EXACT SCIENCES CORP
Form 10-K
February 21, 2019
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10 K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended: December 31, 2018
TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number 001-35092

EXACT SCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

DELAWARE	02 0478229
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
441 Charmany Drive, Madison, WI	53719
(Address of principal executive offices)	(Zip Code)

Registrant’s telephone number, including area code: (608) 284 5700

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

Common Stock, $0.01 Par Value	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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10 K or any amendment to this Form 10 K.

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

Large accelerated filer	Accelerated filer	Non accelerated filer (Do not check if a smaller reporting company)	Smaller reporting company
			Emerging growth company

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

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

The aggregate market value of the voting and non voting common equity held by non affiliates of the Registrant, as of the last business day of the Registrant's most recently completed second fiscal quarter was approximately $7,176,273,883 (based on the closing price of the Registrant's Common Stock on June 29, 2018 of $59.79 per share).

The number of shares outstanding of the Registrant's $0.01 par value Common Stock as of February 20, 2019 was 125,760,907.

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, 2018. Portions of such proxy statement are incorporated by reference into Part III of this Form 10 K.

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EXACT SCIENCES CORPORATION

ANNUAL REPORT ON FORM 10 K

YEAR ENDED DECEMBER 31, 2018

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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 "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, 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, anticipated results of our sales and marketing efforts, expectations concerning payer reimbursement and the anticipated results of our product development efforts. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our 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. Our actual results and financial condition 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 our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following: our ability to successfully and profitably market our products and services; the acceptance of our products and services by patients and healthcare providers; our ability to meet demand for our products and services; 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 from other cancer screening and diagnostic products and services; the effects of the adoption, modification or repeal of any healthcare reform law, rule, order, interpretation or policy; the effects of changes in pricing, coverage and reimbursement for our products and services, including without limitation as a result of the Protecting Access to Medicare Act of 2014; recommendations, guidelines and quality metrics issued by various organizations such as the U.S. Preventive Services Task Force, the American Cancer Society, and the National Committee for Quality Assurance regarding cancer screening or our products and services; our ability to successfully develop new products and services; our ability to effectively utilize strategic partnerships, such as through our Promotion Agreement with Pfizer, Inc., and acquisitions; our success establishing and maintaining collaborative, licensing and supplier arrangements; our ability to maintain regulatory approvals and comply with applicable regulations; 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 of this Annual Report on Form 10 K and our subsequently filed Quarterly Reports on Form 10-Q. 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.

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Item 1. Business

Overview

Exact Sciences Corporation (together with its subsidiaries, "Exact," "we," "us," "our" or the "Company") is a molecular diagnostics company focused on the early detection and prevention of some of the deadliest forms of cancer. We have developed an accurate, non-invasive, patient-friendly screening test called Cologuard® for the early detection of colorectal cancer and pre-cancer, and we are currently working on the development of additional tests for other types of cancer, with the goal of becoming a leader in cancer screening and diagnostics.

Our Cologuard Test

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:

- 146,000 new cases of colorectal cancer
- 51,000 deaths from colorectal cancer

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. Of the more than 85 million people between the ages of 50 and 85, who are at average-risk for colorectal cancer in the U.S., 38 percent have not been screened according to current guidelines. Internal studies have shown that approximately 50% of Cologuard users were previously unscreened for colorectal cancer. Poor compliance with screening guidelines has meant that nearly two-thirds of colorectal cancer diagnoses are made in the disease's late stages. The five-year survival rates for stages 3 and 4 are 70 percent and 13 percent, respectively. We believe the large underserved population of unscreened and inadequately screened patients represents a significant opportunity for a patient-friendly screening test.

Our Cologuard test is a 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.

Changes in DNA methylation, and the occurrence of mutations, alter gene expression and other mechanisms for cell cycle regulation and differentiation. As a result, the affected cells continue to proliferate, often resulting in malignancies associated with colorectal cancer and pre-cancer. Hemoglobin is the protein complex responsible for transporting oxygen in red blood cells. During the progression of cancer, the probability of bleeding into the colon increases. The presence of hemoglobin, released from red blood cells, can be detected in the stool. Using sDNA Cologuard purifies, amplifies and detects increased levels of methylation, and presence of mutations, in specific genes. By combining these DNA indicators with a test for hemoglobin, Cologuard produces a multi-marker result

effective for the detection of colorectal cancer and pre-cancerous adenomas.

