our test, our ability to continue to generate revenues from COVID-19 testing, and our ability to generate profits from COVID-19 testing will depend on a variety of factors, including:

- the level of demand for COVID-19 testing, the price we are able to charge for performing the test, and the length of time for which that demand persists;
- the availability of COVID-19 testing, from other laboratories;
- acceptance of our COVID-19 testing in the medical community;
- the emergence of other forms of COVID-19 testing (including antigen and antibody screening tests) and other sample collection methods, which healthcare providers and patients may prefer to our test;
- our ability to maintain regulatory approvals to perform and market COVID-19 testing and to respond to any changes in regulatory requirements;
- the potential for supply disruptions and our reliance on certain single-source suppliers;
- the potential for disruption in the delivery of patient samples to our laboratories;

- the capacity of our laboratories to satisfy both COVID-19 testing and other testing demands;
- the extent to which we choose to allocate limited laboratory capacity, supplies and other resources to areas of our business other than COVID-19 testing;
- the complexity of billing for, and collecting payment for, our test;
- healthcare provider and patient compliance with instructions for performing the nasal swab and providing samples to our laboratories;
- our ability to maintain laboratory operations during the COVID-19 pandemic and to perform the test accurately and punctually; and
- the ease of use of our ordering and reporting process.

Additionally, we have previously only offered cancer screening and diagnostic tests. The addition of COVID-19 testing may divert resources and distract management's attention from other projects that may be more profitable or strategic. If we are unable to successfully provide COVID-19 testing while continuing to operate our existing Screening and Precision Oncology business, our results of operations, financial position and reputation may suffer.

Risks Relating to Governmental Regulation and Reimbursement

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

Healthcare reform laws, including the Patient Protection, the ACA, and the Protecting Access to Medicare Act of 2014 ("PAMA"), are significantly affecting the U.S. healthcare and medical services industry. Existing legislation, and possible future legal and regulatory changes, including potential repeal or modification of the ACA, elimination of penalties regarding the individual mandate for coverage, or approval of health plans that allow lower levels of coverage for preventive services, 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 in December 2018, a federal district court in Texas found that the ACA's "individual mandate" was unconstitutional such that the whole of the ACA is invalid. The decision was appealed and, in December 2019, the Fifth Circuit Court of Appeals affirmed certain portions of the district court's decision, but remanded to the district court to determine if any portions of the ACA may still be valid. In March 2020, the United States Supreme Court granted certiorari in the consolidated cases which address the Fifth Circuit decision. The Supreme Court has heard oral arguments, but has not ruled in the case. If the plaintiffs in this case, or in any other case challenging the ACA, are ultimately successful, insurance coverage for our Cologuard test 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 Cologuard test 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, such as our Cologuard test or other products or tests 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.

PAMA presents significant uncertainty for future CMS reimbursement rates for our tests. 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". The CMS reimbursement rates for clinical diagnostic laboratory tests are updated based on the volume-weighted median of private payer rates for each clinical diagnostic laboratory test based on data submitted by certain applicable laboratories. Based on current regulations, we expect that the current CMS reimbursement rate for our Cologuard and Oncotype IQ tests will remain unchanged until December 2022 and then will be reset for calendar years 2023-2025 based on the volume-weighted median of private payer rates for Cologuard and Oncotype IQ tests during the data collection period from January 1, 2019 to June 30, 2019. The Coronavirus Aid, Relief, and Economic Security ("CARES") Act further delayed the next reporting period by another year to the period from January 1, 2022 to March 31, 2022. Laboratories that fail to report or erroneously report required payment information may be subject to substantial civil money penalties. 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 products that we may develop may also depend, in whole or in part, on whether payers determine, or courts and/or regulatory authorities determine, coverage is required under applicable federal or state laws mandating coverage of certain cancer screening services. For example, Section 2713 of the ACA mandates that certain 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 (“ACA Mandate”). Similarly, federal regulations require that Medicare Advantage plans cover “A” or “B” rated preventive services without patient cost-sharing. Following the June 2016 update to the USPSTF colorectal cancer screening 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 for average risk individuals between the ages of 50 and 75 without patient cost-sharing. While we believe the ACA Mandate requires most health insurers to cover our Cologuard test for most patients between the ages of 50 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. It may be difficult for us or patients to enforce the ACA Mandate directly, and we may need to rely on states to take enforcement action, which they may choose not to do. It is also possible that the ACA Mandate will be repealed or overturned or significantly modified in the future.

Several states have laws mandating coverage for preventive services, such as colorectal cancer screening services, applicable to certain health insurers. However, not all of these laws apply to our Cologuard test and not all of these laws presently mandate coverage for patients within the 45-49 age range. We and payers may disagree about how these mandates apply to our Cologuard test and we may find the mandates difficult to enforce. Further, if the ACA is repealed, replaced or overturned, or even if it is not, states may decide to modify their laws, which may include repeal of those coverage mandates that we believe currently apply to our Cologuard test.

Outside of the U.S., we largely depend on public or government-controlled or regulated payers for coverage of our Oncotype IQ tests. As compared to many more routine diagnostic tests, our Oncotype IQ tests are more complicated, expensive and are performed in a central, specialized lab. In order to accommodate the unique characteristics of our Oncotype IQ tests, public payers in certain non-U.S. markets have designed reimbursement frameworks specifically for our tests. These payers could decide to modify or discontinue these special frameworks, potentially leading to lower reimbursement prices or the impossibility of providing the test in the market. Existing reimbursement processes or changes to those processes could impose additional administrative burdens on us, such as complex public tendering procedures, or on ordering physicians, which could adversely affect the number of payers covering the test or the number of orders placed. Public payers could condition reimbursement of our tests upon performance of our tests locally or, even in laboratories owned or operated by the payers. Any such change would adversely affect our ability to continue to serve those patients through our centralized labs in the U.S.

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

Our commercial success depends, in large part, on the availability of adequate reimbursement from government insurance plans, managed care organizations and private 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. 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 are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new healthcare products. 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 guidelines organizations; subject to applicable federal or state coverage mandates; reliable, safe and effective; medically necessary; appropriate for the specific patient; and cost-effective.

Our Oncotype DX Breast Recurrence Score test has received certain negative assessments in the past relating to technology criteria for clinical effectiveness and appropriateness for use in patients with N+ disease, and our tests may receive similar negative assessments in the future. Since each payer makes its own decision as to whether to establish a policy to reimburse our tests, seeking these approvals is a time-consuming and costly process. To date, we have positive coverage determinations for our Oncotype DX breast cancer test for N-, ER+ patients from most third party payers in the United States through contracts, agreements or policy decisions. We cannot be certain that coverage for this test will be provided in the future by additional third party payers or that existing contracts, agreements or policy decisions or reimbursement levels, including tests processed as out of network, will remain in place or be fulfilled within existing terms and provisions.

We have obtained limited reimbursement from private third-party payers in the U.S. for our Oncotype DX colon cancer test and for our Oncotype DX breast cancer test for N+ and DCIS patients. Until further clinical data is presented, our N+ and DCIS indication for our breast cancer test and our colon cancer test may be considered investigational by payers and therefore may not be covered under their reimbursement policies.

We have obtained Medicare reimbursement coverage for our Oncotype DX GPS prostate cancer test for low and very-low risk patients, unfavorable and favorable intermediate risk patients, and high risk patients. However, we may not be able to obtain other third-party payer reimbursement for our tests for patients with colon or prostate cancer or with N+ breast cancer or DCIS that is similar to the coverage we have obtained for our invasive breast cancer test for N-, ER+ patients.

Under the terms of the coverage determinations for our Oncotype DX GPS prostate cancer test, coverage for the test for patients with certain risk profiles is limited to tests ordered by healthcare providers who agree to participate in a Certification and Training Registry, or CTR, and to provide certain information about Medicare beneficiaries who receive our test. If healthcare providers do not timely submit necessary information as part of participating in the CTR, the timeframe in which we are reimbursed and recognize revenue for those tests may be accordingly delayed.

From time to time payers change processes that may affect timely payment. These changes may result in uneven cash flow or impact the timing of revenue recognized with these payers. Additionally, on a five-year rotational basis, Medicare requests bids for its regional Medicare Administrative Contractor, or MAC, services. In September 2013, the claims processing function for the jurisdiction in which we process Oncotype IQ tests transitioned from Palmetto to Noridian Healthcare Solutions, although coverage determinations for those tests remain with Palmetto at this time through the MolDx Program. Future changes in the MAC with jurisdiction over our tests may affect our ability to obtain Medicare coverage and reimbursement for tests for which we have or may seek coverage.

Successful commercialization of our newly developed products and products in development will also depend on our ability to obtain adequate coverage from government insurance plans, managed care organizations and private insurance plans for such products.

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 Cologuard and Oncotype IQ tests, they will continue to apply in the future. As noted above, under PAMA, our Medicare reimbursement rates will be subject to adjustment based on our volume-weighted median commercial reimbursement rate. Any reduction in our Medicare reimbursement rates could significantly and adversely affect our business prospects, financial condition and results of operations.

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 require that they give prior authorization for a test before they are willing to pay for it or review claims post-service to ensure the service was medically appropriate for specific patients. Prior authorization and other medical management practices may require that we, patients or healthcare providers provide the payer with extensive medical records and other information. Prior authorization and other medical management practices impose a significant additional cost 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.

Because of Medicare billing rules or changes in Medicare billing rules and processes, we may not receive reimbursement for all tests provided to Medicare patients or may experience delays in receiving payments.

Under Medicare billing rules, payment for our Oncotype IQ tests performed on Medicare beneficiaries who were hospital patients at the time the tumor tissue samples were obtained and whose tests were ordered less than 14 days from discharge must be bundled into the payment that the hospital receives for the services provided. Effective January 1, 2018, CMS changed its rules to permit laboratories that perform molecular pathology tests on specimens collected during a hospital outpatient stay to bill Medicare directly for such tests if they were performed following a hospital outpatient's discharge from the hospital outpatient department. The rule remains unchanged with respect to payment for our Oncotype IQ tests performed on Medicare beneficiaries who were hospital inpatients at the time the tumor tissue was collected and whose tests were ordered less than 14 days from discharge – payment for those tests must be bundled into the payment that the hospital receives for its services provided. In these circumstances, hospitals are required to furnish services such as our tests as "services furnished under arrangements between a provider and an outside vendor" and only the hospital may bill Medicare for such tests. Under these circumstances, where the date of service for Medicare billing purposes is the date the specimen was collected and such date is within 14 days of inpatient discharge, we are required to bill hospitals for such tests. We refer to this rule, as it has been in effect and most recently amended as of January 1, 2018, as the Medicare Date of Service billing regulation.

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 Date of Service rule, 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. Our inability to successfully collect payment from a hospital financially responsible for a test affected by the Medicare Date of Service rule may lead us to reject orders from that hospital that implicate the Medicare Date of Service billing regulation until any outstanding bills are paid. Compared to our breast cancer tests, a greater proportion of eligible patients for our colon and prostate Oncotype IQ tests are covered by Medicare. We cannot assure you that Medicare will continue the Medicare Date of Service billing regulation in its current form, that Medicare will not seek to include molecular pathology tests in hospital outpatient bundling rules in the future, or that other payers will not adopt similar billing rules. As described in Note 15 of the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K, the United States DOJ is investigating Genomic Health's compliance with the Medicare Date of Service billing regulation. An adverse outcome could include our being required to pay treble damages, incur civil and criminal penalties, paying attorneys' fees, entering into a corporate integrity agreement, being excluded from participation in government healthcare programs, including Medicare and Medicaid, and other adverse actions that could materially and adversely affect our business, financial condition and results of operations.

If we are unable to obtain or maintain adequate reimbursement 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, prostate and colon cancer test revenues come from payer reimbursement, payments from our distributors, and patient self-pay. In many countries outside of the U.S., various coverage, pricing and reimbursement approvals are required for our tests to be available to patients in significant volume. We expect that it will take several years to establish broad coverage and reimbursement for our tests with payers in countries outside of the U.S., and our efforts may not be successful.

Even if public or private reimbursement is obtained, it may 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. We may also be negatively affected by the financial instability of, and austerity measures implemented by, several countries in the European Union and elsewhere.

If we fail to meet any applicable requirements of CLIA or similar state laws, that failure could adversely affect any future payer consideration of our technologies, prevent their approval entirely, and/or interrupt the commercial sale and/or marketing of any products and services and otherwise cause us to incur significant expense.

We and certain laboratories with whom we collaborate are subject to federal and state laws and regulations regarding the operation of clinical laboratories. Federal CLIA requirements and laws of certain states, including New York, impose certification requirements for clinical laboratories, establish standards for quality assurance and quality control, among other things. Some state laws restrict laboratory marketing activities, which may adversely affect our ability to market our laboratory services. Clinical laboratories are subject to inspection by regulators, and to sanctions for failing to comply with applicable requirements. Sanctions available under CLIA include prohibiting a laboratory from running tests, requiring a laboratory to implement a corrective plan, and imposing civil monetary penalties. If we or our third party partners fail to meet any applicable requirements of CLIA or state law, that failure could adversely affect any payer consideration of our current or future technologies, prevent their approval entirely, and/or interrupt the commercial sale and/or marketing of any products and services and otherwise cause us to incur significant expense.

Failure to maintain compliance with FDA requirements may prevent or delay the development, marketing or manufacturing of our Cologuard test, or future improvements to that test.

As a condition of the FDA approval of our Cologuard test, we were required to conduct a post-approval study. The post-approval study concluded in 2020 and final results were submitted to FDA in late 2020. There is a risk that the FDA may modify or withdraw the approval of our Cologuard test if the results of this post-approval study are not satisfactory. We anticipate feedback from FDA in 2021 on the acceptance of these data to close the post-approval order.

Additionally, our Madison, Wisconsin manufacturing and laboratory facilities are periodically subject to inspection by the FDA and other governmental agencies to ensure they meet production and quality requirements. Operations at these facilities could be interrupted or halted if the FDA or other governmental agency deems the findings of such inspections unsatisfactory.

Further, failure to comply with FDA or other regulatory requirements regarding the development, marketing, promotion, manufacturing and distribution of our tests could result in fines, unanticipated compliance expenditures, recall or seizures of our products, total or partial suspension of production or distribution, restrictions on labeling and promotion, termination of ongoing research, disqualification of data for submission to regulatory authorities, enforcement actions, injunctions and criminal prosecution.

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 obtaining regulatory clearances or approvals for new medical devices, or improvements to or expanded indications for our current offerings, could prevent, delay or adversely impact future product commercialization.

We may develop new tests that are regulated by the FDA as medical devices. Unless otherwise exempted, medical devices must receive either FDA regulatory approval or clearance before being marketed in the U.S. 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. However, we believe 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 not just required for new medical devices we develop, but would also be required for certain enhancements we may seek to make to our Cologuard test.

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.

If the FDA were to change its position with respect to its regulation of the laboratory developed tests we offer or may seek to offer in the future, we could 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.

The FDA has regulatory responsibility over, among other areas, instruments, test kits, reagents and other medical devices used by clinical laboratories to perform diagnostic testing. Clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, frequently develop internal LDTs to provide diagnostic results to customers. LDTs are subject to CMS oversight through its enforcement of CLIA. The FDA has also claimed regulatory authority over all LDTs, but indicates that it has exercised enforcement discretion with regard to most LDTs offered by CLIA-certified laboratories, and has not subjected these tests to the panoply of FDA rules and regulations governing medical devices. IVDs like our Cologuard test are regulated as medical devices by the FDA. We believe that our Oncotype IQ tests are not diagnostic kits and also believe that they are LDTs that are subject to regulation under CLIA and applicable state laws. As a result, we believe our Oncotype IQ products fall within the scope of FDA's exercise of enforcement discretion and should not be subject to FDA oversight or review under current FDA guidelines. Packaging requirements for receipt of tumor tissue for our Oncotype IQ products may be subject to regulation under Department of Transportation, International Air Transport Association, and other state, regional, or local laws.

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. For example, in October 2014, the FDA published two draft guidance documents describing a proposed risk-based framework under which the FDA might regulate LDTs. The FDA's draft framework proposed, among other things, premarket review for higher-risk LDTs, such as those that have the same intended use as FDA-approved or cleared diagnostics currently on the market. In November 2015, the FDA issued a report citing evidence for the need for additional regulation of LDTs and stated the FDA is continuing to work to finalize premarket review requirements for LDTs. However, in November 2016 the FDA announced it would not issue a final guidance for LDTs. In January 2017, the FDA issued a Discussion Paper on LDTs, which confirmed it would not finalize its guidance on the regulation of LDTs to allow more time for public discussion and time for the congressional authorizing committees to develop a legislative solution. In August, 2020, the U.S. Department of Health and Human Services ("HHS") published a policy stating that FDA must engage in notice-and-comment rulemaking before requiring premarket review of LDTs. It is unclear whether the Biden administration and a new Secretary of HHS will retain this policy or whether FDA will proceed with rulemaking to regulate LDTs in the future.

In addition, legislative proposals addressing oversight of LDTs have been introduced in previous Congresses, and we expect that new legislative proposals will be introduced from time to time in the future. Notably, the Verifying Accurate Leading-edge IVCT Development Act which was introduced into both houses of Congress in March 2020, would provide FDA with Authority to regulate LDTs. However, it remains unknown whether Congress will enact this or any other legislation regulating LDTs and, if so, what regulatory approach Congress and FDA will adopt. Accordingly, we cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for our Oncotype IQ tests or new tests we develop, whether through finalization of guidance issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. It is possible that legislation will be enacted into law or guidance could be issued by the FDA which may result in increased regulatory burdens for us to continue to offer our Oncotype IQ tests or to develop and introduce new LDTs.

If pre-market review is required for our current LDTs, our business could be negatively impacted in the U.S. until such review is completed and clearance or approval is obtained, and the FDA could require that we stop selling our tests pending pre-market clearance or approval.

If our Oncotype IQ 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. The regulatory approval process may involve, among other things, successfully completing additional clinical trials and submitting a pre-market clearance notice or filing a pre-market approval application with the FDA. 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. Ongoing compliance with FDA regulations with respect to our current LDTs would increase the cost of conducting our business, and subject us to inspection by and the regulatory requirements of the FDA, for example registration and listing and medical device reporting, and penalties in the event we fail to comply with these requirements. We may also decide voluntarily to pursue FDA pre-market review of our LDTs if we determine that doing so would be appropriate.

We cannot predict the ultimate timing or form of final FDA guidance, legislation or regulation of LDTs and the potential impact on our existing tests, our tests in development or the materials used to perform our tests. While we qualify all materials used in our LDTs according to CLIA regulations, we cannot be certain that the FDA will not enact rules or guidance documents that could impact our ability to purchase certain materials necessary for the performance of our LDTs, such as products labeled for research use only. Should any of the reagents obtained by us from suppliers and used in conducting our LDTs be affected by future regulatory actions, our business could be adversely affected by those actions, including increasing the cost of testing or delaying and limiting or prohibiting the purchase of reagents necessary to perform testing.

If we were required to conduct additional clinical trials prior to continuing to sell our current LDTs or launching any other LDTs we may develop, those trials could result in delays or failure to obtain necessary regulatory approvals or clearances, which could harm our business.

If the FDA decides to regulate any of our LDTs, it may require additional pre-market clinical testing before clearing or approving such tests for commercial sales. 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 LTDs, and interrupt sales of our current LTDs. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial.

We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of those trials. We may also depend on clinical investigators, medical institutions and contract research organizations to perform certain aspects of the trials. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may have to be extended, delayed or terminated. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or approvals as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our LDTs. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our LDTs, or to achieve sustained profitability.

Changes in funding or disruptions at FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA 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, federal government shutdowns, 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, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new medical devices or modifications to cleared or approved medical devices to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to 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), it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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 United States by both the federal government and the states in which we conduct our business, as well as in other jurisdictions outside of the United States, including:

- Medicare billing and payment regulations applicable to clinical laboratories;
- 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 Federal Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA") and the California Consumer Privacy Act of 2018;
- the Medicare civil money penalty and exclusion requirements;
- the Federal False Claims Act civil and criminal penalties and state equivalents; and
- the Foreign Corrupt Practices Act, 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.

The U.S. Attorney's Offices have increased their scrutiny over the healthcare industry in recent years. The U.S. Congress, 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, governmental enforcement action may result in substantial fines, penalties or administrative remedies, including exclusion from government reimbursement programs and entry into corporate integrity agreements with governmental agencies, which 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, we are currently responding to civil investigative demands initiated by the U.S. DOJ concerning (1) Genomic Health's compliance with the Medicare Date of Service billing regulations and (2) allegations that we offered or gave gift cards to patients in exchange for returning the Cologuard screening test, in violation of the Federal Anti-Kickback Statute and False Claims Act. Adverse outcomes from these investigations could include our being required to pay treble damages, incur civil and criminal penalties, paying attorney's fees, entering into a corporate integrity agreement, being excluded from participation in government healthcare programs, including Medicare and Medicaid, and other adverse actions that could materially and adversely affect our business, financial condition and results of operations.

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 United States 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. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, we could be required to refund payments received by us, and we could lose the ability to bill for our tests and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

Our business is subject to various complex laws and regulations applicable to clinical diagnostics. We could be subject to significant fines and penalties if we or our partners fail to comply with these laws and regulations.

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 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, including Pfizer, 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. 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, the U.S. DOJ is investigating Genomic Health's compliance with the Medicare Date of Service billing regulation. An adverse outcome could include our being required to pay treble damages, incur civil and criminal penalties, paying attorneys' fees, entering into a corporate integrity agreement, being excluded from participation in government healthcare programs, including Medicare and Medicaid, and other adverse actions that could materially and adversely affect our business, financial condition and results of operations.

Due to billing complexities in the diagnostic and laboratory service industry, we may not be able to collect payment for the tests we perform.

Billing for diagnostic and laboratory services is a complex process. Laboratories 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 have to litigate to enforce coverage obligations under Medicare laws and laws that mandate coverage for certain screening or diagnostic tests or to enforce contractual coverage obligations. Such litigation may be costly, may divert management attention from other responsibilities, may cause payers, including those not directly involved in the litigation, to resist contracting with us, and may ultimately prove unsuccessful for a variety of reasons. We 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. We may face write-offs of doubtful accounts, disputes with payers and patients, and long collection cycles. 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 do 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:

- 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; and
- failure by patients or healthcare providers to provide complete and correct billing information.

Sometimes, 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.

The uncertainty of receiving payment for our tests and complex laboratory billing processes could negatively affect our business and our operating results.

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. 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.

In 2018, Congress passed EKRA as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. Similar to the Medicare/Medicaid anti-kickback law, 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. However, unlike the Medicare/Medicaid anti-kickback law, EKRA is not limited to services covered by federal or state healthcare programs but applies more broadly to services covered by "healthcare benefit programs," including commercial insurers. As currently drafted, EKRA potentially expands the universe of arrangements that could be subject to government enforcement under federal fraud and abuse laws. In addition, while the Medicare/Medicaid anti-kickback law includes certain exceptions that are widely relied upon in the healthcare industry, not all of those same exceptions apply under EKRA. Because EKRA is a relatively new law, there is no agency guidance or 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.

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 foreign laws prohibiting 'kickbacks' as well as the Foreign Corrupt Practices Act.

Many countries in which we 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 U.S. 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 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.

The standard of intent and knowledge in the anti-bribery cases is minimal, and intent and knowledge are usually inferred from that fact that bribery took place. The accounting provisions do not require intent. Violations of the FCPA's anti-bribery provisions for corporations and other business entities may result in a fine of up to $2 million and officers, directors, stockholders, employees, and agents are subject to a fine of up to $100,000 and imprisonment for up to five years. Other countries, including the U.K. and other OECD Anti-Bribery Convention members, have similar extraterritorial anti-corruption laws.

Compliance with the HIPAA security, privacy and breach notification regulations may increase our costs.

The HIPAA privacy, security and breach notification regulations, including the expanded requirements under HITECH, establish comprehensive federal standards with respect to the uses and disclosures of protected health information ("PHI") by health plans, healthcare providers and healthcare clearinghouses, in addition to setting standards to protect the confidentiality, integrity and security of PHI. The regulations establish a complex regulatory framework on a variety of subjects, including:

- the circumstances under which uses and disclosures of PHI are permitted or required without a specific authorization by the patient, including but not limited to treatment purposes, activities to obtain payments for our services, and our healthcare operations activities;
- a patient's rights to access, amend and receive an accounting of certain disclosures of PHI;
- requirements to notify individuals if there is a breach of their PHI;
- the contents of notices of privacy practices for PHI;
- administrative, technical and physical safeguards required of entities that use or receive PHI; and
- the protection of computing systems maintaining electronic PHI.

We have implemented practices intended to meet the requirements of the HIPAA privacy, security and breach notification regulations, as required by law. We are required to comply with federal privacy, security and breach notification regulations as well as varying state privacy, security and breach notification laws and regulations, which may be more stringent than federal HIPAA requirements. In addition, for healthcare data transfers from other countries relating to citizens of those countries, we must comply with the laws of those countries. The federal privacy regulations restrict our ability to use or disclose patient identifiable data, without patient authorization, for purposes other than payment, treatment, healthcare operations and certain other specified disclosures such as public health and governmental oversight of the healthcare industry.

HIPAA provides for significant fines and other penalties for wrongful use or disclosure of PHI, including potential civil and criminal fines and penalties. Computer networks are always vulnerable to breach and unauthorized persons may in the future be able to exploit weaknesses in the security systems of our computer networks and gain access to PHI. Additionally, we share PHI with third-parties who are legally obligated to safeguard and maintain the confidentiality of PHI. Unauthorized persons may be able to gain access to PHI stored in such third-parties computer networks. Any wrongful use or disclosure of PHI by us or such third-parties, including disclosure due to data theft or unauthorized access to our or our third-parties computer networks, could subject us to fines or penalties that could adversely affect our business and results of operations. Although the HIPAA statute and regulations do not expressly provide for a private right of damages, we could also incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information.

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 United States and similar foreign fraudulent misconduct 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 have adopted a code of business conduct and ethics, 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 US 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, including the post-approval studies required by the FDA for our Cologuard test. 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 third parties that we do not control 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, and we may not be able to obtain a required regulatory approval.

We are subject to increasingly complex taxation rules and practices, which may affect how we conduct our business and our results of operations.

As our business grows, we are required to comply with increasingly complex taxation rules and practices. We are subject to tax in multiple U.S. tax jurisdictions and in foreign tax jurisdictions as we continue to expand internationally. 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.

Our business is subject to complex and evolving laws, as well as customer and patient expectations, regarding data privacy, protection and security.

The interpretation and application of consumer, health related and data protection laws in the U.S., Europe and elsewhere are often uncertain, contradictory and in flux. In order to mitigate concerns about overseas data transfers and to comply with provisions of the GDPR and its predecessor regulations, we self-certified with the Department of Commerce for compliance with the U.S.-E.U. Privacy Shield. However, the Court of Justice of the European Union invalidated the U.S.-E.U. Privacy Shield program in its July 2020 Schrems II decision. Although we are taking other measures to ensure compliance with the GDPR, the changing legal landscape could cause us to incur substantial costs or change our operations and compliance procedures, all of which may adversely affect our business.

If we fail to comply with the GDPR and other applicable data privacy, protection and security laws, or if we fail to satisfy customer or patient concerns regarding data handling, we could be subject to government injunctions or other enforcement actions including a prohibition on processing patient data at our centralized laboratories in the U.S., as well as private litigation, civil, administrative, or criminal penalties, reduced orders and adverse publicity.

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

We have finite resources, which may restrict our success in commercializing our products, and we may be unsuccessful in entering into or maintaining third-party arrangements to support our internal efforts.

To grow our business as planned, we must expand our sales, marketing and customer support capabilities, which will involve developing and administering our commercial infrastructure and/or collaborative commercial arrangements and partnerships. We must also maintain satisfactory arrangements for the manufacture and distribution of our tests. Also, we operate CLIA certified lab facilities to process our tests and provide patient results.

Prior to our combination with Genomic Health in November 2019, we only had one commercial test. We have limited experience managing a sales force, customer support operation and operating manufacturing and clinical laboratory operations for multiple products in multiple locations with divergent regulatory requirements. We may encounter difficulties retaining and managing the specialized workforce these activities require. We may seek to partner with others to assist us with any or all of these functions. However, we may be unable to find appropriate third parties with whom to enter into these arrangements.

Our sales efforts have grown in size and complexity. We now maintain sales forces with primary care, oncology, GI, urology and women's health call points. We must coordinate among our internal sales teams, as well as with Pfizer's, to ensure that we are effectively and compliantly marketing our tests.

If we are unable to deploy and maintain effective sales, marketing and medical affairs capabilities, we will have difficulty achieving market awareness and selling our products and services.

To achieve commercial success for our Cologuard and Oncotype IQ tests and our future products and services, we must continue to develop and grow our sales, marketing and medical affairs organizations to effectively explain to healthcare providers the reliability, effectiveness and benefits of our current and future products and services as compared to alternatives. 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.

Establishing and maintaining sales, marketing and medical affairs capabilities will be expensive and time-consuming. Our expenses associated with maintaining our sales force may be disproportional compared to the revenues we may be able to generate on sales of the Cologuard and Oncotype IQ tests or any future products or services.

The success of our Cologuard test, our Oncotype IQ 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.

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 Oncotype IQ tests, and other products and services that we may 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, 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 preventative services. In June 2016, USPSTF issued an updated recommendation statement for colorectal cancer screening, and gave an "A" grade to colorectal cancer screening starting at age 50 and continuing until age 75. The statement specifies seven screening methods, including FIT-DNA (which is our Cologuard test). USPSTF updates its screening recommendations periodically, approximately every five to eight years. In October 2020, the USPSTF issued a draft recommendation statement for colorectal cancer screening. Under the updated draft recommendation statement, our Cologuard test was given a "B" grade for ages 45 to 49. Following the draft recommendation statement that was released in October 2020, a final recommendation statement is expected to be announced in 2021. However, we cannot be certain when USPSTF will next update its colorectal cancer screening recommendations, whether updated recommendations will continue to give an "A" grade to colorectal cancer screening between the ages of 50 and 75, whether updated recommendations will lower the screening

commencement age to 45, whether updated recommendations will continue to include FIT-DNA, whether updated recommendations may take a different format, including by ranking or tiering different methodologies and positioning FIT-DNA below other methodologies, or whether updated recommendations will include new technologies that are competitive with our Cologuard test and that may have greater appeal to healthcare providers, patients and payers. 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. Further, while FDA expanded our Cologuard test's indication in September 2019 to include average-risk individuals ages 45-49 and while ACS recommends colorectal cancer screening for that population, if updated USPSTF recommendations do not recommend that screening commence at age 45, adoption of screening generally, and our Cologuard test specifically, within the 45-49 age band may be limited.

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, the Centers for Medicare & Medicaid Services ("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 50 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 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 could be materially and adversely affected. If the ACA Mandate for preventive services is repealed, overturned or modified, if the ACA Mandate is determined not to require coverage of our Cologuard test, if the ACA Mandate is otherwise interpreted in a manner unfavorable to us, or if we are unable to influence or secure effective enforcement of the ACA Mandate, even if it is held to require coverage of our Cologuard test, our business prospects may be adversely affected.

While we believe the ACA Mandate requires certain health insurers to cover our Cologuard test for individuals between the ages of 50 and 75, the ACA Mandate does not currently extend to screening within the 45-49 age group because USPSTF currently does not currently recommend screening for that group. If USPSTF does not include the 45-49 age group in its final updated recommendation statement, reimbursement for our Cologuard test within that group would not be compelled by the ACA and therefore might be adversely affected.

The healthcare industry in the United States 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 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 make significant investments to research and develop new cancer tests, which may not be successful.

We are seeking to increase our Cologuard test's specificity by substituting new biomarkers and to develop a pipeline for future products and services, including screening and diagnostic tests for liver, pancreatic, esophageal, lung and other types of cancers. We expect to incur significant expenses on these development efforts, but they 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 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 trials 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 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. Product development is expensive, may take years to complete and can have uncertain outcomes. Failure can occur at any stage of the 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. The FDA's clearance or approval pathways are likely to involve significant time, as well as additional research, development and clinical study expenditures. There can be no guarantee that the FDA would clear or approve any future product or service we may develop. Even if the FDA clears or approves 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. Additionally, development of any product or service may be disrupted or made less viable by the development of competing products or services.

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 outside of the U.S. could limit or prevent us from selling our tests in foreign markets and impact our revenue.

As of December 31, 2020, we have entered into exclusive distribution agreements for the sale of our Oncotype IQ tests with distributors in dozens of countries. We may enter into other similar arrangements to distribute our tests in other countries in the future. We intend to continue to grow 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.

If we or Pfizer fail to adequately perform under our Cologuard Promotion Agreement, or if the Promotion Agreement is terminated prior to its full term, our business, prospects, financial condition and results of operations could be adversely affected.

In August 2018, we entered into a Promotion Agreement with Pfizer, which was amended and restated in October 2020 (the "Promotion Agreement"), pursuant to which Pfizer promotes our Cologuard test and provide certain sales, marketing, analytical and other commercial operations support services. We and Pfizer committed in the Promotion Agreement to invest specified amounts in the advertising and promotion of our Cologuard test. Under the Promotion Agreement we are required to pay Pfizer certain fixed fees and performance-related bonuses and royalties for our Cologuard-related revenues for a specified period after the expiration or termination of the Promotion Agreement.

The term of the Promotion Agreement is scheduled to run through December 31, 2022, but may be terminated by either party at any time upon six months' written notice to the other party.

We have dedicated significant time and resources to negotiating, implementing and coordinating performance under the Promotion Agreement. The growth in our Cologuard test revenue we anticipate as a result of the Promotion Agreement may not occur. We may not realize the expected benefits from the Promotion Agreement for a number of reasons including, among others, if we and Pfizer fail to coordinate our promotional efforts effectively, if Pfizer fails to optimally or effectively promote, market and sell our Cologuard test or otherwise fails to perform under the Promotion Agreement, if Pfizer prioritizes the promotion of its own, or other partners', products or services over our Cologuard test, if the Promotion Agreement is terminated before its anticipated benefits can be fully realized, or if other factors, extraneous to the Promotion Agreement, adversely impact sales of our Cologuard test (for example, reimbursement, competition, or seasonal factors). We have limited experience executing under co-promotion agreements and Pfizer has limited experience promoting molecular diagnostic products. Our strategic partnership with Pfizer will impact the retention and development of our own sales and marketing capabilities, both for our Cologuard test and other products in our pipeline. If we do not realize the expected benefits from the Promotion Agreement, either because Pfizer's marketing strategy and sales and marketing expertise do not translate well to the promotion of our Cologuard test or for any other reason, our business, prospects, financial condition and results of operations may be adversely affected.

Our research and development efforts will be hindered if we are not able to obtain samples, contract with third parties for access to samples or complete timely enrollment in future clinical trials.

Access to human sample types, such as blood, tissue, stool, or urine is necessary for our research and product development. Acquiring samples from individuals with clinical diagnoses or associated clinical outcomes through purchase or clinical studies is necessary. Lack of available samples can delay development timelines and increase costs of development. Generally, the agreements under which we gain access to human samples are non-exclusive. Other companies may compete with us for access. Additionally, the process of negotiating access to samples can be lengthy and it may involve numerous parties and approval levels to resolve complex issues such as usage rights, institutional review board approval, privacy rights, publication rights, intellectual property ownership and research parameters. If we are not able to negotiate access to clinical samples with research institutions, hospitals, clinical partners, pharmaceutical companies, or companies developing therapeutics on a timely basis, or at all, or if other laboratories or our competitors secure access to these samples before us, our ability to research, develop and commercialize future products will be limited or delayed. Finally, we may not be able to conduct or complete clinical trials on a timely basis if we are not able to enroll sufficient numbers of patients in such trials, and our failure to do so could have an adverse effect on our research and development and product commercialization efforts.

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 Hologic, Johns Hopkins University, Ludwig Institute for Cancer Research, Translational Genomics Research Institute and others. Such arrangements 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 incorporate 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.

We expect to continue and expand our reliance on collaborative and licensing arrangements. 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 IQ 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 & Trademark Office 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 us or our partners. 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.

Also, patents and patent applications owned by us may become the subject of interference proceedings in the U.S. Patent and Trademark Office ("USPTO") to determine priority of invention, which could result in substantial cost to us as well as a possible adverse decision as to the priority of invention of the patent or patent application involved. An adverse decision in an interference proceeding may result in the loss of rights under a patent or patent application subject to such a proceeding.

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 opposition proceedings relating to our patents. 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. Furthermore, in the life sciences field, courts frequently render opinions that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of isolated DNA and/or methods for analyzing or comparing DNA. Such decisions may adversely impact our ability to obtain new patents and facilitate third-party challenges to our existing 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.

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. In March 2012, the Supreme Court in *Mayo Collaborative Services v. Prometheus Laboratories*, *Inc*, found a patented diagnostic method claim unpatentable because the relationship between a metabolite concentration and optimized dosage was a patent-ineligible “law of nature.” In June 2013, the Supreme Court ruled in *ACLU v. Myriad Genetics*, *Inc*, that an isolated genomic DNA sequence is not patent eligible while cDNA is eligible. The *Prometheus* and *Myriad* decisions, as well as subsequent case law, affect the legal concept of subject matter eligibility by seemingly narrowing the scope of the statute defining patentable inventions.

In December 2014 and again in 2019, the USPTO published revised guidelines for patent examiners to apply when examining process claims for patent eligibility in view of several recent Supreme Court decisions, including *Mayo, Association for Molecular Pathology v. Myriad Genetics, Inc*., and *Alice Corporation Pty. Ltd. v. CLS Bank International,* and others. The guidance indicates that claims directed to a law of nature, a natural phenomenon, or an abstract idea that do not meet the eligibility requirements should be rejected as non-statutory, patent ineligible 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 described 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

We are required to assess our internal control over financial reporting on an annual basis and any future adverse results from such assessment could result in a loss of investor confidence and have an adverse effect on our stock price.

Pursuant to the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated by the SEC, we are required to furnish in our Form 10-K a report by our management regarding the effectiveness of our internal control over financial reporting. The report includes, among other things, an assessment of the effectiveness of our internal control over financial reporting as of the end of our fiscal year, including a statement as to whether our internal control over financial reporting is effective. This assessment must include disclosure of any material weaknesses in our internal control over financial reporting identified by management. While we believe our internal control over financial reporting is currently effective, the effectiveness of our internal controls in future periods is subject to the risk that our controls may become inadequate because of changes in conditions. Moreover, as described further in Item 9A – Controls and Procedures, in accordance with SEC staff guidance, we have excluded the business of Genomic Health, Inc. we acquired in November 2019 from the assessment of the effectiveness of our internal control over financial reporting as of December 31, 2019 contained in this Annual Report on Form 10-K, and it is therefore possible we will later determine that corrective action is needed to ensure the effectiveness of the internal control over financial reporting for this acquired business. Establishing, testing and maintaining an effective system of internal control over financial reporting requires significant resources and time commitments on the part of our management and our finance staff, may require additional staffing and infrastructure investments and would increase our costs of doing business. If we are unable to assert that our internal control over financial reporting is effective in any future period (or if our auditors are unable to express an opinion on the effectiveness of our internal controls or conclude that our internal controls are ineffective), we could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on our stock price.

We face risks associated with currency exchange rate fluctuations, which could adversely affect our operating results.

As a result of our international operations, we receive a portion of our revenues and pay a portion of our expenses in currencies other than the U.S. dollar, such as the Euro, the Swiss franc, the British pound and the Canadian dollar. In addition, many of our distribution agreements contain clauses requiring regular U.S. dollar price re-adjustments to account for fluctuations in the exchange rate between the U.S. dollar and the local currency. As a result, we are at risk from exchange rate fluctuations between such foreign currencies and the U.S. dollar, which could adversely affect our results of operations. Additionally, the volume of our international orders may be negatively impacted by a strong U.S. dollar. For the year ended December 31, 2020, approximately 5.2% of our revenues came from foreign denominated currencies. If the U.S. dollar strengthens against foreign currencies, the translation of these foreign currency denominated transactions will result in decreased revenues and operating expenses. We may not be able to offset adverse foreign currency impact with increased revenues. 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. Even with this strategy in place to mitigate balance sheet foreign currency risk, we will not eliminate our exposure to foreign exchange rate fluctuations on our financial results.

Delaware law, our charter and bylaw documents and certain provisions of our convertible notes could impede or discourage a takeover or change of control that stockholders may consider favorable.

As a Delaware corporation, we are subject to certain anti-takeover provisions. Under Delaware law, a corporation may not engage in a business combination with any holder of 15 percent or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Accordingly, our board of directors could rely on Delaware law to prevent or delay an acquisition of our company. In addition, certain provisions of our certificate of incorporation and bylaws may have the effect of delaying or preventing a change of control or changes in our management. These provisions include the following:

- Our board of directors is divided into three classes serving staggered three-year terms.
- Only our board of directors can fill vacancies on the board.
- Our stockholders may not act by written consent.
- There are various limitations on persons authorized to call a special meeting of stockholders and advance notice requirements for stockholders to make nominations of candidates for election as directors or to bring matters before an annual meeting of stockholders.
- Our board of directors may issue, without stockholder approval, shares of undesignated preferred stock.

These types of provisions could make it more difficult for a third party to acquire control of us, even if the acquisition would be beneficial to our stockholders.

Certain provisions of the convertible notes we issued in 2018, 2019, and 2020 could make it more difficult or more expensive for a third party to acquire us. Upon the occurrence of certain transactions constituting a "fundamental change," as such term is defined in the indenture for the notes, holders of the convertible notes will have the right, at their option, to require us to repurchase all of their convertible notes or any portion of the principal amount of such convertible notes in integral multiples of $1,000. We may also be required to increase the conversion rate in the event of a "make-whole fundamental change," as such term is defined in the indenture for the notes. In addition, the indenture and the convertible notes will prohibit us from engaging in certain mergers or acquisitions unless, among other things, the surviving entity assumes our obligations under the convertible notes and the indenture. These and other provisions in the indenture could deter or prevent a third party from acquiring us.

Our bylaws provide, subject to certain exceptions, that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain stockholder litigation matters, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or stockholders.

Our bylaws provide, subject to limited exceptions, that the Court of Chancery of the State of Delaware will, to the fullest extent permitted by law, be the sole and exclusive forum for any claims, including any derivative actions or proceedings brought on our behalf, (1) that are based upon a violation of a duty by a current or former director or officer or stockholder in such capacity or (2) that may be brought in the Court of Chancery pursuant to the Delaware General Corporation Law. This provision would not apply to suits brought to enforce a duty or liability created by the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended. Any person or entity purchasing or otherwise acquiring any interest in shares of our common stock shall be deemed to have notice of and to have consented to the provisions of our bylaws described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provision that is contained in our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially adversely affect our business, financial condition and results of operations.

Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations.

As of December 31, 2020, we had federal, state, and foreign net operating loss carryforwards ("NOLs") of approximately $1.55 billion, $709.2 million, and $4.3 million, respectively. In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. An ownership change is generally defined as a greater than 50 percent change in equity ownership by value over a specified time period (generally three years). Given the Code's broad definition, an ownership change could be the unintended consequence of otherwise normal market trading in our stock that is outside our control. An ownership change under Section 382 of the Code could also be triggered by certain strategic transactions. Additionally, tax law limitations may result in our NOLs expiring before we have the ability to use them. Pursuant to the Tax Cuts and Jobs Act (H.R. 1) of 2017, federal NOLs arising in tax years beginning after December 31, 2017 have an indefinite carryover period and may only be used to offset 80 percent of current year taxable income. For these reasons, even if we attain profitability, our ability to utilize our NOLs may be limited, potentially significantly so.

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

The market price for our common stock varied between a high of $144.00 and a low of $35.25 in the twelve-month period ended December 31, 2020. Our stock price is likely to continue to be volatile and subject to significant price and volume fluctuations in response to market and other factors, including those listed in this "Item 1A. Risk Factors" section and other, unknown factors. Among numerous other factors, our stock price also may be affected by:

- 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;
- our entering into merger, acquisition or other similar transactions;

- general fluctuations in the stock market or in the stock prices of companies in the life sciences or healthcare diagnostics industries; and
- general conditions and publicity regarding the life sciences or healthcare diagnostics industries.

Consequently, the current market price of our common stock may not be indicative of future market prices, and we may be unable to sustain or increase the value of an investment in our common stock. Further, sharp drops in the market price of our common stock, such as we experienced at certain times in our history, may expose us to securities class-action litigation. Such litigation could result in substantial expenses and diversion of management's attention and corporate resources, which would seriously harm our business, financial condition, and results of operations.

We have never paid cash dividends and do not intend to do so.

We have never declared or paid cash dividends on our common stock. We currently plan to use any cash proceeds from our operations to finance the growth of our business rather than to pay cash dividends. Payments of any cash dividends in the future will depend on our financial condition, results of operations and capital requirements, as well as other factors deemed relevant by our board of directors.

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 42% of our total assets at December 31, 2020. These assets consist primarily of goodwill and identified intangible assets 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 management has broad discretion over the use of our available cash and marketable securities and might not spend available cash and marketable securities in ways that increase the value of your investment.

From time to time we may carry high levels of cash and marketable securities. As of December 31, 2020, we had $1.84 billion in combined cash and marketable securities. Our management currently expects to deploy our cash and marketable securities primarily to expand our Cologuard and Oncotype IQ operations and commercialization activities, to fund our product development efforts and for general corporate purposes, including working capital and possible acquisitions. However, our management has broad discretion to pursue other objectives, we may raise additional capital, and we may use our current and future resources for other purposes. Our management might not effectively deploy our cash and marketable securities which could have an adverse effect on our business.

Our indebtedness could adversely affect our business, financial condition and results of operations and our ability to meet our payment obligations under such indebtedness.

Pursuant to the convertible note offerings we completed in 2018, 2019, and 2020, we incurred $2.21 billion of indebtedness, and we have a construction loan outstanding of $23.8 million as of December 31, 2020. 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 the convertible notes.

Our ability to meet our payment and other obligations under the convertible notes 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 the convertible notes 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, including the convertible notes, sell assets, reduce or delay capital investments, or seek to raise additional capital. If we are unable to implement one or more of these alternatives, we may not be able to meet our payment obligations under the convertible notes, and such a default could cause us to be in default on any other currently existing or future outstanding indebtedness.

Servicing our debt will require a significant amount of cash, and we may not have sufficient cash flow from our business to pay amounts due under our indebtedness, including the convertible notes.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the $2.21 billion aggregate principal amount of our 1.0%, 0.375%, and 0.375% convertible senior notes due 2025, 2027, and 2028, respectively, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt, including the convertible notes, and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital or share-settling the convertible notes which could be highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

As of December 31, 2020, we occupied approximately 983,000 square feet of space at our significant facilities in the Madison, Wisconsin area and 229,000 square feet in our facilities in Redwood City, California. 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 and Note 9 in the Notes to our Consolidated Financial Statements for further discussion surrounding mortgages on our owned properties.

As of December 31, 2020, 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	983,000	Leased/Owned
Redwood City, California	Research and development, corporate, operations and clinical laboratory	229,000	Leased
Phoenix, Arizona	Operations and clinical laboratory	11,000	Leased

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 15, 2021, there were 169,093,162 shares of our common stock outstanding held by approximately 336 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.

Item 6. Selected Financial Data

The selected historical financial data for the five years ended December 31, 2020 is derived from our audited consolidated financial statements. The selected historical financial data should be read in conjunction with, and is qualified by reference to "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our consolidated financial statements and notes thereto.

	Year Ended December 31,				
	2020 (1)	2019 (2)	2018	2017	2016
	(Amounts in thousands, except per share data)				
Statements of Operations Data:					
Revenue:	$ 1,491,391	$ 876,293	$ 454,462	$ 265,989	$ 99,376
Loss from operations	(768,019)	(233,782)	(159,471)	(118,310)	(169,016)
Net loss before tax	(857,105)	(268,851)	(175,057)	(114,584)	(167,211)
Net loss	(848,533)	(83,993)	(175,149)	(114,397)	(167,211)
Net loss per share—basic and diluted	(5.61)	(0.64)	(1.43)	(0.99)	(1.63)
Balance Sheet Data:					
Total assets	$ 4,925,092	$ 3,505,768	$ 1,524,022	$ 598,560	$ 377,040
Long-term liabilities	1,525,759	981,213	706,912	10,018	11,053

(1) In March 2020, we completed our acquisition of Paradigm Diagnostics, Inc. and Viomics, Inc. in transactions that are deemed to be a single business combination. In October 2020 we completed the acquisition of Base Genomics. The results of these acquisitions have been included in our results from the date of the acquisition. Refer to Note 19 in our Notes to Consolidated Financial Statements for further discussion of these acquisitions.

In the third quarter of 2020, we recognized two non-cash, pre-tax impairment losses on intangible assets previously acquired. Refer to Note 6 in our Notes to Consolidated Financial Statements for further discussion of the impairment losses recorded.

(2) In November 2019, we completed our combination with Genomic Health, Inc. The results of Genomic Health have been included in our results from the date of combination. Refer to Note 19 in our Notes to Consolidated Financial Statements for further discussion of this combination.

Item 7. Management's Discussion and Analysis of 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 2018 results where it would be redundant to the discussion previously included in Management's Discussion and Analysis of Financial Condition and Results of Operations on Form 10-K for the year ended December 31, 2019, which has been filed with the SEC.

Overview

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

Acquisitions

On January 4, 2021, we completed the acquisition ("Thrive Merger") of Thrive Earlier Detection Corporation, which merged Thrive with and into one of our wholly-owned subsidiaries. Thrive is a healthcare company dedicated to incorporating earlier cancer detection into routine medical care. We intend to combine Thrive's early-stage screening test, CancerSEEK, with our scientific platform, clinical organization and commercial infrastructure to establish us as a leading competitor in blood-based, multi-cancer screening. Under the terms of the Thrive Merger, we agreed to pay the Thrive owners total consideration of up to $2.15 billion, of which $1.70 billion was payable at closing, comprised of 35% in cash and 65% of our common stock. An additional $450.0 million would be payable in cash based upon the achievement of certain milestones related to the development and commercialization of a blood-based, multi-cancer screening test.

On October 26, 2020, we completed the acquisition of Base Genomics Limited, an epigenetics company working to set a new standard in DNA methylation analysis to detect cancer in its earliest stages. As part of the combination, we acquired all of the outstanding equity interest of the company for an aggregate purchase price of $416.5 million in cash.

On March 3, 2020, we completed the acquisition of Paradigm Diagnostics, Inc. and Viomics, Inc., two related companies, in transactions that are deemed to be a single business combination under Accounting Standards Codification ("ASC") 805. The acquired entities provide comprehensive genomic-based profiling tests that assist in the diagnosis and therapy recommendations for late-stage cancer. As part of the acquisition, we acquired all of the outstanding equity interests of the companies for an aggregate purchase price of $40.4 million, which consists of $32.2 million payable in shares of our common stock and $8.2 million which was settled through a cash payment. Of the $32.2 million to be settled through the issuance of common stock, $28.8 million was issued as of December 31, 2020, and the remaining $3.4 million, which was withheld and may become payable as additional merger consideration, is included in other current liabilities in the consolidated balance sheet as of December 31, 2020.

COVID-19 Testing Business

In late March 2020, we began providing COVID-19 testing. We have partnered with various customers, including the State of Wisconsin Department of Health, to administer testing. Customers are responsible for employing trained personnel to collect specimens. Specimens are sent to our laboratory in Madison, Wisconsin,where we allocated space to run the assay in our laboratories and provide test results to ordering providers. We also manufacture and assemble our COVID-19 test kits at our manufacturing facilities in Madison, Wisconsin. In light of the uncertainty surrounding the COVID-19 pandemic, we intend to periodically reassess our COVID-19 testing business.

2021 Priorities

Our top priorities for 2021 are to (1) get more people tested, (2) advance new solutions, and (3) enhance our customer experience.

Get More People Tested

We are committed to delivering critical answers to patients by getting more people tested with our Cologuard and Oncotype tests. We will also continue to provide COVID-19 testing to support our employees, the states where they live, and to improve the country's testing capacity.

Advance New Solutions

In 2021, we are focused on advancing new solutions for screening and guiding treatment decisions for cancer. We'll do this by investing in ongoing and additional clinical trials to support our product development efforts in enhancing existing products and bringing new products to patients and providers.

We are seeking opportunities to improve upon our Cologuard test's performance characteristics. In October 2019, we and Mayo presented at the American College of Gastroenterology's 2019 Annual Scientific Meeting findings from a blinded-case control study showing enhanced colorectal cancer and advanced adenoma detection using newly discovered methylation biomarkers. In October 2020, we acquired Base Genomics, whose methylation analysis technologies promise to build upon other contemplated enhancements to our Cologuard test. To establish the performance of an enhanced multi-target stool DNA test, we expect to enroll more than 10,000 patients 40 years of age and older in our multi-center, prospective BLUE-C study. The timing of any such enhancements to our Cologuard test is unknown and would be subject to FDA approval. We are also working to develop a blood-based screening test for colorectal cancer.

We are currently seeking to develop a blood-based, multi-cancer screening test. In January 2021, we completed the acquisition of Thrive, a healthcare company dedicated to developing a blood-based, multi-cancer screening test. An early version of Thrive's test has achieved promising results in a 10,000-patient, prospective, interventional study detecting 10 different types of cancer, including seven with no current recommended screening guidelines, with very few false positives. We are exploring opportunities to incorporate Exact's and Base Genomics' methylation technologies into Thrive's test in order to enhance the test's accuracy and accelerate the widespread adoption of this potentially life-saving advancement.

We are currently seeking to develop a blood-based biomarker test to serve as an alternative to ultrasound and the AFP test for use in HCC testing. HCC is the most common type of liver cancer. Our goal is to develop a patient-friendly test that performs better than the current standard of care. In November 2019, we released the results of a 450-patient study which demonstrated 80% overall sensitivity for HCC at 90% specificity with a novel combination of six blood-based biomarkers for HCC. The study also showed 71% sensitivity for early-stage HCC at 90% specificity. The study compared performance to the AFP test, which demonstrated 45% sensitivity at 90% specificity for early-stage HCC.

In January 2021 we acquired an exclusive license to the TGen proprietary TARDIS technology. We are currently seeking to utilize this compelling and technically distinct approach to develop a test to detect small amounts of tumor DNA that may remain in patients' blood after they have undergone initial treatment. In a study published in Science Translational Medicine, TARDIS demonstrated high accuracy in assessing molecular response and residual disease during neoadjuvant therapy to treat breast cancer. TARDIS achieved up to 100-fold improvement beyond the current limit of circulating tumor DNA detection. We intend to expand our precision oncology business to become a leader in minimal residual disease testing, which will leverage our existing foundation to deliver better solutions to patients navigating cancer. Additionally, we may also use a number of other technologies across our various development programs and to implement our products. While early-stage cancer continues to be our main focus, we believe we also have an opportunity to expand our business further along the patient's cancer journey, both through our research and development process and strategic collaborations.

We may also conduct or fund clinical studies that could support additional opportunities for our Oncotype IQ products. For example, we are exploring clinical studies to expand the use of genomic testing to address additional populations, including higher-risk patients.

Enhance Our Customer Experience

Another priority for 2021 is to enhance our customer service. We plan to improve customer communications and outreach to make doing business with Exact Sciences easier than ever. Our goal is to become the cancer diagnostic provider of choice for physicians and patients.

Results of Operations

The spread of COVID-19 has affected many segments of the global economy, including the cancer screening and diagnostics industry. The COVID-19 outbreak, which the World Health Organization has classified as a pandemic, has prompted governments and regulatory bodies throughout the world to enact broad precautionary measures, including "stay at home" orders, restrictions on the performance of "non-essential" services, public gatherings and travel. Health systems, including in key markets where we operate, have been, or may be, overwhelmed with high volumes of patients suffering from COVID-19. The territories in which we market, sell, distribute and perform our tests are attempting to address the COVID-19 pandemic in varying ways, including stay-at-home orders, temporarily closing businesses, restricting gatherings, restricting travel, and mandating social distancing and face coverings. Certain jurisdictions have begun re-opening only to return to restrictions due to increases in new COVID-19 cases. Even in the absence of legal restrictions, businesses and individuals may voluntarily continue to limit in-person interactions and practice social distancing, and such behaviors may continue beyond the formal end of the pandemic. The level and nature of the disruption caused by COVID-19 is unpredictable, may be cyclical and long-lasting and may vary from location to location.

The pandemic and related precautionary measures began to materially disrupt our business in March 2020 and may continue to disrupt our business for an unknown period of time. As a result, the pandemic had a significant impact on our 2020 operating results, including our revenues, margins, and cash utilization, among other measures.

As a result of COVID-19 and its impact to our business, we re-prioritized our goals for 2020 with a focus on serving patients who continued to need the healthcare services we provide while aligning our cost structure with the anticipated lower sales volumes and revenues. Our top priorities for 2020 were to (1) get people tested using our Cologuard, Oncotype IQ, and COVID-19 tests, (2) take care of our customers by taking steps to limit exposure to COVID-19 based on recommendations from government and health agencies, and (3) preserve financial strength by taking proactive measures to achieve cost savings.

Due to social distancing, stay-at-home orders, and other actions taken in response to COVID-19, in 2020 there was a significant and widespread decline in standard wellness visits and preventive services. We took steps to limit exposure to COVID-19 based on recommendations from government and health agencies, including limiting field-based, face-to-face interactions by our sales force. The sales team that was not engaged in face-to-face interactions served healthcare providers via telephone and online technologies until it was safe to return to the field and practices allowed representatives back in their offices. Our commercial partner for our Cologuard test, Pfizer, took similar precautions, including suspending face-to-face interactions between sales representatives and healthcare providers. The decline in field-based, face-to-face interactions with health care providers negatively impacted Cologuard test orders during the second quarter of 2020 in our Screening business, notwithstanding the availability of alternative ordering channels such as telehealth. Starting in the third quarter, orders began to recover to pre-pandemic levels and continued to recover during the fourth quarter. Our Precision Oncology business started to see weakening underlying conditions in April 2020 because of COVID-19, more notably in the U.S. prostate business and in certain international geographies. The widespread decrease in preventive services, including mammograms and prostate cancer screenings, negatively impacted Precision Oncology test volumes beginning in May 2020 and continuing throughout the third quarter of 2020 due to the typical lag between cancer screening and genomic test ordering. We began to see orders recovering during the fourth quarter of 2020 to near pre-pandemic levels. As a result of the pandemic, we began providing COVID-19 testing in March 2020, the revenue from which has partially offset the pandemic's impact on our Screening and Precision Oncology testing revenue.

During 2020, business continuity plans were in place at all of our sites to help sustain operations and ensure continuity of services for patients during this unprecedented time. Despite the COVID-19 pandemic, many people still needed to be screened for colorectal cancer, and treated for breast, colon, and prostate cancers. Our lab facilities remained operational so that we could continue to process results of our Cologuard, Oncotype IQ and COVID-19 tests.

We expect to adjust our precautionary measures at our various locations based on local recovery levels and applicable governmental regulations. For example, a portion of the Company's and Pfizer's sales force has recommenced field-based interactions, although access to healthcare providers remains limited and the resumption of normal activities is expected to be gradual. Our business could be negatively affected if we take excessive, ineffective or inadequate precautions.

In order to minimize the adverse impacts to our business and operations due to the COVID-19 pandemic, beginning in April 2020, we initiated proactive measures to achieve cost savings. Actions we took included a temporary reduction of base pay for our executive officers and other employees at or above the director level, a reduction in the annual retainer payable to our board of directors, and a reduction of quarterly sales commissions. We implemented a workforce reduction, involuntary furloughs, work schedule reductions, as well as a voluntary furlough program. Additionally, we reduced investments in marketing and other promotional activities, paused certain clinical trial activities, reduced travel and professional services, and delayed or terminated certain capital projects. We also saw a reduction in certain volume based cost of goods sold expenses consistent with the reduction in revenue. These actions contributed to significant cost savings in 2020.

As our Screening and Precision Oncology businesses started to recover, we adjusted the proactive cost-saving measures discussed above in order to support the recovery as well as prepare for future growth. During the fourth quarter of 2020, we continued to plan for future growth through investing in our existing operations and through the business combinations further discussed above.

We also ensured that we were well capitalized to meet our future goals by raising $1.13 billion, net of issuance costs, through an underwritten public offering of convertible notes completed in February 2020 and $861.7 million, net of issuance costs, through a registered direct offering of our common stock completed in October 2020. We finished the year with $1.84 billion in cash, cash equivalents, and marketable securities.

Comparison of the years ended December 31, 2020 and 2019

Revenue. Our revenue is primarily generated by our laboratory testing services, from our Cologuard, Oncotype IQ, and COVID-19 tests. Our Screening revenue, which primarily includes laboratory service revenue from our Cologuard tests, was $815.1 million and $810.1 million for the years ended December 31, 2020 and 2019, respectively. The increase was primarily due to an increase in the number of completed Cologuard tests. Our Precision Oncology revenue, which primarily includes laboratory service revenue from our global Oncotype products, was $440.5 million and $66.2 million for the years ended December 31, 2020 and 2019, respectively. The increase was primarily due to a full year of Precision Oncology operations in 2020 after completing our combination with Genomic Health in November 2019. For the year ended December 31, 2020, we also generated $235.8 million in revenue from our COVID-19 testing.

For the year ended December 31, 2020, our Screening and Precision Oncology laboratory service revenue was impacted by the effects of the COVID-19 outbreak as discussed above. In response to the pandemic, we are conducting COVID-19 testing, which has served as additional source of revenue outside our normal Screening and Precision Oncology laboratory testing services.

Our cost structure. Our selling, general, and administrative expenses consist primarily of non-research personnel salaries, office expenses, professional fees, sales and marketing expenses incurred in support of our commercialization efforts and non-cash stock-based compensation.

Cost of sales includes costs related to inventory production and usage, shipment of collection kits and tissue samples, royalties and the cost of services to process tests and provide results to healthcare providers.

We expect that revenue and cost of sales for our services will continue to fluctuate and be affected by the test volume of our products, our operating efficiencies, patient adherence rates, payer mix, the levels of reimbursement, and payment patterns of payers and patients.

Cost of sales (exclusive of amortization of acquired intangible assets). Cost of sales increased to $354.3 million for the year ended December 31, 2020 from $216.7 million for the year ended December 31, 2019. The increase in cost of sales is primarily due to costs incurred to support Oncotype DX products after the completion of our combination with Genomic Health in November 2019 and costs incurred from COVID-19 testing, which began in March 2020. We also incurred an increase in personnel and facility and support services to support future growth of our Cologuard test.

Amounts in millions	2020	2019	Change
Production costs	$ 186.3	$ 144.8	$ 41.5
Personnel expenses	103.3	42.5	60.8
Facility and support services	51.4	23.0	28.4
Stock-based compensation	12.9	5.8	7.1
Other cost of sales expenses	0.4	0.6	(0.2)
Total cost of sales expense	$ 354.3	$ 216.7	$ 137.6

Research and development expenses. Research and development expenses increased to $554.1 million for the year ended December 31, 2020 compared to $139.7 million for the year ended December 31, 2019. The increase in research and development expenses was primarily due to our acquisition of Base Genomics in October 2020, which was accounted for as an asset acquisition and resulted in an expense of $412.6 million that is included in research and development expenses. The acquisition is further described in Note 19 of our consolidated financial statements included in this Annual Report on Form 10-K. In addition, there was an increase in personnel related costs and facility and support services as a result of our combination with Genomic Health in November 2019. This increase was partially offset by decreased clinical trial activity, professional fees, and other direct research and development expenses due to measures taken in response to the COVID-19 pandemic for a portion of the year.

Amounts in millions	2020	2019	Change
Intellectual property acquisition	$ 412.6	$ —	$ 412.6
Personnel expenses	60.5	38.5	22.0
Direct research and development expenses	42.9	69.8	(26.9)
Stock-based compensation	20.0	17.2	2.8
Facility and support services	12.7	6.4	6.3
Professional fees	3.1	5.0	(1.9)
Other research and development expenses	2.3	2.8	(0.5)
Total research and development expenses	$ 554.1	$ 139.7	$ 414.4

General and administrative expenses. General and administrative expenses increased to $481.7 million for the year ended December 31, 2020 compared to $352.5 million for the year ended December 31, 2019. The increase in general and administrative expenses was primarily related to the inclusion of a full year of Genomic Health's operations after the completion of our combination in November 2019. As part of the combination with Genomic Health, we incurred $62.8 million in acquisition and integration related costs during the year ended December 31, 2019. Due to the COVID-19 pandemic and the protective measures put in place in the first half of 2020, we saw a decrease in expected spend in our personnel and professional fees. As our business began to recover in the second half of 2020, personnel expenses and stock-based compensation increased due to additional headcount. We also incurred additional costs as we invested in our information technology infrastructure and customer care center costs to support the growth of the Company.

Amounts in millions	2020	2019	Change
Personnel expenses	$ 222.0	$ 136.1	$ 85.9
Professional and legal fees	86.4	77.0	9.4
Stock-based compensation	76.0	64.2	11.8
Facility and support services	58.3	56.5	1.8
Other general and administrative	39.0	18.7	20.3
Total general and administrative expenses	$ 481.7	$ 352.5	$ 129.2

Sales and marketing expenses. Sales and marketing expenses increased to $589.9 million for the year ended December 31, 2020 compared to $385.2 million for the year ended December 31, 2019. The increase in sales and marketing expenses was primarily a result of the additional personnel, facility and support services, and stock-based compensation costs incurred after completing the combination with Genomic Health in November 2019. As discussed above, our sales force and Pfizer took several steps to limit exposure to COVID-19 and many healthcare provider offices prohibited sales representatives throughout the year, which ultimately reduced certain professional and personnel related costs, primarily in the second and third quarters of 2020. As our business began to recover in the second half of 2020, we ended our involuntary furloughs and hired additional sales and marketing personnel, and we also increased our direct marketing spend to support the future growth of our products, which resulted in an overall increase in spend during the year.

Amounts in millions	2020	2019	Change
Personnel expenses	$ 280.3	$ 166.7	$ 113.6
Direct marketing costs	133.8	99.9	33.9
Professional and legal fees	77.7	87.7	(10.0)
Facility and support services	45.5	9.0	36.5
Stock-based compensation	44.0	21.3	22.7
Other sales and marketing expenses	8.6	0.6	8.0
Total sales and marketing expenses	$ 589.9	$ 385.2	$ 204.7

Amortization of acquired intangible assets. Amortization of acquired intangible assets increased to $93.4 million for the year ended December 31, 2020 compared to $16.0 million for the year ended December 31, 2019. This increase in amortization of acquired intangible assets was primarily due to the Genomic Health combination.

Intangible asset impairment charge. Intangible asset impairment charge was $209.7 million for the year ended December 31, 2020 compared to zero for the year ended December 31, 2019. The impairment charge recorded during the year ended December 31, 2020 relates to the impairment charges recorded on the in-process research and development intangible asset acquired as part of the combination with Genomic Health of $200.0 million and the intangible asset acquired through an asset purchase agreement with Armune Biosciences, Inc. of $9.7 million.

Other operating income. Other operating income increased to $23.7 million for the year ended December 31, 2020 compared to zero for the year ended December 31, 2019. The income generated during the year ended December 31, 2020 represents the funding received under the CARES Act Provider Relief Fund, which was accepted from the Department of Health & Human Services in May 2020.

Investment income, net. Investment income, net decreased to $6.9 million for the year ended December 31, 2020 compared to $26.5 million for the year ended December 31, 2019. The decrease in investment income, net was due to a decrease in realized gains generated from the sale of marketable securities and a decrease in the average rate of return on investments due to a decrease in market interest rates and a lower average balance in marketable securities for the year ended December 31, 2020 when compared to the same period in 2019.

Interest expense. Interest expense increased to $96.0 million for the year ended December 31, 2020 compared to $61.6 million for the year ended December 31, 2019. The increase is primarily due to the issuance of additional convertible notes in February 2020. Interest expense recorded from our outstanding convertible notes totaled $86.1 million and $49.6 million for the years ended December 31, 2020 and 2019, respectively. Of the $86.1 million and $49.6 million in interest expense recorded on outstanding convertible notes, $76.5 million and $42.3 million of interest expense relates to amortization of debt discount and debt issuance costs for the years ended December 31, 2020 and 2019, respectively. The remaining interest expense recorded on outstanding convertible notes relates to the stated interest that is paid out in cash. In addition to the interest expense recorded on outstanding convertible notes, an additional $8.0 million and $10.6 million was recorded during the years ended December 31, 2020 and 2019, respectively, as a result of the settlement of convertible notes. The convertible notes are further described in Note 10 of our consolidated financial statements included in this Annual Report on Form 10-K. The remaining interest expense for the years ended December 31, 2020 and 2019 relates to the stated interest on our construction loan further described in Note 9 of our consolidated financial statements included in this Annual Report.

Income tax benefit (expense). An income tax benefit of $8.6 million was recorded for the year ended December 31, 2020 compared to a benefit of $184.9 million for the year ended December 31, 2019. The income tax benefit recorded during the year ended December 31, 2019 was primarily a result of a change in deferred tax asset valuation allowance resulting from the Genomic Health combination. The income tax benefit of $8.6 million for the year ended December 31, 2020 was recorded primarily as a result of future limitations on and expiration of certain Federal and State deferred tax assets.

Liquidity and Capital Resources

We have financed our operations since inception primarily through public offerings of our common stock and convertible debt and through revenue generated by the sale of our Cologuard test, and since the completion of our Genomic Health combination, of Oncotype IQ tests. As of December 31, 2020, we had approximately $1.49 billion in unrestricted cash and cash equivalents and approximately $348.7 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.

Net cash provided by operating activities was $136.5 million for the year ended December 31, 2020 compared to cash used in operating activities of $111.7 million for the year ended December 31, 2019. The increase in cash provided by operating activities for the year ended December 31, 2020 was primarily due to the increase in cash receipts as a result of an increase in revenue. The increase in revenue was driven by having a full year of Precision Oncology operations in 2020 after completing our combination with Genomic Health in November 2019. This was partially offset by an increase in cash payments made related to an increase in inventory and other expenses necessary to process our tests. Additionally, we saw a reduction in discretionary spend due to proactive cost saving measures taken throughout the year as a result of the COVID-19 pandemic.

Net cash used in investing activities was $702.0 million for the year ended December 31, 2020. We purchased $1.09 billion in marketable securities, while $886.7 million of our marketable securities were sold or matured during the year. We used net cash of $411.4 million in the acquisition of Base, and also invested $64.4 million in property and equipment, and $15.9 million in strategic investments in privately held companies. Net cash used in investing activities was $124.4 million for the year ended December 31, 2019. We purchased $634.1 million in marketable securities, while $1.66 billion of our marketable securities were sold or matured during the year in order to prepare for our combination with Genomic Health in November 2019, which resulted in using net cash of $973.9 million. Additionally, we invested $171.8 million in property and equipment, consisting primarily of increased laboratory equipment purchases, computer equipment and computer software purchases, and assets under construction in order to support our operations for future expected growth of our business.

Net cash provided by financing activities was $1.88 billion for the year ended December 31, 2020. We received proceeds of $1.13 billion from the issuance of convertible notes with a maturity date of March 1, 2028 (the “2028 Notes”), and we used $150.1 million of cash to settle convertible notes with an original maturity date of January 15, 2025 (the "2025 Notes"). We also received proceeds of $861.7 million from the sale of common stock, net of issuance costs. Additionally, we received proceeds of $27.1 million from the exercise of stock options, $18.4 million from our employee stock purchase plan, and made payments on the principal of our outstanding construction loan and finance leases of $3.0 million. Net cash provided by financing activities was $253.2 million for the year ended December 31, 2019. We received proceeds of $729.5 million from the issuance of convertible notes with a maturity date of March 15, 2027 (the "2027 Notes," and collectively with the 2025 Notes and 2028 Notes, the "Notes"), and we used $493.4 million of cash to settle a portion of the 2025 Notes. Additionally, we received proceeds of $8.8 million from the exercise of stock options, and $8.4 million from our employee stock purchase plan.

As described above, on January 4, 2021, we completed the Thrive Merger in a cash and stock transaction valued at approximately $2.15 billion, of which $1.70 billion was paid at closing including cash consideration of approximately $600 million.

We expect that cash and cash equivalents and marketable securities on hand at December 31, 2020 will be sufficient to fund our current operations for at least the next twelve months including the cash consideration paid as part of the Thrive Merger in January 2021, based on current operating plans. However, we may need to raise additional capital to fully fund our current strategic plan, which includes successfully commercializing our Cologuard and Oncotype IQ products and developing a pipeline of future products. Additionally, we may enter into transactions to acquire other businesses, products, services, or technologies as part of our strategic plan. If we are unable to obtain sufficient additional funds to enable us to fund our operations through the completion of such plan, our results of operations and financial condition would be materially adversely affected, and we may be required to delay the implementation of our plan and otherwise scale back our operations. Even if we successfully raise sufficient funds to complete our plan, there is no certainty that we will be successful in generating sufficient cash flow from operations or achieving and maintaining profitable operations in the future to enable it to meet our obligations as they come due.

The following table sets forth certain information concerning our obligations to make contractual future payments, such as pursuant to debt and lease agreements, as of December 31, 2020:

		Payments Due by Period (5)			
(In thousands)	Total	Less Than One Year	1 - 3 Years	3 - 5 Years	More Than 5 Years
Convertible notes (1)	$ 2,277,290	$ 10,266	$ 20,532	$ 334,006	$ 1,912,486
Long-term debt obligations (2)	24,847	1,914	22,933	—	—
Other liabilities (3)	22,991	3,834	5,422	2,121	11,614
Purchase obligations (4)	36,200	32,450	2,500	1,250	—
Operating lease obligations	180,519	19,881	40,902	40,595	79,141
Finance lease obligations	20,706	5,674	11,160	3,872	—
Total	$ 2,562,553	$ 74,019	$ 103,449	$ 381,844	$ 2,003,241

(1) Includes the principal amount of our senior convertible notes due in 2025, 2027, and 2028, as well as the interest payments associated with the notes. The notes are presented in the table in line with their maturity dates, but they may be converted earlier if certain conditions are met. The holders of the convertible notes with a maturity date in 2025 will have the right to convert beginning on January 1, 2021 and are classified as current on the consolidated balance sheet as of December 31, 2020. See Note 10 in the Notes to Consolidated Financial Statements for further information.

(2) Includes obligations associated with outstanding construction loan agreement. See Note 9 in the Notes to Consolidated Financial Statements for further information.

(3) Primarily includes obligations under a financing obligation. This also includes miscellaneous unrestricted grants that were made to third parties.

(4) Primarily includes fixed obligations under the Restated Promotion Agreement with Pfizer, which is further discussed in Note 12 in the Notes to Consolidated Financial Statements. This also includes payments to Mayo under our license agreement discussed in Note 11 and a land purchase obligation agreement with the owner of the land adjacent to one of our current Madison, Wisconsin facilities.

(5) Contingent consideration and contingent license payments are excluded from this table as the amount and timing of such outflows cannot be reasonably determined. See Note 7 and Note 11 in the Notes to Consolidated Financial Statements for further information.

Net Operating Loss Carryforwards

As of December 31, 2020, we had federal, state, and foreign NOL carryforwards of approximately $1.55 billion, $709.2 million, $4.3 million, respectively. We also had federal and state research tax credit carryforwards of approximately $54.3 million and $34.0 million, respectively. The net operating loss and tax credit carryforwards will expire at various dates through 2040, 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 percent 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, 2020, we had $615.1 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 $19.5 million remaining at the end of 2020, which is included in other long-term liabilities on our consolidated balance sheet. Additionally, an income tax benefit of $8.6 million was recorded primarily as a result of future limitations on and expiration of certain Federal and State deferred tax assets.

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 accounting policies and judgments are most critical to aid in fully understanding and evaluating our reported financial results.

Revenue Recognition. Revenues are recognized when we release a 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 constrained 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. Our ability to collect is not contingent on the customer's ability to collect through their downstream billing efforts.

In the case of some of our laboratory service agreements ("LSAs") with various organizations, 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 cycle for areas of opportunity as we believe adequate operations support our ability 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 contractual allowance 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. 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. We have incurred significant losses since our inception and due to the uncertainty of the amount and timing of future taxable income, management has determined that a valuation allowance of $157.6 million and $120.7 million at December 31, 2020 and 2019, 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.

Convertible Notes. We account for convertible debt instruments that may be settled in cash or equity upon conversion by separating the liability and equity components of the instruments in a manner that reflects our nonconvertible debt borrowing rate. We determined the carrying amount of the liability component of the convertible debt instruments by using assumptions that market participants would use in pricing a debt instrument, including market interest rates, credit standing, yield curves, volatilities, and the expected life of the instrument. Determining the fair value of the debt component requires the use of accounting estimates and assumptions. These estimates and assumptions are judgmental in nature and could have a significant impact on the determination of the debt component, and the associated non-cash interest expense.

The amount allocated to the equity component is the difference between the principal value of the instrument and the fair value of the liability component at issuance. The equity component, less any premium, is treated as a discount on the liability component. The debt discount is amortized to interest expense over the contractual term of the debt instrument using the effective interest rate method. In addition, debt issuance costs related to the debt instrument are allocated to the liability and equity components based on their relative values. The debt issuance costs allocated to the liability component are amortized over the contractual term of the debt instrument as additional non-cash interest expense. The transaction costs allocated to the equity component are netted with the equity component of the convertible debt instrument in stockholders equity.

Business Combinations. 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 the ASC 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.

Impairment of Long-Lived Assets. We evaluate the fair value of long-lived assets, which include property, plant and equipment, 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.

Recent Accounting Pronouncements

See Note 1 in the Notes to Consolidated Financial Statements for the discussion of Recent Accounting Pronouncements.

Off-Balance Sheet Arrangements

As of December 31, 2020, we had no off-balance sheet arrangements.

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. 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, 2020 and December 31, 2019 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 ten percent adverse movement in 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.

A hypothetical ten percent change in interest rates would not have a material adverse impact on our future operating results or cash flows. All of our 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

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.

Prior to our acquisition of Genomic Health in November 2019, the functional currency for each of our international subsidiaries was its local currency. For 2019 our international subsidiaries use the U.S. dollar as the functional currency, resulting in us not being subject to gains and losses from foreign currency translation of the subsidiary financial statements. In September 2017, Genomic Health (now a wholly owned subsidiary) started entering 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, 2020, we had open foreign currency forward contracts with notional amounts of $22.4 million. Although the impact of currency fluctuations on our financial results has been immaterial in the past, there can be no guarantee that the impact of currency fluctuations related to our international activities will not be material in the future.

Item 8. Consolidated Financial Statements and Supplementary Data

EXACT SCIENCES CORPORATION
Index to Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Exact Sciences Corporation

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheet of Exact Sciences Corporation and its subsidiaries (the "Company") as of December 31, 2020, and the related consolidated statements of operations, of comprehensive loss, of stockholders' equity and of cash flows for the year then ended, 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, 2020, 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, 2020, and the results of its operations and its cash flows for the year then ended 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, 2020, 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 audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit 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 audit 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 audit 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 audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides 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 2 to the consolidated financial statements, the Company's revenue is primarily generated from laboratory services from its Cologuard and Oncotype DX products. The Company's customer is the patient. Management estimates the amount of variable consideration using the expected value method, which represents 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, patient insurance eligibility and payer reimbursement contracts. The Company's net accounts receivable as of December 31, 2020 was $233.2 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 the significant judgment by management when developing the estimate of the amount of variable consideration, due to the estimation uncertainty involved in developing the estimate; this in turn led to significant auditor judgment, subjectivity and effort in performing procedures and evaluating the 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 the estimate. These procedures also included, among others, testing management's process for developing the estimated amount of variable consideration, including evaluating the appropriateness of the analysis and testing completeness and accuracy of the underlying historical collection data used in the analysis; testing, on a sample basis, the accuracy of revenue transactions and cash collections from the historical billing and collection data used in management's analysis; and performing a retrospective comparison of actual cash collected subsequent to year-end to evaluate the reasonableness the prior year estimate of the amount of variable consideration.

Issuance and Settlement of Convertible Notes

As described in Notes 1 and 10 to the consolidated financial statements, the Company issued and sold $1.15 billion in aggregate principal amount of convertible notes due in 2028 (the "2028 Notes"). Management accounts for convertible notes that may be settled in cash or equity upon conversion by separating the liability and equity components of the instruments in a manner that reflects the Company's nonconvertible debt borrowing rate. Management determines the carrying amount of the liability component of the convertible notes by using assumptions that market participants would use in pricing a debt instrument, including market interest rates, credit standing, yield curves, volatilities, and expected life of the instrument. Determining the fair value of the debt component requires the use of accounting estimates and assumptions. Management used $150.1 million of the proceeds from the issuance of the 2028 Notes to settle $100.0 million of convertible notes due in 2025 (the "2025 Notes"). The consideration transferred was allocated to the liability and equity components of the 2025 Notes using the equivalent rate that reflected the borrowing rate for a similar non-convertible debt instrument immediately prior to settlement. The transaction resulted in a loss on settlement of convertible notes of $8.0 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 liability component and (ii) the sum of the carrying value of the debt component and any unamortized debt issuance costs at the time of repurchase.

The principal considerations for our determination that performing procedures relating to the issuance and settlement of convertible notes is a critical audit matter are the significant judgment by management to determine the fair value of the liability component of the convertible debt at the time of issuance and to determine the fair value of the liability component of the convertible debt settled at the time of repurchase in order to calculate the loss on settlement; this in turn led to a high degree of auditor judgment, subjectivity and effort in performing procedures relating to management's estimated market interest rate that reflects the Company's nonconvertible borrowing rate and the expected life of the convertible notes issued. In addition, 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 accounting for the convertible notes transactions, including controls over the determination of fair value of the liability components of the convertible debt issued and settled. These procedures also included, among others, evaluating the methodology used by management to determine the fair value of a similar liability that does not have an associated conversion feature, testing the completeness and accuracy of the underlying data used in the model, and evaluating the reasonableness of significant assumptions related to (i) estimated market interest rate that reflects the Company's nonconvertible borrowing rate, considering external market and industry data, and (ii) the expected life of the notes issued. Professionals with specialized skill and knowledge were used to assist in evaluating whether the market interest rate used by management was reasonable.

/s/ PricewaterhouseCoopers LLP
Chicago, Illinois
February 16, 2021
We have served as the Company's auditor since 2020.

Report of Independent Registered Public Accounting Firm
Shareholders and Board of Directors
Exact Sciences Corporation
Madison, Wisconsin

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Exact Sciences Corporation (the "Company") as of December 31, 2019, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2019**,** in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Method Related to Leases

As discussed in Notes 1 and 15 to the consolidated financial statements, the Company has changed its method of accounting for leases in 2019 due to the adoption of Topic 842 — Leases.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits 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. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor from 2012 to 2020.

Madison, Wisconsin
February 21, 2020

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

	December 31, 2020	December 31, 2019
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 1,491,288	$ 177,254
Marketable securities	348,699	146,401
Accounts receivable, net	233,185	130,362
Inventory	92,265	61,724
Prepaid expenses and other current assets	33,157	38,195
Total current assets	2,198,594	553,936
Long-term Assets:		
Property, plant and equipment, net	450,683	455,325
Operating lease right-of-use assets	125,947	126,444
Goodwill	1,237,672	1,203,197
Intangible assets, net	848,426	1,143,550
Other long-term assets, net	63,770	23,316
Total assets	$ 4,925,092	$ 3,505,768
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 35,709	$ 25,973
Accrued liabilities	233,604	193,329
Operating lease liabilities, current portion	11,483	7,891
Convertible notes, net, current portion	255,464	—
Debt, current portion	1,319	834
Other current liabilities	38,265	8,467
Total current liabilities	575,844	236,494
Long-term Liabilities:		
Convertible notes, net, less current portion	1,320,760	803,605
Long-term debt, less current portion	22,342	24,032
Other long-term liabilities	61,582	34,911
Operating lease liabilities, less current portion	121,075	118,665
Total liabilities	2,101,603	1,217,707
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.01 par value Authorized—5,000,000 shares issued and outstanding—no shares at December 31, 2020 and December 31, 2019	—	—
Common stock, $0.01 par value Authorized—400,000,000 shares issued and outstanding—159,423,410 and 147,625,696 shares at December 31, 2020 and December 31, 2019	1,595	1,477
Additional paid-in capital	4,789,657	3,406,440
Accumulated other comprehensive income (loss)	526	(100)
Accumulated deficit	(1,968,289)	(1,119,756)
Total stockholders' equity	2,823,489	2,288,061
Total liabilities and stockholders' equity	$ 4,925,092	$ 3,505,768

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

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

	Year Ended December 31,		
	2020	2019	2018
Revenue	$ 1,491,391	$ 876,293	$ 454,462
Operating expenses:			
Cost of sales (exclusive of amortization of acquired intangible	354,324	216,717	116,644
Research and development	554,052	139,694	67,285
Sales and marketing	589,919	385,176	249,448
General and administrative	481,716	352,453	178,016
Amortization of acquired intangible assets	93,398	16,035	2,540
Intangible asset impairment charge	209,666	—	—
Total operating expenses	2,283,075	1,110,075	613,933
Other operating income	23,665	—	—
Loss from operations	(768,019)	(233,782)	(159,471)
Other income (expense)			
Investment income, net	6,897	26,530	21,203
Interest expense	(95,983)	(61,599)	(36,789)
Total other income (expense)	(89,086)	(35,069)	(15,586)
Net loss before tax	(857,105)	(268,851)	(175,057)
Income tax benefit (expense)	8,572	184,858	(92)
Net loss	$ (848,533)	$ (83,993)	$ (175,149)
Net loss per share—basic and diluted	$ (5.61)	$ (0.64)	$ (1.43)
Weighted average common shares outstanding—basic and diluted	151,137	131,257	122,207

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

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

	Year Ended December 31,		
	2020	2019	2018
Net loss	$ (848,533)	$ (83,993)	$ (175,149)
Other comprehensive loss:			
Unrealized gain (loss) on available-for-sale investments	771	1,322	(708)
Foreign currency adjustment	25	—	36
Comprehensive loss, before tax	(847,737)	(82,671)	(175,821)
Income tax expense related to items of other comprehensive loss	(170)	—	—
Comprehensive loss, net of tax	$ (847,907)	$ (82,671)	$ (175,821)

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

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

	Common Stock		Additional Paid In Capital	Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	$0.01 Par Value				
Balance, January 1, 2018	120,497,426	$ 1,205	$ 1,380,577	$ (750)	$ (860,614)	$ 520,418
Equity component of convertible debt, net of issuance costs	—	—	260,246	—	—	260,246
Exercise of common stock options	1,033,012	10	6,626	—	—	6,636
Issuance of common stock to fund the Company's 2017 401(k) match	86,882	1	4,302	—	—	4,303
Compensation expense related to issuance of stock options and restricted stock awards	1,228,611	13	60,251	—	—	60,264
Purchase of employee stock purchase plan shares	346,609	3	4,892	—	—	4,895
Net loss	—	—	—	—	(175,149)	(175,149)
Accumulated other comprehensive income	—	—	—	(672)	—	(672)
Balance, December 31, 2018	123,192,540	$ 1,232	$ 1,716,894	$ (1,422)	$ (1,035,763)	$ 680,941
Settlement of convertible notes	—	—	(300,768)	—	—	(300,768)
Shares issued to settle convertible notes	2,159,716	22	182,455	—	—	182,477
Equity component of convertible debt, net of issuance costs	—	—	268,368	—	—	268,368
Exercise of common stock options	641,925	6	8,781	—	—	8,787
Issuance of common stock to fund the Company's 2018 401(k) match	86,532	1	7,408	—	—	7,409
Compensation expense related to issuance of stock options and restricted stock awards	4,322,366	43	108,440	—	—	108,483
Purchase of employee stock purchase plan shares	176,458	2	8,394	—	—	8,396
Issuance of common stock for	17,046,159	171	1,406,909	—	—	1,407,080
Stock issuance costs	—	—	(441)	—	—	(441)
Net loss	—	—	—	—	(83,993)	(83,993)
Accumulated other comprehensive loss	—	—	—	1,322	—	1,322
Balance, December 31, 2019	147,625,696	$ 1,477	$ 3,406,440	$ (100)	$ (1,119,756)	$ 2,288,061
Equity component of convertible debt, net of issuance costs	—	—	346,641	—	—	346,641
Settlement of convertible notes,	—	—	(64,199)	—	—	(64,199)
Exercise of common stock options	702,907	7	27,070	—	—	27,077
Issuance of common stock to fund the Company's 2019 401(k) match	136,559	1	12,006	—	—	12,007
Compensation expense related to issuance of stock options and restricted stock awards	1,665,408	17	152,889	—	—	152,906
Purchase of employee stock purchase plan shares	301,064	3	18,352	—	—	18,355
Issuance of common stock for business combinations	386,293	4	28,843	—	—	28,847
Issuance of common stock for	8,605,483	86	861,615	—	—	861,701
Net loss	—	—	—	—	(848,533)	(848,533)
Accumulated other comprehensive loss	—	—	—	626	—	626
Balance, December 31, 2020	159,423,410	$ 1,595	$ 4,789,657	$ 526	$ (1,968,289)	$ 2,823,489

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

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

	Year Ended December 31,		
	2020	2019	2018
Cash flows from operating activities:			
Net loss	$ (848,533)	$ (83,993)	$ (175,149)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and other amortization	69,964	34,212	20,544
Loss on disposal of property, plant and equipment	2,470	1,394	353
Unrealized net (gain) loss on revaluation of equity securities	(1,179)	207	—
Loss on preferred stock investment	—	—	765
Deferred tax benefit	(9,862)	(185,109)	—
Stock-based compensation	152,906	108,483	60,264
Loss on settlement of convertible notes	7,954	10,558	—
Amortization of convertible note debt discount and issuance costs	76,479	42,256	28,564
Amortization of deferred financing costs and other liabilities	(3,889)	(4,467)	(2,394)
Accretion (Amortization) of discount (premium) on short-term investments	1,549	(3,102)	(3,516)
Amortization of acquired intangibles	93,398	16,035	2,540
Asset acquisition IPR&D expense	412,568	—	—
Intangible asset impairment charge	209,666	—	—
Non-cash lease expense	15,720	5,427	—
Changes in assets and liabilities, net of effects of acquisition:			
Accounts receivable, net	(100,526)	(27,633)	(17,292)
Inventory, net	(30,310)	(19,041)	(12,729)
Operating lease liabilities	(8,784)	(4,114)	—
Accounts payable and accrued liabilities	55,165	3,469	33,076
Other assets and liabilities	41,726	(6,237)	(3,966)
Net cash provided by (used in) operating activities	136,482	(111,655)	(68,940)
Cash flows from investing activities:			
Purchases of marketable securities	(1,089,953)	(634,117)	(1,192,506)
Maturities of marketable securities	886,675	1,657,204	578,786
Purchases of property, plant and equipment	(64,352)	(171,802)	(150,093)
Investment in privately held companies	(15,947)	(1,000)	—
Business combination, net of cash acquired	(6,658)	(973,861)	(17,908)
Asset acquisition, net of cash acquired	(411,421)	—	—
Other investing activities	(381)	(852)	(578)
Net cash used in investing activities	(702,037)	(124,428)	(782,299)
Cash flows from financing activities:			
Proceeds from issuance of convertible notes, net	1,125,547	729,477	896,430
Proceeds from exercise of common stock options	27,077	8,787	6,636
Proceeds from sale of common stock, net of issuance costs	861,701	—	—
Proceeds in connection with the Company's employee stock purchase plan	18,355	8,396	4,895
Payments on settlement of convertible notes	(150,054)	(493,356)	—
Proceeds from construction loan, net deferred financing costs	—	319	24,236
Other financing activities	(3,005)	(442)	1,945
Net cash provided by financing activities	1,879,621	253,181	934,142
Effects of exchange rate changes on cash and cash equivalents	—	—	36
Net increase in cash, cash equivalents and restricted cash	1,314,066	17,098	82,939
Cash, cash equivalents and restricted cash at the beginning of period	177,528	160,430	77,491
Cash, cash equivalents and restricted cash at the end of period	$ 1,491,594	$ 177,528	$ 160,430

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

	Year Ended December 31,		
	2020	2019	2018
Supplemental disclosure of non-cash investing and financing activities:			
Property, plant and equipment acquired but not paid	$ 2,685	$ 10,265	$ 33,452
Property acquired under build-to-suit lease	$ —	$ —	$ 2,092
Unrealized loss on available-for-sale investments	$ 771	$ 1,322	$ (708)
Issuance of 136,559, 86,532, and 86,882 shares of common stock to fund the Company's 401(k) matching contribution for 2019, 2018, and 2017, respectively	$ 12,007	$ 7,409	$ 4,303
Issuance of 2,159,716 shares of common stock upon settlement of convertible notes	$ —	$ 182,477	$ —
Retirement of equity component of convertible notes settled	$ (64,199)	$ (300,768)	$ —
Issuance of 386,293 and 17,046,159 shares of common stock in 2020 and 2019, respectively,	$ (28,847)	$ (1,407,080)	$ —
Business acquisition contingent consideration liability	$ —	$ —	$ 3,060
Supplemental disclosure of cash flow information:			
Interest paid	$ 9,384	$ 5,128	$ 4,638

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 cancer screening and diagnostics company. It has developed some of the most impactful brands in cancer screening and diagnostics, including Cologuard® and Oncotype DX®. Exact is currently working on the development of 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 and variable interest entities. 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 convertible notes, valuation of intangible assets and goodwill, and accounting for income taxes among others.

The spread of the coronavirus ("COVID-19") has affected many segments of the global economy, including the cancer screening and diagnostics industry. The COVID-19 outbreak, which the World Health Organization has classified as a pandemic, has prompted governments and regulatory bodies throughout the world to enact broad precautionary measures, including "stay-at-home" orders, restrictions on the performance of "non-essential" services, public gatherings and travel. Health systems, including key markets where the Company operates, have been, or may be, overwhelmed with high volumes of patients suffering from COVID-19. Even in areas where "stay-at-home" restrictions have been lifted and the number of cases of COVID-19 has declined, many individuals remain cautious about resuming activities such as preventive-care medical visits. Medical practices continue to be cautious about allowing individuals, such as sales representatives, into their offices. Many individuals continue to work from home rather from an office setting. The Company cannot forecast when the COVID-19 pandemic will end or the extent to which practices that have emerged during the pandemic will continue once it subsides.

The extent to which COVID-19 impacts the Company's business and financial results will depend on numerous evolving factors including, but not limited to: the magnitude and duration of COVID-19, the extent to which it will impact worldwide macroeconomic conditions including interest rates, employment rates and health insurance coverage, the speed of the anticipated recovery, access to capital markets, and governmental and business reactions to the pandemic. The Company assessed certain accounting matters that generally require consideration of forecasted financial information in context with the information reasonably available to the Company and the unknown future impacts of COVID-19 as of December 31, 2020 and through the date of the filing of this Annual Report on Form 10-K. The accounting matters assessed included, but were not limited to, the Company's allowance for doubtful accounts and credit losses, equity investments, software, and the carrying value of the goodwill and other long-lived assets. The Company's future assessment of the magnitude and duration of COVID-19, as well as other factors, could result in additional material impacts to the Company's consolidated financial statements in future reporting periods.

The pandemic and related precautionary measures began to materially disrupt the Company's operations in March 2020 and may continue to disrupt the business for an unknown period of time. As a result, the pandemic had a significant impact on the Company's 2020 revenues and operating results.

The ultimate impact of COVID-19 depends on factors beyond the Company's knowledge or control, including the duration and severity of the outbreak, as well as third-party actions taken to contain its spread and mitigate its public health effects. As a result, the Company is unable to estimate the extent to which COVID-19 will negatively impact its financial results or liquidity.

Coronavirus Aid, Relief, and Economic Security Act ("CARES Act")

In April 2020, the Company received $23.7 million from the United States Department of Health and Human Services ("HHS") as a distribution from the Public Health and Social Services Emergency Fund provided for in the CARES Act. The fund payments are grants, not loans, and HHS will not require repayment provided the funds are utilized to offset expenses incurred to address COVID-19 or to replace lost revenues. The Company accepted the terms and conditions of the grant in May 2020 and recognized the entire $23.7 million during the year ended December 31, 2020, due to lost revenue attributable to COVID-19, which is reflected in other operating income in the consolidated statement of operations. The Company cannot predict the extent to which it might receive any additional funds to be paid out under the Provider Relief Fund, and to what extent the financial impact of receiving such funds might offset the broad implications of the COVID-19 pandemic, which include increases in the Company's costs and lost revenues.

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 indicate that expected collections will be less than applicable accrual rates. At December 31, 2020 and 2019, the allowance for doubtful accounts recorded was not material to the Company's consolidated balance sheets. For the years ended December 31, 2020, 2019 and 2018, there was an immaterial 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 meet 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, have been 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 basis 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, in accordance with the applicable accounting guidance for such investments. 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 are accounted for as non-marketable 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, in accordance with the applicable accounting guidance for such investments.

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 Accounting Standards Codification ("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 the ASC 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.

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, 2020, 2019 and 2018 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 value assigned to acquired IPR&D is determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting revenues from the projects and discounting the net cash flows to present value. The revenues and cost projections used to value acquired IPR&D are, as applicable, reduced based on the probability of success. IPR&D projects acquired in a business combination that are not complete are capitalized and accounted for as indefinite-lived intangible assets until completion or abandonment of the related R&D efforts. 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. There are often major risks and uncertainties associated with IPR&D projects as we are required to obtain regulatory approvals in order to be able to market the resulting products. Such approvals require completing clinical trials that demonstrate the products 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 and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. 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.

Goodwill

The Company evaluates goodwill for possible impairment in accordance with Financial Accounting Standards Board ("FASB") ASC 350 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, 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)	2020	2019	2018
Shares issuable in connection with acquisitions	157	—	—
Shares issuable upon exercise of stock options	2,231	2,700	2,532
Shares issuable upon the release of restricted stock awards	3,968	3,801	3,847
Shares issuable upon the release of performance share units	619	583	2,399
Shares issuable upon conversion of convertible notes	20,309	12,196	12,044
	27,284	19,280	20,822

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. 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 estimated fair value of these awards is recognized to expense using the straight-line method over the 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 estimated fair value of these awards is recognized to expense using the straight-line method over the vesting period.

The fair value of performance-based equity awards is determined on the date of grant using the closing stock price on that day. The expense recognized each period is partially 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, so no compensation cost would be recognized and any previously recognized stock-based compensation expense would be reversed.

Research and Development Costs

Research and development costs are expensed as incurred. These expenses include the costs of our 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. 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.

The Company incurred research and development expenses of $554.1 million, $139.7 million, and $67.3 million during the years ended December 31, 2020, 2019, and 2018, respectively, including IPR&D of $412.6 million that was acquired in an asset acquisition in 2020 and had no alternative future use. The value of the acquired IPR&D that was expensed was determined by identifying those acquired specific IPR&D projects that would be continued and which (a) were incomplete and (b) had 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 statement of cash flows.

Advertising Costs

The Company expenses the costs of media advertising at the time the advertising takes place. The Company expensed approximately $93.2 million, $88.7 million, and $93.7 million of media advertising during the years ended December 31, 2020, 2019, and 2018, respectively, which is recorded in sales and marketing expenses on the Company's consolidated statements of operations.

Fair Value Measurements

The 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.

Convertible Notes

The Company accounts for convertible debt instruments that may be settled in cash or equity upon conversion by separating the liability and equity components of the instruments in a manner that reflects the Company’s nonconvertible debt borrowing rate. The Company determines the carrying amount of the liability component of the convertible debt instrument by using assumptions that market participants would use in pricing a debt instrument, including market interest rates, credit standing, yield curves, volatilities, and expected life of the instrument. Determining the fair value of the debt component requires the use of accounting estimates and assumptions. These estimates and assumptions are judgmental in nature and could have a significant impact on the determination of the debt component, and the associated non-cash interest expense.

The amount allocated to the equity component is the difference between the principal value of the instrument and the fair value of the liability component at issuance. The equity component, less any premium, is treated as a discount on the liability component. The debt discount is amortized to interest expense over the contractual term of the debt instrument using the effective interest rate method. In addition, debt issuance costs related to the debt instrument are allocated to the liability and equity components based on their relative values. The debt issuance costs allocated to the liability component are amortized over the contractual term of the debt instrument as additional non-cash interest expense. The transaction costs allocated to the equity component are netted with the equity component of the convertible debt instrument in stockholders equity.

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. At the beginning of fiscal year 2019, the company adopted ASC Topic 842. 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 most of the Company’s leases do not provide an implicit interest rate, 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. In order to determine the appropriate incremental borrowing rates, the Company has used a number of factors including the credit rating, and the lease term.

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. To determine revenue recognition for the arrangements that the Company determines are within the scope of FASB ASC Topic 606, Revenue from Contracts with Customers, the Company performs the following five steps: (1) identify the contract(s) with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract and (5) recognize revenue when (or as) the entity satisfies a performance obligation. See Note 2 for further discussion.

Foreign Currency Transactions

Prior to 2019, the Company's international subsidiaries' functional currency was the local currency and assets and liabilities were translated into U.S. dollars at the period-end exchange rate or historical rates, as appropriate. Consolidated statements of operations were translated at average exchange rates for the period, and the cumulative translation adjustments resulting from changes in exchange rates were included in the Company's consolidated balance sheet as a component of additional paid-in capital. In 2019 and 2020, the Company's international subsidiaries use the U.S. dollar as the functional currency, resulting in the Company not being subject to gains and losses from foreign currency translation of the subsidiary financial statements. The Company recognizes gains and losses from foreign currency transactions in the consolidated statements of operations. Net foreign currency transaction gains or losses were not material to the consolidated statements of operations for the periods presented.

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, 2020, 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 $237.0 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, 2020, the Company's revenues have been primarily derived from the sale of Cologuard, Oncotype DX, 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	**2020**	**2019**	**2018**	**2020**	**2019**	**2018**
Centers for Medicare and Medicaid Services	21%	29%	36%	14%	19%	32%
UnitedHealthcare	10%	13%	13%	7%	7%	10%
State of Wisconsin	12%	—%	—%	22%	—%	—%

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 $157.6 million and $120.7 million valuation allowance at December 31, 2020 and 2019 is necessary to reduce the tax assets to the amount that is more likely than not to be realized. The change in valuation allowance as of December 31, 2020 and 2019 was an increase of $36.9 million and a decrease of $89.2 million, respectively. An income tax benefit of $8.6 million was recorded primarily as a result of future limitations on and expiration of certain Federal and State deferred tax assets. Due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact our effective tax rate.

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The updated guidance requires companies to measure all expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions, and reasonable supportable forecasts. This replaces the existing incurred loss model and is applicable to the measurement of credit losses on financial assets, including trade receivables. The updates also require available-for-sale debt security credit losses to be recognized as allowances rather than a reduction in amortized cost. The guidance was adopted by the Company on January 1, 2020. The requirements of the ASU did not result in the recognition of a material allowance for current expected credit losses, as the Company's analysis of collectability looks at historical experience as well as current and future implications surrounding the ability to collect. Adoption of the updated guidance did not have a material impact on the Company's consolidated financial statements.

In April 2019, the FASB issued ASU 2019-04, *Codification Improvements to Topic 326, Financial Instruments –Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments*. The updated guidance provides clarity regarding measurement of securities without readily determinable fair values. The guidance was adopted on January 1, 2020 and did not have a material impact on the Company's consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, *Intangibles –Goodwill and Other –Internal-Use Software (Subtopic 350-40)*. The update provided guidance for evaluating the accounting for fees paid by a customer in a cloud computing arrangement that is a service contract. The guidance was adopted on a prospective basis, beginning on January 1, 2020 and it did not have a material impact on the Company's consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820); Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement*. The guidance provided an update to the disclosure requirements for fair value measurements under the scope of ASC 820. The updates were adopted on January 1, 2020 and did not have a material impact on the Company's consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808)*. The update provided additional guidance regarding the interaction between Topic 808 on Collaborative Arrangements and Topic 606 on Revenue Recognition. The guidance was adopted on January 1, 2020 and did not have a material impact on the Company's consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. The update simplifies the accounting for income taxes through removing exceptions related to certain intraperiod allocations and deferred tax liabilities; clarifying guidance primarily related to evaluating the step-up tax basis for goodwill in a business combination; and reflecting enacted changes in tax laws or rates in the annual effective tax rate. The amended guidance is effective for interim and annual periods in 2021, however early adoption is permitted. The guidance was early adopted on January 1, 2020 and did not have a material impact on the Company's consolidated financial statements.

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*. The updated guidance provides optional expedients for applying the requirements of certain topics in the codification for contracts that are modified because of reference rate reform. In addition to the optional expedients, the update includes a general principle that permits an entity to consider contract modifications due to reference rate reform to be an event that does not require contract remeasurement at the modification date or reassessment of a previous accounting determination. The updated guidance is effective for all entities as of March 12, 2020 and through December 31, 2022. The Company adopted the guidance upon issuance on March 12, 2020. There was no impact on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In August 2020, The Financial Accounting Standards Board issued ASU No. 2020-06, *Debt – Debt with Conversion and Other Options (subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40)*. This update simplifies the accounting for convertible debt instruments by removing the beneficial conversion and cash conversion separation models for convertible instruments. Under the update, the embedded conversion features are no longer separated from the host contract for convertible instruments with conversion features that are not required to be accounted for as derivatives or that do not result in substantial premiums accounted for as paid-in capital. The update also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. In addition, the new guidance modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the computation of diluted earnings per share. The amendments in this update are effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The Company is currently evaluating the impact of this guidance on its consolidated financial statements.

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, 2020 and 2019.

Reclassifications

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

(2) REVENUE

The Company's revenue is primarily generated by its laboratory testing services utilizing its Cologuard, Oncotype IQ®, and COVID-19 tests. The services are completed upon release of a patient's test result to the ordering healthcare provider.

The core principle of ASC 606 is that the Company recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to collect in exchange for those goods or services. The Company recognizes revenues from its products in accordance with that core principle, and key aspects considered by the Company include the following:

Contracts

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, the Company requires payment from the patient prior to the commencement of the Company's performance obligations. The Company's consideration can be deemed variable or fixed depending on the structure of specific payer contracts, and the Company considers collection of such consideration to be probable to the extent that it is unconstrained.

Under the Company's Laboratory Service Agreements ("LSA") and Laboratory Reference Agreements ("LRA") the Company contracts with a direct bill payer who is the customer for an agreed upon amount of laboratory testing services for a specified amount of time at a fixed reimbursement rate, and certain of the Company's LSAs obligate the customer to pay for testing services prior to result.

Performance obligations

A performance obligation is a promise in a contract to transfer a distinct good or service (or a bundle of goods or services) to the customer. 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 LSAs, 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 related to the disclosure of 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.

Transaction price

The transaction price is the amount of consideration that the Company expects to collect in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties (for example, some sales taxes). The consideration expected to be collected from a contract with a customer may include fixed amounts, variable amounts, or both.

Fixed consideration is derived from the Company's LSA, LRA, and direct bill payer contracts that exist between the Company and the direct bill payers. The contracted reimbursement rate is deemed to be fixed as the Company expects to fully collect all amounts billed under these relationships. Variable consideration is primarily derived from payer and patient billing and can result due to 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.

The Company estimates the amount of variable consideration using the expected value method, which represents the sum of probability-weighted amounts in a range of possible consideration amounts. When estimating the amount of variable consideration, the Company considers several factors, such as historical collections experience, patient insurance eligibility and payer reimbursement contracts.

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. Revenue recognized from changes in transaction prices was $9.6 million, $9.9 million and $15.0 million for the years ended December 31, 2020, 2019 and 2018, respectively.

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.

Allocate transaction price

The transaction price is allocated entirely to the performance obligation contained within the contract with a customer.

Point in time recognition

The Company's single performance obligation is satisfied at a point in time. That point in time is defined as the date the Company releases a result to the ordering healthcare provider, or, in the context of some of the Company's LSAs, that point in time could be the date the allotted testing window ends if a specimen sample is not returned to the laboratory for processing. The point in time in which revenue is recognized by the Company signifies fulfillment of the performance obligation to the patient or direct bill payer.

Disaggregation of Revenue

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

	Year Ended December 31,		
(In thousands)	2020	2019	2018
Screening			
Medicare Parts B & C	$ 365,471	$ 404,331	$ 254,431
Commercial	409,671	368,006	184,538
Other	39,925	37,783	15,493
Total Screening	815,067	810,120	454,462
Precision Oncology			
Medicare Parts B & C	$ 157,166	$ 24,325	$ —
Commercial	186,043	29,976	—
International	77,484	11,444	—
Other	19,800	428	—
Total Precision Oncology	440,493	66,173	—
COVID-19 Testing	$ 235,831	$ —	$ —
Total	$ 1,491,391	$ 876,293	$ 454,462

Screening revenue primarily includes laboratory service revenue from the Cologuard test while Precision Oncology revenue primarily includes laboratory service revenue from global Oncotype IQ products.

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 subsequent to the release of a patient's test result to the ordering healthcare provider, resulting in an account receivable. However, the Company sometimes receives advance payment from a patient or a direct bill payer before a test result is completed, resulting in deferred revenue. The deferred revenue recorded is recognized as revenue at the point in time results are released to the patient's healthcare provider. Or, in the context of some of the Company's LSAs, 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.

Deferred revenue balances are reported in other current liabilities in the Company's consolidated balance sheets and were $25.0 million and $0.6 million as of December 31, 2020 and 2019, respectively. As of December 31, 2020, $24.2 million of the Company's deferred revenue balance is a result of the billing terms pursuant to the existing COVID-19 LSAs with customers.

Revenue recognized for the years ended December 31, 2020 and 2019, which was included in the deferred revenue balance at the beginning of each period was $0.2 million and $0.2 million, respectively.

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.

(3) MARKETABLE SECURITIES

The following table sets forth the Company's cash, cash equivalents, restricted cash, and marketable securities at December 31, 2020 and 2019:

	December 31,	
(In thousands)	2020	2019
Cash, cash equivalents, and restricted cash		
Cash and money market	$ 901,294	$ 146,932
Cash equivalents	589,994	30,322
Restricted cash (1)	306	274
Total cash, cash equivalents and restricted cash	1,491,594	177,528
Marketable securities		
Available-for-sale debt securities	347,178	144,685
Equity securities	1,521	1,716
Total marketable securities	348,699	146,401
Total cash and cash equivalents, restricted cash and marketable securities	$ 1,840,293	$ 323,929

(1) Restricted cash is included in other long-term assets on the consolidated balance sheets. There was no restricted cash at December 31, 2018.

Available-for-sale debt securities at December 31, 2020 consisted of the following:

(In thousands)	Amortized Cost	Gains in Accumulated Other Comprehensive Income (Loss) (1)	Losses in Accumulated Other Comprehensive Income (Loss) (1)	Estimated Fair Value
Cash equivalents				
U.S. government agency securities	$ 589,986	$ 8	$ —	$ 589,994
Total cash equivalents	589,986	8	—	589,994
Marketable securities				
Corporate bonds	132,301	612	—	132,913
U.S. government agency securities	207,119	52	—	207,171
Asset backed securities	7,070	24	—	7,094
Total marketable securities	346,490	688	—	347,178
Total available-for-sale debt securities	$ 936,476	$ 696	$ —	$ 937,172

(1) Gains and losses in accumulated other comprehensive income (loss)("AOCI") are reported before tax impact.

Available-for-sale debt securities at December 31, 2019 consisted of the following:

(In thousands)	Amortized Cost	Gains in Accumulated Other Comprehensive Income (Loss) (1)	Losses in Accumulated Other Comprehensive Income (Loss) (1)	Estimated Fair Value
Cash equivalents				
U.S. government agency securities	$ 30,320	$ 2	$ —	$ 30,322
Total cash equivalents	30,320	2	—	30,322
Marketable securities				
Corporate bonds	4,017	—	(14)	4,003
U.S. government agency securities	140,745	10	(73)	140,682
Total marketable securities	144,762	10	(87)	144,685
Total available-for-sale debt securities	$ 175,082	$ 12	$ (87)	$ 175,007

(1) There was no tax impact on the gains and losses in accumulated income (loss) at December 31, 2019.

The following table summarizes contractual underlying maturities of the Company's available-for-sale debt securities at December 31, 2020:

	Due one year or less		Due after one year through four years	
(In thousands)	Cost	Fair Value	Cost	Fair Value
Cash equivalents				
U.S. government agency securities	$ 589,986	$ 589,994	$ —	$ —
Total cash equivalents	589,986	589,994	—	—
Marketable securities				
U.S. government agency securities	199,988	199,994	7,131	7,177
Corporate bonds	100,837	101,122	31,464	31,791
Asset backed securities	—	—	7,070	7,094
Total marketable securities	300,825	301,116	45,665	46,062
Total available-for-sale securities	$ 890,811	$ 891,110	$ 45,665	$ 46,062

There were no available-for-sale debt securities in an unrealized loss position as of December 31, 2020.

The following table summarizes the gross unrealized losses and fair value of available-for-sale debt securities in an unrealized loss position as of December 31, 2019, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position:

	Less than 12 months		12 months or greater		Total	
(In thousands)	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
Marketable Securities						
Corporate bonds	$ 4,003	$ (14)	$ —	$ —	$ 4,003	$ (14)
Asset backed securities	140,682	(73)	—	—	140,682	(73)
Total	$ 144,685	$ (87)	$ —	$ —	$ 144,685	$ (87)

The Company evaluates investments, including investments in privately-held companies, 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, 2020 and 2019 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 Company recorded a realized gain on available-for-sale debt securities of $0.1 million, $3.4 million, and $0.4 million for the years ended December 31, 2020, 2019, and 2018, respectively, net of insignificant realized losses.

The Company recorded a loss of $0.2 million and $0.2 million, respectively, from its equity securities for the years ended December 31, 2020 and 2019. The Company held no equity securities during the year ended December 31, 2018, and recorded no gain or loss.

The gains and losses recorded are included in investment income, net in the Company's consolidated statements of operations.

(4) INVENTORY

Inventory consisted of the following:

	December 31,	
(In thousands)	2020	2019
Raw materials	$ 43,083	$ 24,958
Semi-finished and finished goods	49,182	36,766
Total inventory	$ 92,265	$ 61,724

(5) PROPERTY, PLANT AND EQUIPMENT

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

		December 31,	
(In thousands)	Estimated Useful Life	2020	2019
Property, plant and equipment			
Land	n/a	$ 4,466	$ 4,466
Leasehold and building improvements	(1)	117,865	80,352
Land improvements	15 years	4,864	1,766
Buildings	30 - 40 years	200,980	112,815
Computer equipment and computer software	3 years	73,296	65,323
Laboratory equipment	3 - 10 years	142,110	104,008
Furniture and fixtures	3 - 10 years	24,968	14,539
Assets under construction	n/a	18,751	149,687
Property, plant and equipment, at cost		587,300	532,956
Accumulated depreciation		(136,617)	(77,631)
Property, plant and equipment, net		$ 450,683	$ 455,325

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

Depreciation expense for the years ended December 31, 2020, 2019, and 2018 was $69.4 million, $33.9 million, and $20.5 million, respectively.

At December 31, 2020, the Company had $18.8 million of assets under construction which consisted of $3.2 million related to building and leasehold improvements, $7.6 million of costs related to laboratory equipment under construction, $7.9 million of capitalized costs related to software projects, and $0.1 million of furniture and fixtures. Depreciation will begin on these assets once they are placed into service upon completion in 2021 and 2022.

(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, 2020:

(In thousands)	Weighted Average Remaining Life (Years)	Cost	Accumulated Amortization	Net Balance at December 31, 2020
Finite-lived intangible assets				
Trade name	14.9	$ 100,700	$ (7,258)	$ 93,442
Customer relationships	12.8	2,700	(404)	2,296
Patents	3.7	10,441	(5,422)	5,019
Supply agreement	6.5	30,000	(4,527)	25,473
Acquired developed technology	9.0	814,171	(93,278)	720,893
Internally developed technology	2.2	2,121	(921)	1,200
Total finite-lived intangible assets		960,133	(111,810)	848,323
Internally developed technology in process	n/a	103	—	103
Total intangible assets		$ 960,236	$ (111,810)	$ 848,426

The following table summarizes the net-book-value and estimated remaining life of the Company's finite-lived intangible assets as of December 31, 2019:

(In thousands)	Weighted Average Remaining Life (Years)	Cost	Accumulated Amortization	Net Balance at December 31, 2019
Finite-lived intangible assets				
Trade name	15.9	$ 100,700	$ (961)	$ 99,739
Customer relationships	13.8	2,700	(224)	2,476
Patents	8.8	22,690	(5,975)	16,715
Supply agreement	7.5	30,000	(571)	29,429
Acquired developed technology	9.9	806,371	(12,344)	794,027
Internally developed technology	2.5	1,229	(336)	893
Total finite-lived intangible assets		963,690	(20,411)	943,279
In-process research and development	n/a	200,000	—	200,000
Internally developed technology in process	n/a	271	—	271
Total intangible assets		$ 1,163,961	$ (20,411)	$ 1,143,550

As of December 31, 2020, 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)	
2021	$ 93,401
2022	93,196
2023	92,876
2024	92,422
2025	91,374
Thereafter	385,054
	$ 848,323

The Company's acquired intangible assets are being amortized on a straight-line basis over the estimated useful life.

During the third quarter of 2020, the Company began discussions with Biocartis regarding the termination of its agreements with Biocartis related to the development of an in vitro diagnostic ("IVD") version of the Oncotype DX Breast Recurrence Score® test. As a result, and in connection with the preparation of the financial statements included in the Company's Form 10-Q for the period ended September 30, 2020, the Company recorded a non-cash, pre-tax impairment loss of $200.0 million related to the in-process research and development intangible asset that was initially recorded as part of the combination with Genomic Health. The impairment is recorded in intangible asset impairment charge in the consolidated statement of operations for the year ended December 31, 2020. The agreements with Biocartis were terminated in November 2020.

During the third quarter of 2020, the Company abandoned certain research and development assets acquired through an asset purchase agreement with Armune Biosciences, Inc. in 2017. These assets were expected to complement the Company's product pipeline and were expected to have alternative future uses at the time of acquisition; however, due to changes in strategic priorities and efforts during the third quarter of 2020, these assets are no longer expected to be utilized to advance the Company's product pipeline. As a result, the Company wrote-off the gross cost basis of the intangible asset of $12.2 million and accumulated amortization of $2.5 million. This write-off resulted in a non-cash, pre-tax impairment loss of $9.7 million, which is recorded in intangible asset impairment charge in the consolidated statement of operations for the year ended December 31, 2020.

There were no impairment losses for the years ended December 31, 2019 and 2018.

Goodwill

The change in the carrying amount of goodwill for the years ended December 31, 2020 and 2019 is as follows:

(In thousands)	
Balance, January 1, 2019 (1)	$ 17,279
Genomic Health acquisition	1,185,918
Balance, December 31, 2019	1,203,197
Paradigm & Viomics acquisition	30,431
Genomic Health acquisition adjustment (2)	4,044
Balance, December 31, 2020	$ 1,237,672

(1) The beginning balance represents the goodwill acquired from the acquisitions of Sampleminded, Inc. in 2017 and Biomatrica, Inc. in 2018 totaling $2.0 million and $15.3 million, respectively.

(2) The Company recognized a measurement period adjustment to goodwill related to an increase in Genomic Health's pre-acquisition deferred tax liability due to finalization of certain income-tax related items.

There were no impairment losses for the years ended December 31, 2020, 2019, and 2018.

(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, 2020 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, 2020	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	$ 901,294	$ 901,294	$ —	$ —
U.S. government agency securities	589,994	—	589,994	—
Restricted cash	306	306	—	—
Marketable securities				
Corporate bonds	132,913	—	132,913	—
U.S. government agency securities	207,171	—	207,171	—
Asset backed securities	7,094	—	7,094	—
Equity securities	1,521	1,521	—	—
Liabilities				
Contingent consideration	(2,477)	—	—	(2,477)
Total	$ 1,837,816	$ 903,121	$ 937,172	$ (2,477)

The following table presents the Company's fair value measurements as of December 31, 2019 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, 2019	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents				
Cash and money market	$ 146,932	$ 146,932	$ —	$ —
U.S. government agency securities	30,322	—	30,322	—
Restricted cash	274	274	—	—
Marketable securities				
Corporate bonds	4,003	—	4,003	—
U.S. government agency securities	140,682	—	140,682	—
Equity securities	1,716	1,716	—	—
Liabilities				
Contingent consideration	(2,879)	—	—	(2,879)
Total	$ 321,050	$ 148,922	$ 175,007	$ (2,879)

There have been no changes in valuation techniques or transfers between fair value measurement levels during the years ended December 31, 2020 and 2019. 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's marketable equity security investment in Biocartis is classified as a Level 1 instrument. See Note 11 for additional information on Biocartis.

Contingent Consideration

In connection with the Biomatrica acquisition, a contingent earn-out liability was created to account for an additional $20.0 million in contingent consideration that could be earned based upon certain revenue milestones being met. The following table provides a roll-forward of the fair values of the contingent consideration, which includes Level 3 measurements:

(In thousands)	Contingent consideration
Balance, January 1, 2020	$ (2,879)
Changes in fair value	325
Payments	77
Balance, December 31, 2020	$ (2,477)

As of December 31, 2020, the fair value of the contingent earn-out liability is classified as a component of other long-term liabilities in the Company's consolidated balance sheet.

This fair value measurement of contingent consideration related to the Biomatrica acquisition was categorized as a Level 3 liability, as the measurement amount is based primarily on significant inputs not observable in the market. The Company evaluates the fair value of expected contingent consideration and the corresponding liability each annual reporting period using the Monte Carlo Method, which is consistent with the initial measurement of the expected Biomatrica Acquisition earn-out liability. The Company estimates projections during the earn-out period utilizing various potential pay-out scenarios. Probabilities were applied to each potential scenario and the resulting values were discounted using a rate that considers weighted average cost of capital as well as a specific risk premium associated with the riskiness of the earn-out itself, the related projections, and the overall business.

Non-Marketable Equity Investments

The Company has non-marketable equity investments which are initially recorded at the estimated fair value based on observable transactions. The Company has concluded it is not a primary beneficiary with regards to these investments and does not have the ability to exercise significant influence over the investees and thus has not consolidated the investees pursuant to the requirements of ASC 810, Consolidation. The Company will continue to assess its investments and future commitments to the investees and to the extent its relationship with the investees change and whether such change may require consolidation of

the investees in future periods. The Company remeasures the fair value only when an observable transaction occurs during the period that would suggest a change in the carrying value of the investment. As of December 31, 2020 and 2019, the Company had non-marketable equity investments of $29.1 million and $11.8 million, respectively, which are classified as a component of other long-term assets in the Company's consolidated balance sheets. As of December 31, 2020, the balance primarily consists of the Company's preferred stock investments in 18,258,838 shares of Epic Sciences, Inc. ("Epic Sciences") and 5,025,764 shares of Thrive Earlier Detection Corp. ("Thrive") of $10.8 million and $12.5 million, respectively. As of December 31, 2019, the balance consists of the Company's preferred stock investments in Epic Sciences and Thrive Earlier Detection Corp. ("Thrive") of $10.8 million and $1.0 million, respectively.

The Company purchased 4.0 million shares of Series B Preferred Stock of Thrive for $10.0 million in July 2020. The Company previously held a $1.0 million investment in the Series A Preferred Stock of Thrive, which does not have a readily determinable fair value and therefore, the Company elected the measurement alternative. The rights and obligations of the Series B Preferred Stock are generally the same as the Series A Preferred Stock previously held indicating that the transactions are identical or similar investments. As a result, the Company recorded an unrealized gain of $1.5 million during the year ended December 31, 2020 in investment income, net on the Company's consolidated statement of operations to revalue the Company's initial investment to the value of the Series B Preferred Stock, which was the most recent observable transaction. As discussed in Note 22 below, the Company acquired Thrive in January 2021.

There have been no other observable transactions during the years ended December 31, 2020 and 2019.

Derivative Financial Instruments

As of December 31, 2020 and 2019, the Company had open foreign currency forward contracts with notional amounts of $22.4 million and $17.9 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 foreign currency forward contracts was zero at December 31, 2020 and 2019, and there were no gains or losses recorded for the years ended December 31, 2020 and 2019.

Fair Value of Long-Term Debt and Convertible Notes

The Company measures the fair value of its convertible notes and long-term debt for disclosure purposes. The following table summarizes the Company's outstanding convertible notes and long-term debt:

	December 31, 2020		December 31, 2019	
(In thousands)	Carrying Amount (1)	Fair Value	Carrying Amount (1)	Fair Value
2028 Convertible notes (2)	$ 806,587	$ 1,526,625	$ —	$ —
2027 Convertible notes (2)	514,173	992,306	483,909	843,741
2025 Convertible notes (2)	255,464	601,744	319,696	592,482
Construction loan (3)	23,661	23,661	24,866	24,866

(1) The carrying amounts presented are net of debt discounts and debt issuance costs. See Note 9 and Note 10 of the consolidated financial statements for further information.

(2) The fair values are based on observable market prices for this debt, which is traded in active markets and therefore is classified as a Level 2 fair value measurement. A portion of the 2025 convertible notes were settled in 2019 resulting in a decrease in the liability.

(3) The carrying amount of the construction loan approximates fair value due to the short-term nature of this instrument. The construction loan is privately held with no public market for this debt and therefore is classified as a Level 3 fair value measurement. The change in the fair value was due to payments made on the loan resulting in a decrease in the liability.

(8) ACCRUED LIABILITIES

Accrued liabilities at December 31, 2020 and 2019 consisted of the following:

	December 31,	
(In thousands)	2020	2019
Compensation	$ 117,273	$ 95,166
Pfizer Promotion Agreement related costs	46,937	33,230
Professional fees	36,113	29,108
Other	20,735	13,976
Assets under construction	2,118	10,720
Research and trial related expenses	5,911	8,368
Licenses	4,517	2,761
	$ 233,604	$ 193,329

(9) LONG-TERM DEBT

Construction Loan Agreement

During December 2017, the Company entered into a loan agreement with Fifth Third Bank (formerly MB Financial Bank, N.A.) (the "Construction Loan Agreement"), which provides the Company with a non-revolving construction loan (the "Construction Loan") of $25.6 million. The Company is using the Construction Loan proceeds to finance the construction of an additional clinical laboratory and related facilities in Madison, Wisconsin. The Construction Loan is collateralized by the additional clinical laboratory and related facilities.

Pursuant to the Construction Loan Agreement, funds drawn will bear interest at a rate equal to the sum of the 1-month LIBOR rate plus 2.25 percent. Regular monthly payments are interest-only for the first 24 months, with further payments based on a 20-year amortization schedule. Amounts borrowed pursuant to the Construction Loan Agreement may be prepaid at any time without penalty. The maturity date of the Construction Loan Agreement is December 10, 2022.

In November 2017, Fifth Third Bank, on behalf of the Company, issued an Irrevocable Standby Letter of Credit in the amount of $0.6 million in favor of the City of Madison, Wisconsin (the "City Letter of Credit"). The City Letter of Credit is deemed to have been issued pursuant to the Construction Loan Agreement. The amount of the City Letter of Credit will reduce, dollar for dollar, the amount available for borrowing under the Construction Loan Agreement.

As a condition to Fifth Third's initial advance of loan proceeds under the Construction Loan Agreement, the Company was required to first invest at least $16.4 million of its own cash into the construction project. The Company fulfilled its required initial investment and made its first draw on the Construction Loan in June 2018. In December 2019, the Company began making monthly payments towards the outstanding principal balance plus accrued interest. As of December 31, 2020 and 2019, the outstanding balance was $23.8 million and $25.0 million, respectively, from the Construction Loan, including $0.7 million of interest incurred, which is accrued for as an interest reserve and represents a portion of the loan balance. The Company capitalized the $0.7 million of interest to the construction project. The Company incurred approximately $0.2 million of debt issuance costs related to the Construction Loan, which are recorded as a direct deduction from the liability. The debt issuance costs are being amortized over the life of the Construction Loan.

The Construction Loan Agreement was amended effective June 30, 2020 to include a financial covenant to maintain a minimum liquidity of $250.0 million and remove the minimum tangible net worth covenant. As of December 31, 2020, the Company is in compliance with the covenant included in the amended agreement.

The table below represents the future principal obligations as of December 31, 2020. Amounts included in the table are in thousands:

Year ending December 31	
2021	$ 1,319
2022	22,431
Total	$ 23,750

Tax Increment Financing Loan Agreements

The Company entered into two separate Tax Increment Financing Loan Agreements ("TIFs") in February 2019 and June 2019 with the City of Madison, Wisconsin. The TIFs provide for $4.6 million of financing in the aggregate. In return for the loans, the Company is obligated to create and maintain 500 full-time jobs over a five-year period, starting on the date of occupancy of the buildings constructed. In the event that the job creation goals are not met, the Company would be required to pay a penalty.

The Company records the earned financial incentives as the full-time equivalent positions are filled. The amount earned is recorded as a liability and amortized as a reduction of operating expenses over a two-year period, which is the timeframe when the TIFs will be repaid through property taxes.

As of December 31, 2019, the Company had earned and received payment of $4.6 million from the City of Madison. As of December 31, 2020, the corresponding liability, which reflected when the expected benefit of the tax credit amortization would reduce future operating expenses, has been fully amortized and has a balance of zero. As of December 31, 2019, the Company had recorded a liability of $2.7 million in other current liabilities on the Company's balance sheet.

(10) CONVERTIBLE NOTES

Convertible note obligations included in the consolidated balance sheets consisted of the following:

(In thousands)	Coupon Interest Rate	Effective Interest Rate	Fair Value of Liability Component at Issuance (1)	December 31, 2020	December 31, 2019
2028 Convertible notes	0.375 %	5.2 %	$ 790,608	$1,150,000	$ —
2027 Convertible notes	0.375 %	6.3 %	472,501	747,500	747,500
2025 Convertible notes	1.000 %	6.0 %	227,103	315,049	415,049
Total Convertible notes				2,212,549	1,162,549
Less: Debt discount (2)				(608,685)	(342,463)
Less: Debt issuance costs (3)				(27,640)	(16,481)
Net convertible debt including current maturities				1,576,224	803,605
Less: Current maturities (4)				(255,464)	—
Net long-term convertible debt				$1,320,760	$ 803,605

(1) As each of the convertible instruments may be settled in cash upon conversion, for accounting purposes, they were separated into a liability component and an equity component. The amount allocated to the equity component is the difference between the principal value of the instrument and the fair value of the liability component at issuance. The resulting debt discount is being amortized to interest expense at the respective effective interest rate over the contractual term of the debt. A portion of the 2025 Convertible Notes have been extinguished or converted. The fair value of the liability component at issuance reflected above represents the liability value at issuance for the applicable portion of the 2025 Notes which remain outstanding at December 31, 2020. The fair value of the liability component of the 2025 Notes at issuance was $654.8 million with the equity component being $267.9 million.

(2) The unamortized discount consists of the following:

(In thousands)	December 31, 2020	December 31, 2019
2028 Convertible notes	$ 328,372	$ —
2027 Convertible notes	224,517	253,340
2025 Convertible notes	55,796	89,123
Total unamortized discount	$ 608,685	$ 342,463

(3) Debt issuance costs consist of the following:

(In thousands)	December 31, 2020	December 31, 2019
2028 Convertible notes	$ 15,041	$ —
2027 Convertible notes	8,810	10,251
2025 Convertible notes	3,789	6,230
Total debt issuance costs	$ 27,640	$ 16,481

(4) Based on the share price on trading days leading up to December 31, 2020, holders of the 2025 Convertible Notes will have the right to convert their debentures beginning on January 1, 2021. As a result, the 2025 Convertible Notes are included within convertible notes, net, current portion on the consolidated balance sheet. As of December 31, 2019, the 2025 Convertible Notes were not convertible and included within long-term convertible notes, net on the consolidated balance sheet.

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 will be 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 $375.0 million was allocated to the liability component, $300.8 million was allocated to the equity component, and $0.7 million was used to pay off interest accrued on the 2025 Notes. The consideration transferred was allocated to the liability and equity components of the 2025 Notes using the equivalent rate that reflected the borrowing rate for a similar non-convertible debt instrument immediately prior to settlement. The transaction resulted in a loss on settlement of convertible notes of $10.6 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 liability component and (ii) the sum of the carrying value of the debt component and any unamortized debt issuance costs 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 $85.5 million was allocated to the liability component, $64.2 million, net of a tax impact of $0.3 million, was allocated to the equity component, and $0.1 million was used to pay off interest accrued on the 2025 Notes. The consideration transferred was allocated to the liability and equity components of the 2025 Notes using the equivalent rate that reflected the borrowing rate for a similar non-convertible debt instrument immediately prior to settlement. The transaction resulted in a loss on settlement of convertible notes of $8.0 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 liability component and (ii) the sum of the carrying value of the debt component and any unamortized debt issuance costs at the time of repurchase.

Summary of Conversion Features

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, as set forth in the Indenture. 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. 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.

It is the Company's intent and policy to settle all conversions through combination settlement. The initial conversion rate is 13.26, 8.96, and 8.21 shares of common stock per $1,000 principal amount for the 2025 Notes,2027 Notes, and 2028 Notes, respectively, which is equivalent to an initial conversion price of approximately $75.43, $111.66, and $121.84 per share of the Company's common stock for the 2025 Notes, 2027 Notes, and 2028 Notes, respectively. The conversion rate is subject to adjustment upon the occurrence of certain specified events 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 Indenture), will, under certain circumstances, be entitled to an increase in the conversion rate.

If the Company undergoes a "fundamental change" (as defined in the Indenture), 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.

As of December 31, 2020, the 2025 Notes are classified as current on the Company's consolidated balance sheet. The holders of the 2025 Notes will have the right to convert their debentures beginning on January 1, 2021 based on the share price on trading days leading up to December 31, 2020. As of December 31, 2020, the 2027 and 2028 Notes are classified as long-term on the Company's consolidated balance sheet as the holders do not have the right to convert. During 2019, the holders of the 2025 Notes had the right to convert their debentures between July 1, 2019 and December 31, 2019, and 55 notes were converted during the period, which were settled through the issuance of common shares equivalent to the conversion rate with any fractional shares settled in cash. The 2025 Notes no longer met any of the conversion features as of December 31, 2019. The future convertibility and resulting balance sheet classification of this liability will be monitored at each quarterly reporting date and will be analyzed dependent upon market prices of the Company's common stock during the prescribed measurement periods. In the event that the holders of the Notes have the election to convert the Notes at any time during the prescribed measurement period, the Notes would then be considered a current obligation and classified as such.

Based on the closing price of our common stock of $132.49 on December 31, 2020, the if-converted values on our 2025, 2027, and 2028 Notes exceed the principal amount by $238.3 million, $139.4 million, and $100.5 million, respectively.

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; equal in right of payment to all of the Company's future liabilities that are not so subordinated, unsecured indebtedness; (ii) are effectively junior to all of our 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 (iii) are structurally subordinated to all indebtedness and other liabilities of the Company's subsidiaries.

The Company allocates total transaction costs of the Notes to the liability and equity components based on their relative values. Transaction costs attributable to the liability component are amortized to interest expense over the term of the Notes, and transaction costs attributable to the equity component are netted with the equity component in stockholders' equity. The following table summarizes the original transaction costs at the time of issuance for each set of Notes and the respective allocation to the liability and equity components:

(In thousands)	January 2025 Notes	June 2025 Notes	2027 Notes	2028 Notes
Transaction costs allocated to liability component	$ 13,569	$ 5,052	$ 11,395	$ 16,811
Transaction costs allocated to equity component	5,340	2,311	6,632	7,642
Total transaction costs	$ 18,909	$ 7,363	$ 18,027	$ 24,453

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.

Interest expense includes the following:

	Year Ended December 31,		
(In thousands)	2020	2019	2018
Debt issuance costs amortization	$ 4,207	$ 2,661	$ 2,273
Debt discount amortization	72,272	39,595	26,291
Loss on settlement of convertible notes	7,954	10,558	—
Coupon interest expense	9,631	7,325	7,823
Total interest expense on convertible notes	94,064	60,139	36,387
Other interest expense	1,919	1,460	402
Total interest expense	$ 95,983	$ 61,599	$ 36,789

The remaining period over which the unamortized debt discount will be recognized as non-cash interest expense is 4.04 years, 6.21 years, and 7.17 years for the 2025 Notes, 2027 Notes and 2028 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 royalties based on net revenues received using the technologies and may require minimum royalty amounts or maintenance fees.

Mayo

In June 2009, the Company entered into a license agreement with Mayo Foundation for Medical Education and Research ("Mayo"). The Company's license agreement with Mayo was most recently amended in September 2020. Under the license agreement, 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 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 January 2016 amendment to the Mayo license agreement established various low-single-digit royalty rates on net sales of current and future products and clarified how net sales will be calculated. As part of the January 2016 and October 2017 amendments, the royalty rate on the Company's net sales of the Cologuard test increased but the rate remains a low-single-digit percentage of net sales.

In addition to the royalties described above, the Company is required to pay Mayo cash of $0.2 million, $0.8 million and $2.0 million upon each product using the licensed Mayo intellectual property reaching $5.0 million, $20.0 million and $50.0 million in cumulative net sales, respectively.

As part of the most recent amendment, the Company agreed to pay Mayo an additional $6.3 million, payable in five annual installments, through 2024. The Company paid Mayo the first annual installment of $1.3 million in the third quarter of 2020 and will make subsequent annual payments in the first quarter of the year beginning in January 2021.

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 2038 (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 incurred charges of $3.9 million, $4.8 million, and $4.5 million for the years ended December 31, 2020, 2019, and 2018, respectively. The charges incurred in connection with this collaboration are recorded in research and development expenses in the Company's consolidated statements of operations.

Hologic

In October 2009, the Company entered into a technology license agreement with Hologic, Inc. ("Hologic"). Under the license agreement, Hologic granted the Company an exclusive, worldwide license within the field of human stool based colorectal cancer and pre-cancer detection or identification with regard to certain Hologic patents, patent applications and improvements, including Hologic's Invader detection chemistry (the "Covered Hologic IP"). The license agreement also provided the Company with non-exclusive, worldwide licenses to the Covered Hologic IP within a field covering clinical diagnostic purposes relating to colorectal cancer (including cancer diagnosis, treatment, monitoring or staging) and the field of detection or identification of colorectal cancer and pre-cancers through means other than human stool samples. In December 2012, the Company entered into an amendment to this license agreement with Hologic pursuant to which Hologic granted the Company a non-exclusive worldwide license to the Covered Hologic IP within the field of any disease or condition within, related to or affecting the gastrointestinal tract and/or appended mucosal surfaces. The Company is required to pay Hologic a low single-digit royalty on the Company's net sales of products using the Covered Hologic IP.

Epic Sciences

In June 2016, Genomic Health (now a wholly-owned subsidiary of the Company) entered into a collaboration agreement with Epic Sciences, which was superseded and replaced in March 2019 by a license agreement and laboratory services agreement with Epic Sciences, under which Genomic Health was granted exclusive distribution rights to commercialize Epic Sciences' AR-V7 Nucleus Detect® test in the United States, which is marketed as Oncotype DX AR-V7 Nucleus Detect®. The Company has primary responsibility, in accordance with applicable laws and regulations, for marketing and promoting the test, order fulfillment, billing and collections of receivables, claims appeals, customer support, and providing and maintaining order management systems for the test. Epic Sciences is responsible for performing all tests, performing studies including analytic and clinical validation studies, and seeking Medicare coverage and a Medicare payment rate from the CMS for the test. The license and laboratory service agreement has a term of 10 years from June 2016, unless terminated earlier under certain circumstances. The Oncotype DX AR-V7 Nucleus Detect test became commercially available in February 2018. The Company recognizes revenues for the test performed under this arrangement and Epic Sciences receives a fee per test performed that represents the fair market value for the testing services they perform.

Biocartis

In September 2017, Genomic Health entered into an exclusive license and development agreement with Biocartis, a molecular diagnostics company based in Belgium, to develop and commercialize an IVD version of the Oncotype DX Breast Recurrence Score test on the Biocartis Idylla platform. Under the terms of the license and development agreement, the Company had an exclusive, worldwide, royalty-bearing license to develop and commercialize an IVD version of the Oncotype DX Breast Recurrence Score test on the Biocartis Idylla platform, and certain options to expand the collaboration .

Pursuant to the license and development agreement, Genomic Health recorded a one-time upfront license and option fee of $3.2 million. In December 2017, Genomic Health purchased 270,000 ordinary shares of Biocartis, a public company listed on the Euronext exchange, for a total cost of $4.0 million. This investment was subject to a lock-up agreement that expired in December 2018. The investment has been recognized at fair value, which the Company estimated to be $1.5 million as of December 31, 2020 and is included in marketable securities on the Company's consolidated balance sheet.

In October 2020, the Company and Biocartis agreed to terminate all agreements between them with a mutual release. As part of the termination, the Company made a payment of $12.0 million and returned certain equipment to Biocartis. The remaining net book value of the equipment was previously written off when it was determined that the agreement with Biocartis would be terminated. The termination payment and equipment write-off are both recorded in general and administrative expenses on the Company's consolidated statement of operations.

Ludwig Institute for Cancer Research Ltd ("Ludwig")

Through the acquisition of Base Genomics Limited ("Base"), the Company acquired a worldwide exclusive license agreement with Ludwig for use of patents and know-how. The license is designed to leverage technology related to DNA methylation detection and bisulfite sequencing for product research, development and commercialization. The agreement terms include low single-digit sales-based royalties on the Company's net sales of products using the technology. The license agreement will remain in effect, unless earlier terminated by the parties in accordance with the agreement, until the tenth anniversary of the first commercial sale.

(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 extends the relationship between the Company and Pfizer and restructures 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 also includes additional fixed and performance-related fees, some of which retroactively went into effect on April 1, 2020. All payments to Pfizer are recorded in sales and marketing in the Company's consolidated statements of operations. The Company incurred charges of $85.3 million, $68.9 million and $5.8 million for promotion, sales and marketing services performed by Pfizer on behalf of the Company during the years ended December 31, 2020, 2019 and 2018, respectively. Under the Original Promotion Agreement, the service fee was calculated based on incremental gross profits over specified baselines during the term. The Company incurred charges of $68.5 million and $4.8 million for the service fee during the years ended December 31, 2019 and 2018, respectively. Under the Restated Promotion Agreement, the service fee was revised to a fee-for-service model, and includes certain fixed fees and performance-related bonuses. The Company incurred charges of $51.2 million for the service fee during the year ended December 31, 2020. The performance-related bonuses are contingent upon the achievement of certain annual performance criteria with any applicable expense being recognized ratably upon achievement of the payment becoming probable. During 2022, and contingent upon the achievement of certain Cologuard test revenue metrics during 2021, the Company will pay Pfizer a royalty based on a low single-digit royalty rate applied to actual 2022 Cologuard test revenues. The term of the Restated Promotion Agreement runs through December 31, 2022.

(13) STOCKHOLDERS' EQUITY

Amendment to Certificate of Incorporation

In July 2020, the Company filed a Certificate of Amendment (the “Certificate of Amendment”) to its Sixth Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware to increase the number of authorized shares of the Company’s common stock from 200 million to 400 million shares. The Certificate of Amendment was approved by the Company’s stockholders at the Company’s 2020 annual meeting in July 2020.

Convertible Notes Settlement Stock Issuance

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 convertible notes. Refer to Note 10 for further discussion of this settlement transaction.

Genomic Health Combination Stock Issuance

In November 2019, the Company completed the combination with Genomic Health in a cash and stock transaction valued at $2.47 billion. Of the $2.47 billion purchase price, $1.41 billion was settled through the issuance of 17.0 million shares of common stock. The Company incurred $0.4 million in stock issuance costs as part of the transaction. Refer to Note 19 for further discussion of the consideration transferred as part of the combination with Genomic Health.

Paradigm Diagnostics, Inc. ("Paradigm") and Viomics, Inc. ("Viomics") Acquisition Stock Issuance

In March 2020, the Company completed the acquisitions of Paradigm and Viomics. The purchase price for these acquisitions consisted of cash and stock valued at $40.4 million. Of the $40.4 million purchase price, $32.2 million is expected to be settled through the issuance of 0.4 million shares of common stock. Of the $32.2 million that will be settled through the issuance of common stock, $28.8 million was issued as of December 31, 2020, and the remainder was withheld and may become issuable as additional merger consideration on June 3, 2021.

Registered Direct Offering

In October 2020, the Company entered into securities purchase agreements with a limited number of institutional investors for the registered direct offering of 8.6 million shares of common stock at a price of $101.00 per share. The Company received, in the aggregate, approximately $861.7 million of net proceeds from the offering, after deducting $7.5 million for the offering expenses and other stock issuance costs paid by the Company.

Changes in Accumulated Other Comprehensive Income (Loss)

The amount recognized in AOCI for the years ended December 31, 2020, 2019 and 2018 were as follows:

(In thousands)	Cumulative Translation Adjustment	Unrealized Gain (Loss) on Securities	Accumulated Other Comprehensive Income (Loss)
Balance, January 1, 2018	$ (61)	$ (689)	$ (750)
Other comprehensive income (loss) before reclassifications	36	(1,025)	(989)
Amounts reclassified from accumulated other comprehensive loss	—	317	317
Net current period change in accumulated other comprehensive income (loss) (1)	36	(708)	(672)
Balance at December 31, 2018	$ (25)	$ (1,397)	$ (1,422)
Other comprehensive income (loss) before reclassifications	—	681	681
Amounts reclassified from accumulated other comprehensive loss	—	641	641
Net current period change in accumulated other comprehensive income (loss) (1)	—	1,322	1,322
Balance at December 31, 2019	$ (25)	$ (75)	$ (100)
Other comprehensive income (loss) before reclassifications	—	771	771
Amounts reclassified from accumulated other comprehensive loss	25	—	25
Net current period change in accumulated other comprehensive income (loss)	25	771	796
Balance at Income tax expense related to items of other comprehensive income	—	(170)	(170)
Balance at December 31, 2020	$ —	$ 526	$ 526

(1) There was no tax impact from the amounts recognized in AOCI for the years ended December 31, 2019 and 2018.

Amounts reclassified from accumulated other comprehensive loss for the years ended December 31, 2020, 2019 and 2018 were as follows:

		Year Ended December 31,		
Details about AOCI Components (In thousands)	Affected Line Item in the Statements of Operations	2020	2019	2018
Change in value of available-for-sale investments				
Sales and maturities of available-for-sale investments	Investment income	$ —	$ 641	$ 317
Foreign currency adjustment	General and administrative	25	—	—
Total reclassifications		$ 25	$ 641	$ 317

(14) STOCK-BASED COMPENSATION

Stock-Based Compensation Plans

The Company maintains the following plans for which awards were granted from in 2020: the 2010 Omnibus Long-Term Incentive Plan (As Amended and Restated Effective July 27, 2017), the 2019 Omnibus Long-Term Incentive Plan, the 2010 Employee Stock Purchase Plan, and the 2016 Inducement Award Plan. The Company also maintained the 2000 Stock Option and Incentive Plan, of which the final options were exercised in 2020. These plans are collectively referred to as the “Stock Plans”.

The Stock Plans are administered by the compensation committee of the Company's board of directors. The plans for share-based equity awards provide 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.

2000 Stock Option and Incentive Plan. The Company adopted the 2000 Stock Option and Incentive Plan (the "2000 Option Plan") on October 17, 2000 to grant share-based awards to employees, officers, directors, consultants and advisors. Awards granted under the 2000 Option 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 compensation committee of the Company's board of directors, subject to the provisions of the 2000 Option Plan. The 2000 Option Plan expired October 17, 2010 and after such date no further awards could be granted under the plan. Options granted under the 2000 Option Plan expire ten years from the date of grant. Grants made from the 2000 Option Plan generally vest over a period of three to four years. At December 31, 2020, there were no options outstanding under the 2000 Option Plan. There were no shares of restricted stock outstanding under the 2000 Option 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 compensation committee of the Company's board of directors, 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, 2020, options to purchase 1,763,865 shares were outstanding under the 2010 Stock Plan and 2,138,282 shares of restricted stock and restricted stock units were outstanding. At December 31, 2020, there were no shares available for future grant under the 2010 Stock Plan.

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 compensation committee of the Company's board of directors, 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, 2020, options to purchase 467,194 shares were outstanding under the 2019 Stock Plan and 2,388,415 shares of restricted stock and restricted stock units were outstanding. At December 31, 2020, there were 11,898,737 shares available for future grant under the 2019 Stock Plan.

2016 Inducement Award Plan. The Company adopted the 2016 Inducement Award Plan (the "2016 Inducement Plan") on January 25, 2016 to grant share-based awards to employees who were not previously an employee of the Company or any of its Subsidiaries. Awards granted under the 2016 Inducement Plan may include grant 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 compensation committee of the Company's board of directors, subject to the provisions of the 2016 Inducement Plan. The 2016 Inducement Plan expired on July 27, 2017, and after such date no further awards could be granted under the plan. Options granted under the 2016 Inducement Plan expire ten years from the date of grant. Grants made from the 2016 Inducement Plan generally vest over a period of three to four years. At December 31, 2020, there were 60,032 shares of restricted stock and restricted stock units outstanding under the 2016 Inducement Award Plan. At December 31, 2020, there were no shares available for future grant under the 2016 Inducement 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 and 2,000,000 shares on July 24, 2014 and July 28, 2016, respectively. At December 31, 2020, there were 759,015 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 percent and 15 percent 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 percent 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, 2020, there were 2,040,985 cumulative shares issued under the 2010 Purchase Plan.

Stock-Based Compensation Expense

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, 2020, 2019, and 2018 is as follows:

	Year Ended December 31,		
(In thousands)	2020	2019	2018
Cost of sales	$ 12,852	$ 5,799	$ 3,531
Research and development	19,976	17,196	10,189
General and administrative	75,999	64,222	34,181
Sales and marketing	44,079	21,266	12,363
Total stock-based compensation	$ 152,906	$ 108,483	$ 60,264

As of December 31, 2020, there was approximately $262.5 million of expected total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under all equity compensation plans. The Company expects to recognize that cost over a weighted average period of 2.63 years.

In connection with the April 2018 transition of the Company's former Chief Operating Officer, the Company accelerated the vesting of 69,950 shares under his previously unvested stock options and 54,350 shares under his previously unvested restricted stock units whereby such unvested stock options and unvested restricted stock units vest on December 31, 2018. It was determined that the continuing service to be provided by the Company's Chief Operating Officer to the Company through December 31, 2018 was substantive and, as a result, the Company recognized the additional non-cash stock-based compensation expense for the modified awards evenly over the transition term of April 25, 2018 to December 31, 2018. During the year ended December 31, 2018, the Company recorded $3.9 million of non-cash stock-based compensation expense for the modified awards.

In connection with the combination with Genomic Health, 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, 2020, the Company accelerated 83,593 shares of previously unvested stock options and 93,770 shares of previously unvested restricted stock units. During the year ended December 31, 2019, the Company accelerated 364,281 shares of previously unvested stock options and 70,138 shares of previously unvested restricted stock units. During the years ended December 31, 2020 and 2019, the Company recorded $9.7 million and $21.6 million, respectively, of non-cash stock-based compensation expense for the accelerated awards.

Stock Options

The Company determines the fair value of each service-based option award on the date of grant using the Black-Scholes option-pricing mode, which utilizes several key assumptions which are disclosed in the following table:

	Year Ended December 31		
	2020	2019	2018
Option Plan Shares			
Risk-free interest rates	1.26% -	2.54% -	2.73% -
Expected term (in years)	6.15	6.28	5.45 - 6.44
Expected volatility	65.67% -	64.95% -	61.82% -
Dividend yield	0%	0%	0%

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

Options	Shares	Weighted Average Exercise Price (1)	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value(2)
(Aggregate intrinsic value in thousands)				
Outstanding, January 1, 2020	2,700,293	$ 34.01	6.7	
Granted	309,143	97.66		
Exercised	(707,013)	39.07		
Forfeited	(71,364)	82.76		
Outstanding, December 31, 2020	2,231,059	$ 39.67	6.0	$ 207,090
Vested and expected to vest, December 31, 2020	2,231,059	$ 39.67	6.0	$ 207,090
Exercisable, December 31, 2020	1,399,721	$ 22.53	4.9	$ 153,912

(1) The weighted average grant date fair value of options granted during the years ended December 31, 2020, 2019, and 2018 was $58.57, $57.11, and $24.55.

(2) The total intrinsic value of options exercised during the years ended December 31, 2020, 2019, and 2018 was $40.6 million, $52.0 million, and $53.0 million, respectively, determined as of the date of exercise.

The Company received approximately $27.1 million, $8.8 million, and $6.6 million from stock option exercises during the years ended December 31, 2020, 2019 and 2018, 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 (2)
Outstanding, January 1, 2020	3,800,722	$ 58.68
Granted	2,236,535	92.55
Released (1)	(1,731,631)	50.67
Forfeited	(337,412)	81.36
Outstanding, December 31, 2020	3,968,214	$ 79.38

(1) The fair value of restricted stock units vested and converted to shares of the Company's common stock was $152.4 million, $173.8 million, and $63.8 million for the years ended December 31, 2020, 2019, and 2018, respectively.

(2) The weighted average grant date fair value of the restricted stock units granted during the years ended December 31, 2019 and 2018 was $93.20, and $50.45, respectively.

Performance Share Units

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

In June 2020 and December 2020, the Company modified certain of the operational milestones and financial performance targets, respectively, within the outstanding performance-based equity awards, which were not deemed to have an impact on vesting and no incremental stock-based compensation expense was recorded for the year ended December 31, 2020. This modification impacted awards held by 36 employees.

A summary of performance share unit activity is as follows:

	Performance Share Units (2)	Weighted Average Grant
Outstanding, December 31, 2019	583,283	$ 93.40
Granted	35,232	90.17
Released (1)	—	—
Forfeited	—	—
Outstanding, December 31, 2020	618,515	$ 93.22

(1) The fair value of performance share units vested and converted to shares of the Company's common stock was $183.8 million for the year ended December 31, 2019. There were no performance share units vested and converted to shares of the Company's common stock during the years ended December 31, 2020 and 2018.

(2) Participants may ultimately earn between zero and 200% of the target number of performance share units granted based on the degree of achievement of the performance criteria. 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, 2020 was 158,958.

(3) The weighted average grant date fair value of the performance share units granted during the years ended December 31, 2019 was $93.40. There were no performance share units granted during the year ended December 31, 2018.

Employee Stock Purchase Plan ("ESPP")

A summary of ESPP activity is as follows:

	Year Ended December 31,		
(in thousands, except share and per share amounts)	2020	2019	2018
Shares issued under the 2010 Purchase Plan	301,064	176,458	346,609
Cash received under the 2010 Purchase Plan	$ 18,355	$ 8,396	$ 4,895
Weighted average fair value per share of stock purchase rights granted	$ 32.57	$ 29.21	$ 20.47

The 301,064 shares issued during the year ended December 31, 2020 were as follows:

Offering period ended	Number of Shares	Weighted Average price per Share
April 30, 2020	167,921	$ 57.95
November 2, 2020	133,143	$ 64.35

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

	Year Ended December 31,		
	2020	2019	2018
ESPP Shares			
Risk-free interest rates	0.11% - 0.2%	1.6% - 2.4%	2.1% - 2.8%
Expected term (in years)	0.5 - 2	0.4 - 2	0.5 - 2
Expected volatility	61.59% -	43.2% -	51.7% -
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, 2020, as follows:

Shares reserved for issuance	
2019 Stock Plan	11,898,737
2010 Purchase Plan	759,015
	12,657,752

(15) COMMITMENTS AND CONTINGENCIES

Leases

The components of lease expense were as follows:

	Year Ended December 31,	
(In thousands)	2020	2019
Finance lease cost		
Amortization of right-of-use assets	$ 1,935	$ 27
Interest on lease liabilities	383	2
Operating lease cost	22,551	9,200
Short-term lease cost	356	219
Variable lease cost	2,703	896
Total Lease Cost	$ 27,928	$ 10,344

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

	Year Ended December 31,	
(In thousands)	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 17,531	$ 9,641
Operating cash flows from finance leases	381	1
Finance cash flows from finance leases	1,756	15
Non-cash investing and financing activities:		
Right-of-use assets obtained in exchange for new operating lease liabilities (1)	13,261	51,030
Right-of-use assets obtained in exchange for new finance lease liabilities	20,349	237
Weighted-average remaining lease term - operating leases (in years)	8.75	9.80
Weighted-average remaining lease term - finance leases (in years)	3.68	1.20
Weighted-average discount rate - operating leases	6.80 %	6.80 %
Weighted-average discount rate - finance leases	5.67 %	5.60 %

(1) For the year ended December 31, 2019, this includes right-of-use assets obtained from the initial adoption of ASC 842 of approximately $17.9 million.

As of December 31, 2020 and 2019, the Company’s right-of-use assets from operating leases are $125.9 million and $126.4 million, respectively, which are reported in operating lease right-of-use assets in the Company’s consolidated balance sheet. As of December 31, 2020, the Company has outstanding lease obligations of $132.6 million, of which $11.5 million is reported in operating lease liabilities, current portion and $121.1 million is reported in operating lease liabilities, less current portion in the Company’s consolidated balance sheet. As of December 31, 2019, the Company had outstanding lease obligations of $126.6 million, of which $7.9 million is reported in operating lease liabilities, current portion and $118.7 million is reported in operating lease liabilities, less current portion in the Company’s consolidated balance sheet. The Company calculates its incremental borrowing rates for specific lease terms, used to discount future lease payments, as a function of the U.S. Treasury rate and an indicative Moody’s rating for operating leases.

As of December 31, 2020 and 2019, the Company’s right-of-use assets from finance leases are $20.6 million and $0.3 million, respectively, which are reported in other long-term assets, net in the Company’s consolidated balance sheets. As of December 31, 2020, the Company has outstanding finance lease obligations of $18.7 million, of which $4.7 million is reported in other current liabilities and $14.0 million is reported in other long-term liabilities in the Company’s consolidated balance

sheets. As of December 31, 2019, the Company had outstanding finance lease obligations of $0.2 million, of which $32,000 is reported in other current liabilities and $0.2 million is reported in other long-term liabilities in the Company's consolidated balance sheets. The Company calculates its incremental borrowing rates for specific lease terms, used to discount future lease payments, as a function of the U.S. Treasury rate and an indicative Moody's rating for finance leases.

Maturities of operating lease liabilities on an annual basis as of December 31, 2020 were as follows (amounts in thousands):

(In thousands)	
2021	$ 19,881
2022	19,596
2023	21,306
2024	21,257
2025	19,338
Thereafter	79,141
Total minimum lease payments	180,519
Imputed interest	(47,961)
Total	$ 132,558

Maturities of finance lease liabilities on an annual basis as of December 31, 2020 were as follows (amounts in thousands):

(In thousands)	
2021	$ 5,674
2022	5,635
2023	5,525
2024	3,819
2025	53
Thereafter	—
Total minimum lease payments	20,706
Imputed interest	(1,961)
Total	$ 18,745

The Company executed a lease agreement for a new facility in Redwood City, California in 2020 that will commence in February 2021. The Company anticipates to recognize $8.2 million for the operating lease right-of-use assets and $8.3 million for the operating lease liabilities in the consolidated balance sheet, respectively, upon commencement of the lease.

Rent expense included in the accompanying consolidated statements of operations was approximately $3.6 million for the year ended December 31, 2018.

Legal Matters

The Company is currently responding to civil investigative demands initiated by the United States Department of Justice ("DOJ") concerning (1) Genomic Health's compliance with the Medicare Date of Service billing regulations and (2) allegations that the Company offered or gave gift cards to patients in exchange for returning the Cologuard screening test, in violation of the Federal Anti-Kickback Statute and False Claims Act. The Company has been cooperating with these inquiries and has produced documents in response thereto. Adverse outcomes from these investigations could include the Company being required to pay treble damages, incur civil and criminal penalties, paying attorneys' fees, entering into a corporate integrity agreement, being excluded from participation in government healthcare programs, including Medicare and Medicaid, and other adverse actions that could materially and adversely affect the Company's business, financial condition and results of operation. See Note 19 for additional information on the Company's fair value determination of this pre-acquisition loss contingency related to the Genomic Health DOJ investigation.

In connection with the Company's combination with Genomic Health, on June 22, 2020, Suzanne Flannery, a purported former stockholder of Genomic Health, filed a Verified Individual and Class Action Complaint in the Delaware Court of Chancery, captioned Flannery v. Genomic Health, Inc., et al., C.A. No. 2020-0492. Flannery amended her complaint on November 23, 2020. The amended complaint asserts individual and class action claims, including: (i) a violation of 8 Del. C. § 203 by Genomic Health, Exact Sciences and a purported controlling group of former Genomic Health stockholders; (ii) conversion by Genomic Health, Exact Sciences and Spring Acquisition Corp.; (iii) breach of fiduciary duty by Genomic Health's former directors; (iv) breach of fiduciary duty by the purported controlling group; and (v) aiding and abetting breach of fiduciary duty against Exact Sciences, Spring Acquisition and Goldman Sachs & Co. LLC, Genomic Health's financial advisor in the combination. The amended complaint seeks, among other things, declaratory relief, unspecified monetary damages and attorneys' fees and costs. All defendants moved to dismiss the amended complaint.

These investigations are still in process and the scope and outcome of the investigations is not determinable at this time. There can be no assurance that any settlement, resolution, or other outcome of these matters during any subsequent reporting period will not have a material adverse effect on the Company's results of operations or cash flows for that period or on the Company's financial position.

(16) EMPLOYEE BENEFIT PLAN

The Company maintains a qualified 401(k) retirement savings plan for Exact Sciences employees (the "401(k) Plan"). After the combination with Genomic Health in 2019, the Company maintained a plan for legacy Genomic Health employees (the "Genomic Health Plan") up until the Genomic Health Plan was merged into the 401(k) Plan effective April 3, 2020. 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 Board of Directors.

The Company's Board of Directors approved 401(k) Plan matching contributions for the years ended December 31, 2020, 2019 and 2018 in the form of Company common stock equal to 100 percent up to 6 percent of the participant's eligible compensation for that year. The Company recorded compensation expense of approximately $22.8 million, $12.5 million, and $7.4 million, respectively, in the statements of operations for the years ended December 31, 2020, 2019 and 2018.

(17) NEW MARKET TAX CREDIT

During the fourth quarter of 2014, the Company received approximately $2.4 million in net proceeds from financing agreements related to working capital and capital improvements at one of its Madison, Wisconsin facilities. This financing arrangement was structured with an unrelated third-party financial institution (the "Investor"), an investment fund, and its majority owned community development entity in connection with the Company's participation in transactions qualified under the federal New Markets Tax Credit ("NMTC") program, pursuant to Section 45D of the Internal Revenue Code of 1986, as amended. The Company is required to be in compliance through December 2021 with various regulations and contractual provisions that apply to the NMTC arrangement. Noncompliance with applicable requirements could result in the Investor's projected tax benefits not being realized and, therefore, require the Company to indemnify the Investor for any loss or recapture of NMTC related to the financing until such time as the recapture provisions have expired under the applicable statute of limitations. The Company does not anticipate any credit recapture will be required in connection with this financing arrangement.

The Investor and its majority owned community development entity are considered Variable Interest Entities ("VIEs") and the Company is the primary beneficiary of the VIEs. This conclusion was reached based on the following:

- the ongoing activities of the VIEs—collecting and remitting interest and fees and NMTC compliance—were all considered in the initial design and are not expected to significantly affect performance throughout the life of the VIE;
- contractual arrangements obligate the Company to comply with NMTC rules and regulations and provide various other guarantees to the Investor and community development entity;
- the Investor lacks a material interest in the underlying economics of the project; and
- the Company is obligated to absorb losses of the VIEs.

Because the Company is the primary beneficiary of the VIEs, they have been included in the consolidated financial statements. There are no other assets, liabilities or transactions in these VIEs outside of the financing transactions executed as part of the NMTC arrangement.

(18) WISCONSIN ECONOMIC DEVELOPMENT TAX CREDITS

During the first quarter of 2015, the Company entered into an agreement with the Wisconsin Economic Development Corporation ("WEDC") to earn $9.0 million in refundable tax credits on the condition that the Company expends $26.3 million in capital investments and establishes and maintains 758 full-time positions over a seven-year period. 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 seven-year period. 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 occur. The amount of tax credits earned is recorded as a liability and amortized as a reduction of operating expenses over the expected period of benefit. The tax credits earned from capital investment are recognized 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 over the life of the agreement, as the Company is required to maintain the minimum level of full-time positions through the seven-year period.

As of December 31, 2020, the Company has earned all $9.0 million of the refundable tax credits and has received payment of $5.9 million from the WEDC. The unpaid portion is $3.1 million, of which $1.6 million is reported in prepaid expenses and other current assets and $1.5 million is reported in other long-term assets, reflecting when collection of the refundable tax credits is expected to occur. As of December 31, 2020, the corresponding liability, which reflected when the expected benefit of the tax credit amortization would reduce future operating expenses, has been fully amortized and has a balance of zero.

During the years ended December 31, 2020, 2019 and 2018, the Company amortized $2.2 million, $2.4 million, and $2.2 million, respectively, of the tax credits earned as a reduction of operating expenses.

(19) BUSINESS COMBINATIONS AND ASSET ACQUISITIONS

Business Combinations

Paradigm Diagnostics, Inc. and Viomics, Inc.

On March 3, 2020, the Company acquired all of the outstanding capital stock of Paradigm and Viomics, two related party companies of one another headquartered in Phoenix, Arizona, in transactions that are deemed to be a single business combination in accordance with ASC 805, Business Combinations, ("the Paradigm Acquisition"). Paradigm provides comprehensive genomic-based profiling tests that assist in the diagnosis and therapy recommendations for late-stage cancer. Viomics provides a platform for identification of biomarkers.

The Company entered into this acquisition to enhance its product portfolio in cancer diagnostics and to enhance its capabilities for biomarker identification.

The acquisition date fair value of the consideration to be transferred for Paradigm and Viomics was $40.4 million, which consists of $32.2 million payable in shares of the Company's common stock and $8.2 million which was settled through a cash payment. Of the $32.2 million to be settled through the issuance of common stock, $28.8 million was issued as of December 31, 2020, and the remaining $3.4 million, which was withheld and may become payable as additional merger consideration, is included in other current liabilities in the consolidated balance sheet as of December 31, 2020. The purchase price was allocated to the underlying assets acquired and liabilities assumed based upon their estimated fair values as follows:

(In thousands)	Preliminary Allocation	Measurement Period	Preliminary Allocation
Net operating assets	$ 6,133	$ (760)	$ 5,373
Goodwill	29,695	736	30,431
Developed technology	7,800	—	7,800
Net operating liabilities	(3,123)	(80)	(3,203)
Total purchase price	$ 40,505	$ (104)	$ 40,401

The measurement period adjustments primarily relate to accounts receivable valuation and working capital adjustments.

The fair value of identifiable intangible assets has been determined using the income approach, which involves significant unobservable inputs (Level 3 inputs). These inputs include projected sales, margin, weighted average cost of capital and tax rate.

Developed technology represents purchased technology that had reached technological feasibility and for which development had been completed as of the acquisition date. Fair value was determined using future discounted cash flows related to the projected income stream of the developed technology for a discrete projection period. Cash flows were discounted to their present value as of the closing date. Developed technology is amortized on a straight-line basis over its estimated useful life of 15 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 assembled workforce, and expected synergies. The total goodwill related to this acquisition is not deductible for tax purposes.

The Company agreed to issue to the previous investors in Viomics equity interests with an acquisition-date fair value of up to $8.4 million in Viomics, vesting over 4 years based on certain retention arrangements. Payment is contingent upon continued employment with the Company over the four year vesting period and is recognized as stock-based compensation expense in general and administrative expense in the consolidated statement of operations.

The partial year results from the operations of Paradigm and Viomics are included in the Company's consolidated financial statements and not disclosed separately due to immateriality. Pro forma disclosures have not been included due to immateriality.

Genomic Health, Inc.

On November 8, 2019, the Company acquired all of the outstanding capital stock of Genomic Health. Genomic Health, headquartered in Redwood City, California, provides genomic-based diagnostic tests that address both the overtreatment and optimal treatment of early and late stage cancer. The Company has included the financial results of Genomic Health in the consolidated financial statements from the date of the combination.

The Company entered into this combination to create a leading global cancer diagnostics company and provide a robust platform for continued growth. This combination provides the Company with a commercial presence in more than 90 countries in which the combined company expects to continue to increase adoption of current tests, and to bring new innovative cancer tests to patients around the world.

During 2019, the Company incurred $22.5 million of acquisition-related costs recorded in general and administrative expense. These costs include fees associated with financial, legal, accounting and other advisors incurred to complete the combination.

The combination date fair value of the consideration transferred for Genomic Health was approximately $2.47 billion, which consisted of the following:

(In thousands)	
Cash	$ 1,061,489
Common stock issued	1,389,266
Fair value of replacement stock options and restricted stock awards	17,813
Total purchase price	$ 2,468,568

The fair value of the common stock issued as part of consideration was determined on the basis of the closing market price of the Company's shares at the acquisition date. The fair value of the stock options assumed by the Company was determined using the Black-Scholes option pricing model. The share conversion ratio of 0.76534 was applied to convert Genomic Health's outstanding equity awards for Genomic Health'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	0.88% - 2.90%
Expected term (in years)	3.28 - 6.73
Expected volatility	63.54% - 69.09%
Dividend yield	0%
Weighted average fair value per share of options assumed	$45.75 - $57.44

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

(In thousands)	Preliminary Allocation November 8,	Measurement Period Adjustments	Final Allocation November 8, 2020
Cash and cash equivalents	$ 87,627	$ —	$ 87,627
Marketable securities	201,519	—	201,519
Accounts receivable	57,400	—	57,400
Inventory	3,535	—	3,535
Prepaid expenses and other current assets	8,360	—	8,360
Property, plant and equipment	69,905	(122)	69,783
Goodwill	1,185,918	4,044	1,189,962
Trade name	100,000	—	100,000
Supply agreement intangible	30,000	—	30,000
Developed technology	800,000	—	800,000
In-process research and development (IPR&D)	200,000	—	200,000
Operating lease right-of-use assets	80,790	—	80,790
Other long-term assets	14,972	(96)	14,876
Accounts payable, accrued liabilities and other current liabilities	(88,995)	548	(88,447)
Deferred tax liability	(205,536)	(4,374)	(209,910)
Operating lease liabilities, current portion	(3,258)	—	(3,258)
Operating lease liabilities, less current portion	(71,270)	—	(71,270)
Other long-term liabilities	(2,399)	—	(2,399)
Total fair value consideration	$ 2,468,568	$ —	$ 2,468,568

The measurement period adjustments primarily relate to the fair value of Genomic Health's pre-acquisition deferred tax liability due to finalization of certain income-tax related items.

The fair value of identifiable intangible assets has been determined using the income approach, which involves significant unobservable inputs (Level 3 inputs). These inputs include projected sales, margin, required rate of return and tax rate, as well as an estimated royalty rate in the cases of the developed technology and trade name intangibles. The developed technology and tradename intangibles are valued using a relief-from-royalty method.

Trade names represent the value associated with the Oncotype DX trade name in the market. The trade name intangible is amortized on a straight-line basis over its estimated useful life of 16 years.

Developed technology represents purchased technology that had reached technological feasibility and for which Genomic Health had substantially completed development as of the date of combination. Fair value was determined using future discounted cash flows related to the projected income stream of the developed technology for a discrete projection period. Cash flows were discounted to their present value as of the closing date. Developed technology is amortized on a straight-line basis over its estimated useful life of 10 years.

IPR&D represent capitalized incomplete research projects as of the combination date and had no alternative future use. The amounts capitalized are being accounted for as indefinite-lived intangible assets, subject to impairment testing, until completion or abandonment of the research and development efforts associated with the projects. The primary basis for determining technological feasibility of these projects is obtaining regulatory approval to market the underlying product and expected commercial release. The Company recorded $200.0 million of IPR&D related to the development of an IVD version of the Oncotype DX Breast Recurrence Score test. The IPR&D asset was valued using the multiple-period excess earnings method approach.

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 assembled workforce and expanded market opportunities including a broader global presence. The total goodwill related to this combination is not deductible for tax purposes.

The Company assumed unvested stock options and restricted stock awards with combination-date fair values of $34.3 million and $42.3 million, respectively. Of the total consideration for stock options and restricted stock awards, $2.2 million and $15.6 million, respectively, was allocated to the purchase consideration and $32.1 million and $26.7 million, respectively, was allocated to future services and will be expensed over a weighted average period of 1.69 years and 2.12 years, respectively.

The amounts of revenue and net loss before tax of Genomic Health included in the Company’s consolidated statement of operations from the combination date of November 8, 2019 to December 31, 2019 and for the year ended December 31, 2020 are as follows:

(In thousands)	2020	2019
Total revenues	$ 435,960	$ 66,174
Net loss before tax	(254,162)	(40,446)

The following unaudited pro forma financial information summarized the combined results of operations for the Company and Genomic Health, as though the companies were combined as of the beginning of January 1, 2018.

	Year Ended December 31,	
(In thousands)	2019	2018
Total revenues	$ 1,266,591	$ 848,573
Net loss before tax	(252,203)	(302,173)

The unaudited pro forma financial information for all periods presented above has been calculated after adjusting the results of Genomic Health to reflect the business combination accounting effects resulting from this combination, including the amortization expense from acquired intangible assets and the stock-based compensation expense for unvested stock options and restricted stock awards assumed as though the combination occurred as of January 1, 2018. 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 combination had taken place as of January 1, 2018.

As described in Note 15, the Company identified a pre-acquisition contingency relating to the DOJ investigation. The Company assigned a fair value estimate of zero to this pre-acquisition contingency. Subsequent to the Company's final determination of the pre-acquisition contingency’s estimated value, changes to this estimate could have a material impact on our results of operations and financial position.

In connection with the combination, the Company decided to terminate certain Genomic Health executives in the fourth quarter of 2019 and recorded $32.1 million in severance benefits charges.

Asset Acquisitions

Base Genomics, Limited

On October 26, 2020, The Company acquired all of the outstanding capital stock of Base Genomics, Limited in a cash transaction totaling $416.5 million. Base Genomics headquartered in Oxford, England exclusively licenses from Ludwig a non-bisulfite technology for the detection of methylated DNA and other epigenetic modifications. This technology ("TAPS") simultaneously generates both genetic and epigenetic information at base resolution. TAPS overcomes the issues of the current gold-standard for DNA methylation detection of bisulfite sequencing. The Company has included the financial results of Base Genomics in the consolidated statements from the date of the acquisition and not disclosed separately due to immateriality. Pro forma disclosures have not been included due to immateriality.

While the acquisition was treated legally as a merger of the two entities, for accounting purposes, 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 TAPS technology.

The assets and liabilities acquired in the merger were recorded at fair value as determined as of October 26, 2020, and were substantially comprised of the TAPS IPR&D asset as shown in the table below. The Company incurred approximately $4.6 million of direct transaction costs during 2020 associated with this acquisition. These acquisition-related transaction costs were capitalized to the acquired tangible and intangible assets based on their estimated fair values as of the closing date. The IPR&D asset acquired 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 accounted for the merger in accordance with the accounting standards codification guidance for business combinations, whereby the total purchase price was allocated to the acquired net tangible and intangible assets based on their estimated fair values as of the closing date. As of December 31, 2020, the Company has substantially completed its process for measuring the fair values of the assets acquired and liabilities assumed based on information available as of the closing date.

The following table summarizes the total consideration for the acquisition and the value of assets acquired and liabilities assumed as of October 26, 2020, the Merger closing date. These values are based on internal Company and independent external third-party valuations:

(In thousands)	
Consideration	
Cash paid for acquisition of Base Genomics outstanding shares	$ 416,525
Transaction costs	4,600
Total consideration	421,125
Assets acquired and liabilities assumed	
Cash	9,704
IPR&D asset	412,568
Other assets and liabilities	(1,147)
Net assets acquired	$ 421,125

(20) 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 discrete 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)	2020	2019	2018
United States	$ 1,413,907	$ 864,849	$ 454,462
Outside of United States	77,484	11,444	—
Total revenues	$ 1,491,391	$ 876,293	$ 454,462

Long-lived assets located in countries outside of the United States are not significant.

(21) 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, 2020, the Company had federal net operating loss, state net operating loss, and foreign net operating loss carryforwards of approximately $1.55 billion, $709.2 million, and $4.3 million, respectively for financial reporting purposes, which may be used to offset future taxable income. The Company also had federal and state research tax credit carryforwards of $54.3 million and $34.0 million, respectively which may be used to offset future income tax liability. The federal credit carryforwards expire at various dates through 2040 and are subject to review and possible adjustment by the Internal Revenue Service. The state credit carryforwards expire at various dates through 2035 with the exception 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.

Income (loss) before provision for taxes consisted of the following:

	Year Ended December 31,		
(In thousands)	2020	2019	2018
Income (loss) before income taxes:			
Domestic	$ (451,067)	$ (267,832)	$ (175,275)
Foreign	(406,038)	(1,019)	218
Total income (loss) before income taxes	$ (857,105)	$ (268,851)	$ (175,057)

The expense (benefit) for income taxes consists of:

	Year Ended December 31,		
(In thousands)	2020	2019	2018
Current expense (benefit):			
Federal	$ (3)	$ —	$ —
State	802	314	92
Foreign	933	(63)	—
Deferred tax expense (benefit):			
Federal	(6,453)	(169,727)	—
State	(3,971)	(15,397)	—
Foreign	120	15	—
Total income tax expense (benefit)	$ (8,572)	$ (184,858)	$ 92

The Company recorded an income tax benefit for the year ended December 31, 2020 of $8.6 million primarily as a result of future limitations on and expiration of certain Federal and State deferred tax assets.

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:

	December 31,	
(In thousands)	2020	2019
Deferred tax assets:		
Operating loss carryforwards	$ 369,642	$ 369,695
Tax credit carryforwards	64,760	51,030
Compensation related differences	48,349	33,378
Lease assets	31,938	30,782
Other temporary differences	6,136	7,049
Tax assets before valuation allowance	520,825	491,934
Less - Valuation allowance	(157,629)	(120,679)
Total deferred tax assets	$ 363,196	$ 371,255
Deferred tax liabilities		
Convertible notes	$ (145,925)	$ (83,163)
Amortization	(197,847)	(270,421)
Property, plant and equipment	(4,580)	(5,913)
Lease liabilities	(30,312)	(29,586)
Other temporary differences	(4,078)	(2,607)
Total deferred tax liabilities	(382,742)	(391,690)
Net deferred tax liabilities	$ (19,546)	$ (20,435)

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 $157.6 million and $120.7 million at December 31, 2020 and 2019, 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 $19.5 million remaining at the end of 2020, which is included in other long-term liabilities on the Company's consolidated balance sheet. The overall change in valuation allowance for December 31, 2020 and 2019 was an increase of $36.9 million and a decrease of $89.2 million, respectively.

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

	December 31,		
(In thousands)	2020	2019	2018
Balance as of January 1,	$ (120,679)	$ (209,868)	$ (214,250)
Valuation allowances established	(108,944)	(132,522)	(52,855)
Changes to existing valuation allowances	1,662	1,620	(2,744)
Acquisition and purchase accounting	(5,558)	183,730	(1,739)
Additional paid-in-capital	75,890	36,361	61,720
Balance as of December 31,	$ (157,629)	$ (120,679)	$ (209,868)

During 2020, the Company recorded an increase to the valuation allowance of $108.9 million primarily related to losses from continuing operations. Additionally, the Company recorded a decrease to the valuation allowance of $75.9 million related to convertible debt issuances offset against additional paid-in capital.

During 2019, the Company recorded an increase to the valuation allowance of $132.5 million primarily related to losses from continuing operations. Additionally, the Company recorded a decrease to the valuation allowance of $183.7 million related to the Genomic Health combination offset against goodwill, as well as a decrease of $36.4 million related to convertible debt issuances offset against additional paid-in capital.

During 2018, the Company recorded an increase to the valuation allowance of $52.9 million primarily related to losses from continuing operations. Additionally, the Company recorded a decrease to the valuation allowance of $61.7 million related to convertible debt issuances offset against additional paid-in capital.

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

	December 31,		
	2020	2019	2018
U.S. Federal statutory rate	21.0 %	21.0 %	21.0 %
State taxes	1.9	5.8	3.4
Federal and state tax rate changes	—	(0.4)	—
Foreign tax rate differential	(1.0)	0.6	—
Acquired IPR&D asset expense	(9.1)	—	—
Research and development tax credits	1.6	1.1	1.9
Stock-based compensation expense	1.1	22.1	9.1
Non-deductible executive compensation	(0.8)	(4.1)	(4.9)
Transaction costs	(0.1)	(0.7)	—
Other adjustments	(1.0)	(0.6)	1.1
Valuation allowance	(12.7)	24.0	(31.7)
Effective tax rate	0.9 %	68.8 %	(0.1)%

For the year ended December 31, 2020, the Company recognized an income tax benefit, representing an effective tax rate of 0.9%. The difference between the expected statutory federal tax rate of 21.0% and the effective tax rate of 0.9% for the year ended December 31, 2020, was primarily attributable to the valuation allowance established against the Company's current period losses generated and the non-deductible IPR&D expense related to the Base Genomics acquisition.

For the year ended December 31, 2019, the Company recognized an income tax benefit, representing an effective tax rate of 68.8%. The difference between the expected statutory federal tax rate of 21.0% and the effective tax rate of 68.8% for the year ended December 31, 2019, was primarily attributable to an income tax benefit of $185.1 million recorded as a result of a change in the deferred tax asset valuation allowance resulting from the Genomic Health combination, as well as excess tax benefits on vested stock-based compensation awards.

For the year ended December 31, 2018, the Company recognized an immaterial income tax expense, representing an effective tax rate of (0.1)%. The difference between the expected statutory federal tax rate of 21.0% and the effective tax rate of (0.1)% for the year ended December 31, 2018, was primarily attributable to the valuation allowance established against our current period losses generated.

The Company had unrecognized tax benefits related to federal and state research and development tax credits of $16.6 million, $10.3 million, and $1.9 million as of December 31, 2020, 2019 and 2018, respectively. These amounts have been recorded as a reduction to our 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)	2020	2019	2018
January 1,	$ 10,276	$ 1,926	$ —
Increase due to current year tax positions	3,600	2,142	392
Increase due to prior year tax positions	2,753	6,208	1,534
Decrease due to prior year tax positions	—	—	—
Settlements	—	—	—
December 31,	$ 16,629	$ 10,276	$ 1,926

As of December 31, 2020, 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 2001 through 2020, and to state income tax examinations for the tax years 2001 through 2020. 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, 2020, 2019 and 2018.

(22) SUBSEQUENT EVENTS

On January 5, 2021, the Company completed the acquisition ("Thrive Merger") of Thrive Earlier Detection Corporation, pursuant to a merger through which the Company acquired all of the outstanding shares of Thrive. Thrive is a healthcare company dedicated to incorporating earlier cancer detection into routine medical care. The Company expects that combining Thrive's early-stage screening test, CancerSEEK, with the Company's scientific platform, clinical organization and commercial infrastructure will establish the Company as a leading competitor in blood-based, multi-cancer screening. Under the terms of the Thrive Merger, we paid Thrive's stockholders total consideration of $1.70 billion at closing, comprised of 35% in cash and 65% in the Company's common stock. An additional $450.0 million would be payable in cash based upon the achievement of certain milestones related to the development and commercialization of a blood-based, multi-cancer screening test. Due to the proximity of the completion of the acquisition to the filing of this Form 10-K, the accounting for the preliminary purchase price allocation is not complete, including the valuation of total consideration paid, assets acquired and liabilities assumed.

Through the Thrive Merger, the Company acquired a worldwide exclusive license agreement with John 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, multi-cancer screening test. The agreement terms include single-digit sales-based royalties and sales-based milestone payments of $10.0 million, $15.0 million, $20.0 million and upon achieving calendar year licensed product revenue using JHU proprietary data of $0.50 billion, $1.00 billion, and $1.50 billion, respectively.

On January 11, 2021, the Company acquired a worldwide exclusive license to the proprietary Targeted Digital Sequencing ("TARDIS") technology from the Translational Genomics Research Institute ("TGen"), an affiliate of City of Hope for an up-front cost of $25.0 million in cash and issuance of 191,336 shares of common stock valued at $27.3 million on the date of issuance. This license is a royalty-free, perpetual license. Under the terms of the agreement, the Company is required to pay cash of $10.0 million and $35.0 million upon achieving cumulative product revenue related to minimal residual disease ("MRD") detection and/or treatment totaling $100.0 million and $250.0 million, respectively. These payments are contingent upon achievement of these cumulative revenues on or before December 31, 2030.

On February 12, 2021, the Company entered into an Equity Purchase Agreement (the "Ashion Purchase Agreement") with PMed Management, LLC ("PMed") which is a subsidiary of TGen pursuant to which the Company will purchase all of the outstanding equity interests of Ashion Analytics, LLC ("Ashion"; such transaction, the "Ashion Acquisition") in exchange for cash of approximately $72.0 million and 125,444 shares of the Company's common stock. An additional $20.0 million and $30.0 million would be payable in cash upon the development and commercialization of a test for MRD detection and/or treatment (the "Commercial Launch Milestone") and cumulative revenues from MRD products of $500.0 million (the "MRD Product Revenue Milestone"), respectively. The Commercial Launch Milestone is contingent upon achievement on or before the fifth anniversary of the closing and the MRD Product Revenue Milestone is contingent upon achievement on or before the tenth anniversary of the closing. Ashion is a CLIA-certified and CAP-accredited sequencing lab based in Phoenix, Arizona. Ashion developed GEMExTra®, one of the most comprehensive genomic cancer tests available, and provides access to whole exome, matched germline, and transcriptome sequencing capabilities. The Company currently expects the Ashion Acquisition to close during the second quarter of 2021, subject to customary closing conditions.

(23) QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)

The following table sets forth unaudited quarterly statements of operations data for each of the eight quarters ended December 31, 2020 and 2019. In the opinion of management, this information has been prepared on the same basis as the audited consolidated financial statements and contains all adjustments, consisting only of normal recurring adjustments, considered necessary for a fair statement of the unaudited quarterly results for the periods presented. The quarterly data should be read in conjunction with the Company's audited consolidated financial statements and the notes to the consolidated financial statements appearing elsewhere in this Form 10-K.

	Quarter Ended (3)			
	March 31,	June 30,	0,	,
	(Amounts in thousands, except per share data)			
2020				
Revenue	$ 347,821	$ 268,868	$ 408,363	$ 466,339
Cost of sales (exclusive of amortization of acquired intangible assets)	81,606	77,892	95,061	99,765
Amortization of acquired intangible assets (1)	20,464	20,555	20,555	20,553
Gross profit	245,751	170,421	292,747	346,021
Operating expenses, net (2)	328,124	237,430	496,082	761,323
Interest income and interest expense	(25,056)	(20,000)	(21,059)	(22,971)
Income tax benefit	1,732	867	4,510	1,463
Net loss	$ (105,697)	$ (86,142)	$ (219,884)	$ (436,810)
Net loss per share—basic	$ (0.71)	$ (0.58)	$ (1.46)	$ (2.79)
Net loss per share—diluted	$ (0.71)	$ (0.58)	$ (1.46)	$ (2.79)
Weighted average common shares outstanding—basic	148,151	149,727	150,155	156,470
Weighted average common shares outstanding—diluted	148,151	149,727	150,155	156,470
2019				
Revenue	$ 162,043	$ 199,870	$ 218,805	$ 295,575
Cost of sales (exclusive of amortization of acquired intangible assets)	42,827	51,139	52,335	70,416
Amortization of acquired intangible assets (1)	425	424	424	11,981
Gross profit	118,791	148,307	166,046	213,178
Operating expenses (2)	186,865	182,209	201,772	309,258
Interest income and interest expense	(15,335)	(5,043)	(4,116)	(10,575)
Income tax benefit (expense)	470	443	(683)	184,628
Net income (loss)	$ (82,939)	$ (38,502)	$ (40,525)	$ 77,973
Net income (loss) per share—basic	$ (0.66)	$ (0.30)	$ (0.31)	$ 0.56
Net income (loss) per share—diluted	$ (0.66)	$ (0.30)	$ (0.31)	$ 0.54
Weighted average common shares outstanding—basic	126,248	129,182	129,567	139,901
Weighted average common shares outstanding—diluted	126,248	129,182	129,567	143,200

(1) Includes only amortization of acquired intangible assets identified as developed technology assets through purchase accounting transactions, which otherwise would have been allocated to cost of sales.

(2) Consists of research and development, sales and marketing, general and administrative, and amortization of acquired intangible assets excluding acquired developed technology, which is included in the gross profit calculation above. This also includes intangible asset impairment charges and funding received as part of the CARES Act. Refer to Note 6 for further discussion on the intangible asset impairment charges recorded in the third quarter of 2020. Refer to Note 1 for further discussion on the funding received as part of the CARES Act in the second quarter of 2020.

(3) The quarterly net loss presented for each of the quarterly statements of operations shown above differ from the net loss presented in the Forms 10-Q issued during the year ended December 31, 2019 by an immaterial amount. The differences net to zero for the full year in 2019 and relate to the Company's international subsidiaries' functional currency changing to the U.S. dollar, which is discussed further in Note 1.

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, 2020 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, 2020, 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, 2020. 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, 2020, 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, 2020 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required under this item is incorporated by reference to the following sections of our proxy statement for our 2021 Annual Meeting of Stockholders: "Information Concerning Directors and Nominees for Director," "Information Concerning Executive Officers," "Section 16(a) Beneficial Ownership Reporting Compliance," "Corporate Governance Principles and Board Matters," and "The Board of Directors and Its Committees."

Item 11. Executive Compensation

The information required under this item is incorporated by reference to the following sections of our proxy statement for our 2021 Annual Meeting of Stockholders: "Compensation and Other Information Concerning Directors and Officers," "The Board of Directors and Its Committees," and "Report of The Compensation Committee."

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

The information required under this item is incorporated by reference to the following sections of our proxy statement for our 2021 Annual Meeting of Stockholders: "Equity Compensation Plan Information" and "Securities Ownership of Certain Beneficial Owners and Management."

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

The information required under this item is incorporated by reference to the following sections of our proxy statement for our 2021 Annual Meeting of Stockholders: "Certain Relationships and Related Transactions" and "Corporate Governance Principles and Board Matters."

Item 14. Principal Accountant Fees and Services

The information required under this item is incorporated by reference to the following sections of our proxy statement for our 2021 Annual Meeting of Stockholders: "Independent Registered Public Accounting Firm" and "Pre-Approval Policies and Procedures."

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this Form 10-K:

(1) Financial Statements (see "Consolidated Financial Statements and Supplementary Data" at Item 8 and incorporated herein by reference).

(2) Financial Statement Schedules (Schedules to the Financial Statements have been omitted because the information required to be set forth therein is not applicable or is shown in the accompanying Financial Statements or notes thereto).

(3) Exhibits

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
2.1	Agreement and Plan of Merger, dated July 28, 2019, by and among the Registrant, Spring Acquisition Corp. and Genomic Health, Inc.		8-K (Exhibit 2.1)	7/30/2019	001-35092
2.2	Agreement and Plan of Merger, dated October 26, 2020, by and among the Registrant, certain subsidiaries of the Registrant, Thrive Earlier Detection Corp. and Shareholder Representative Services LLC		8-K (Exhibit 2.1)	10/27/2020	001-35092
2.3	First Amendment to Agreement and Plan of Merger, dated December 23, 2020, by and among the Registrant, certain subsidiaries of the Registrant, Thrive Earlier Detection Corp. and Shareholder Representative Services LLC		8-K (Exhibit 2.1)	1/5/2021	001-35092
2.4	Second Amendment to Agreement and Plan of Merger, dated January 4, 2021, by and among the Registrant, certain subsidiaries of the Registrant, Thrive Earlier Detection Corp. and Shareholder Representative Services LLC		8-K (Exhibit 2.2)	1/5/2021	001-35092
3.1	Sixth Amended and Restated Certificate of Incorporation of the Registrant		S-1 (Exhibit 3.3)	12/4/2000	333-48812
3.2	Amendment to Sixth Amended and Restated Certificate of Incorporation of the Registrant		8-K (Exhibit 3.1)	7/24/2020	001-35092
3.3	Fourth Amended and Restated By-Laws of the Registrant		8-K (Exhibit 3.1)	1/31/2020	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 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 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, 2020, by and between the Registrant and 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 National Association, as Trustee (including the form of 0.3750% Convertible Senior Notes due 2028)		8-K (Exhibit 4.2)	2/27/2020	001-35902
4.6	Description of Common Stock	X			
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 April 2, 2018, by and between Mark Stenhouse and the Registrant	10-Q (Exhibit 10.2)	10/30/2018	001-35092	
10.13*	Employment Agreement, dated October 30, 2015, by and between Scott Coward and the Registrant	10-K (Exhibit 10.13)	2/24/2016	001-35092	
10.14*	First Amendment to Employment Agreement, dated August 1, 2009, by and between Graham Lidgard and the Registrant	10-Q (Exhibit 10)	11/12/2009	001-32179	
10.15*	Employment Agreement, dated February 18, 2019, by and between Jacob Orville and the Registrant	10-K (Exhibit 10.17)	2/21/2020	001-35092	
10.16*	Employment Agreement, dated August 22, 2017, by and between Sarah Condella and the Registrant	X			
10.17*	Employment Agreement, dated August 28, 2017, by and between Ana Hooker and the Registrant	X			
Equity Compensation Plans and Policies					
10.18*	2000 Stock Option and Incentive Plan	10-K (Exhibit 10.2)	3/31/2009	000-32179	
10.19*	The Registrant’s 2010 Employee Stock Purchase Plan	DEF 14A (Appendix B)	4/30/2010	000-32179	
10.20*	First Amendment to the Registrant’s 2010 Employee Stock Purchase Plan	DEF 14A (Appendix A)	6/20/2014	001-35092	
10.21*	Second Amendment to the Registrant’s 2010 Employee Stock Purchase Plan	DEF 14A (Appendix A)	4/29/2016	001-35092	
10.22*	The Registrant’s 2016 Inducement Award Plan	10-Q (Exhibit 10.3)	5/3/2016	001-35092	
10.23*	The Registrant’s 2016 Inducement Award Plan Form Restricted Stock Unit Award Agreement	S-8 (Exhibit 4.7)	5/3/2016	333-211099	
10.24*	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	
10.25*	The Registrant's Non-Employee Director Compensation Policy dated October 22, 2020	X			

10.26*	The Registrant’s Executive Deferred Compensation Plan dated January 1, 2019	10-K (Exhibit 10.22)	2/21/2019	001-35092	
10.27*	Third Amendment to the Registrant's 2010 Employee Stock Purchase Plan	10-Q (Exhibit 10.1)	7/30/2019	001-35092	
10.28*	The Registrant's 2019 Omnibus Long-Term Incentive Plan	S-8 (Exhibit 4.4)	7/31/2019	333-23916	
10.29*	The Registrant's 2019 Omnibus Long-Term Incentive Plan Form Stock Option Award Agreement	10-K (Exhibit 10.29)	2/21/2020	001-35092	
10.30*	The Registrant's 2019 Omnibus Long-Term Incentive Plan Form Restricted Stock Unit Award Agreement	10-K (Exhibit 10.30)	2/21/2020	001-35092	
10.31*	The Registrant's 2019 Omnibus Long-Term Incentive Plan Form Restricted Stock Award Agreement	10-K (Exhibit 10.31)	2/21/2020	001-35092	
10.32*	Genomic Health, Inc. Amended and Restated 2005 Stock Incentive Plan, as amended	S-8 (Exhibit 4.4)	11/8/2019	333-234608	
10.33*	Thrive Earlier Detection Corp. 2019 Stock Option and Grant Plan	S-8 (Exhibit 4.6)	1/5/2021	333-251900	
Other					
10.36**	Technology License Agreement dated as of October 14, 2009 by and among Hologic, Inc., Third Wave Technologies, Inc., and the Registrant	10-K (Exhibit 10.39)	3/12/2010	000-32179	
10.37**	Amendment dated December 7, 2012 to Technology License Agreement dated October 14, 2009 by and among Hologic, Inc., Third Wave Technologies, Inc., and the Registrant	10-K (Exhibit 10.37)	3/1/2013	001-35092	
10.38**	Amended and Restated License Agreement dated effective January 1, 2020, by and between the Registrant and Mayo Foundation for Medical Education and Research	10-Q (Exhibit 10.1)	10/27/2020	001-35092	
10.39	Amended and Restated Promotion Agreement dated October 6, 2020 between the Registrant and Pfizer, Inc.	8-K (Exhibit 10.1)	10/7/2020	001-35092	
21	Subsidiaries of the Registrant	X			
23.1	Consent of PricewaterhouseCoopers, LLP	X			
23.2	Consent of BDO USA, 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
101	The following materials from the Annual Report on Form 10-K of Exact Sciences Corporation for the year ended December 31, 2020 filed with the Securities and Exchange Commission on February 21, 2020, formatted in Inline eXtensible Business Reporting Language (“iXBRL”): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statement of Changes in Stockholders’ Equity, (iv) Consolidated Statements of Cash Flows and (v) related notes to these financial statements	X
104	The cover page from the Annual Report on Form 10-K of Exact Sciences Corporation for the year ended December 31, 2020 filed with the Securities and Exchange Commission on February 21, 2020, formatted in Inline eXtensible Business Reporting Language (“iXBRL”)	X

(*) Indicates a management contract or any compensatory plan, contract or arrangement.

(**) Confidential Treatment requested for certain portions of this Agreement.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

EXACT SCIENCES CORPORATION

Date: February 16, 2021

By: /s/ Kevin T. Conroy
Kevin T. Conroy
President & Chief Executive Officer

POWER OF ATTORNEY AND SIGNATURES

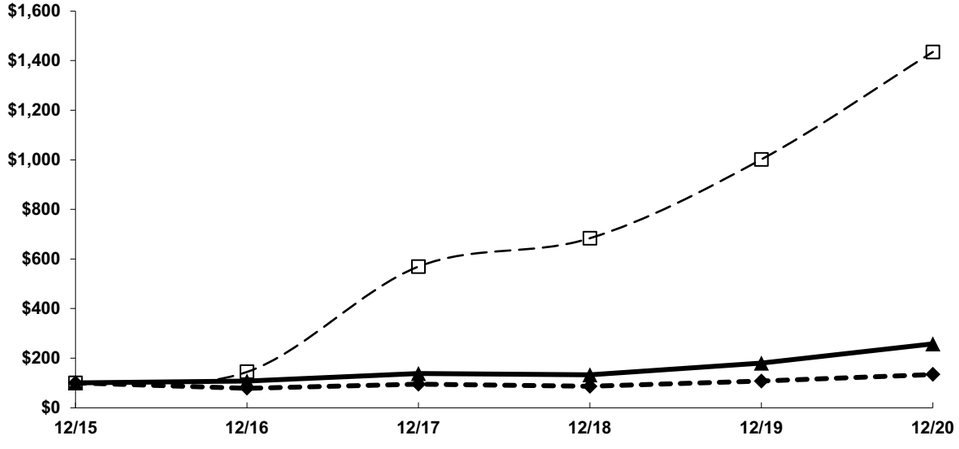
We, the undersigned officers and directors of Exact Sciences Corporation, hereby severally constitute and appoint Kevin T. Conroy our true and lawful attorney, with full power to him to sign for us and in our names in the capacities indicated below, any amendments to this Annual Report on Form 10-K, 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 16, 2021
/s/ Jeffrey T. Elliott Jeffrey T. Elliott	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 16, 2021
/s/ Thomas D. Carey Thomas D. Carey	Director	February 16, 2021
/s/ James E. Doyle James E. Doyle	Lead Independent Director	February 16, 2021
/s/ Freda Lewis-Hall Freda Lewis-Hall	Director	February 16, 2021
/s/ Pierre Jacquet Pierre Jacquet	Director	February 16, 2021
/s/ Daniel J. Levangie Daniel J. Levangie	Director	February 16, 2021
/s/ Shacey Petrovic Shacey Petrovic	Director	February 16, 2021
/s/ Kathleen Sebelius Kathleen Sebelius	Director	February 16, 2021
/s/ Michael S. Wyzga Michael S. Wyzga	Director	February 16, 2021
/s/ Katherine Zanotti Katherine Zanotti	Director	February 16, 2021

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

Among Exact Sciences Corporation, The NASDAQ Composite Index,
and The NASDAQ Biotechnology Index



*$100 invested on 12/31/15 in stock or index including reinvestment of dividends.