In August 2014 the U.S. Food and Drug Administration ("FDA") granted premarket approval ("PMA") to Cologuard for use as a colorectal cancer screening test in adults 50 years of age and older who are at average-risk for colorectal cancer. Upon approval, Cologuard became the first and only FDA-approved sDNA non-invasive colorectal cancer screening test. Our original PMA submission to the FDA for Cologuard included the results of our pivotal DeeP-C clinical trial that had over 10,000 patients enrolled at 90 sites in the U.S. and Canada. The results of our DeeP-C clinical trial for Cologuard were published in the New England Journal of Medicine in April 2014. The peer-reviewed study, "Multi-target Stool DNA Testing for Colorectal-Cancer Screening," highlighted the performance of Cologuard in the trial population:

- Cancer Sensitivity: 92%
- Stage I and II Cancer Sensitivity: 94%
- High-Grade Dysplasia Sensitivity: 69%
- Specificity: 87%

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We believe the competitive advantages of sDNA screening may provide a significant market opportunity. There are 85 million people in the U.S. between the ages of 50-85 who are at average risk for colorectal cancer. At a three-year screening interval and an average revenue per test of $500 this represents a potential $14 billion market for Cologuard, of which our current share is approximately four percent.

Our Cologuard Commercialization Strategy

Our commercialization strategy includes three main elements focusing on physicians, patients, and payers.

Physicians and Patients

Our sales team actively engages with physicians and their staffs to emphasize the need for colorectal cancer screening, educate them on the value of Cologuard, and facilitate their ability to order the test. We focus on specific physicians based on a combination of Cologuard order history and ordering potential. We also focus on physician groups and larger regional and national health systems. We recently expanded our physician engagement and Cologuard marketing campaign through a Promotion Agreement (“Promotion Agreement”) with Pfizer, Inc. (“Pfizer”). The Promotion Agreement is discussed in more detail below.

Securing inclusion in guidelines and quality measures is a key part of our physician engagement strategy since many physicians rely on such guidelines and quality measures when making screening recommendations. In June 2016, the U.S. Preventive Services Task Force (“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, and Cologuard is the only version of FIT-DNA available in the U.S.

Many professional colorectal cancer screening guidelines in the U.S., including those of the American Cancer Society (“ACS”) and the National Comprehensive Cancer Network (“NCCN”), recommend regular screening using any of a variety of methods. Since 2008, joint colorectal cancer screening guidelines endorsed by the ACS have included sDNA screening technology as a screening option for the detection of colorectal cancer in average risk, asymptomatic individuals starting at age 50. In October 2014, the ACS updated its colorectal cancer screening guidelines to specifically include Cologuard as a recommended screening test and, as further discussed below, in May 2018 the ACS updated its colorectal cancer screening guidelines to recommend colorectal cancer screening begin at age 45 for people at average risk of the disease. In June 2016, the NCCN updated its Colorectal Cancer Screening Guidelines to add sDNA screening, at a once-every-three-years interval, to its list of recommended screening tests.

In May 2018, the ACS updated its guidelines to recommend colorectal cancer screening beginning at age 45, rather than 50, for people at average risk of the disease due to the rising incidence rate within the 45-49 year-old population. There are 21 million people who are within the ages of 45-49, and we estimate approximately 19 million of them are at average risk for colorectal cancer and eligible for screening. Cologuard is currently indicated for average risk individuals age 50 years or older. We intend to seek FDA approval to expand Cologuard's indication to people age 45 or older who are at average risk for colorectal cancer to align with the ASC updated guideline. We cannot be certain that FDA will grant such approval, or, if it does, when. Further, even if FDA does approve a label expansion, we cannot be certain that healthcare providers will prescribe, patients will use, or payers will reimburse Cologuard in the 45-49 age population.

In October 2016, the National Committee for Quality Assurance ("NCQA") included sDNA testing on a three-year interval as one of the methods permitted for colorectal cancer screening in the 2017 Healthcare Effectiveness Data and Information Set ("HEDIS") quality measures. More than 90 percent of America's health plans measure quality based on HEDIS. In April 2017, the Centers for Medicare & Medicaid Services ("CMS") included Cologuard in its updated 2018 Medicare Advantage Star Ratings program.

A critical part of the value proposition of Cologuard is its compliance 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 compliance including letters, text messages, emails, phone calls, and incentives such as gift cards.

After the launch of Cologuard, we initiated a significant public relations effort to engage patients in the U.S., and

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launched demographically-targeted direct-to-patient advertising campaigns in digital, social, print, and other channels. In 2016, we began a national television advertising campaign, with a majority of placements in national cable and syndicated programming widely viewed by our target patient demographic. In the second quarter of 2018, we extended our television advertising campaign to highlight the accuracy, ease of use, and commercial coverage of Cologuard. In 2019 we plan to increase our television advertising efforts, accelerate our investment in digital and social media, and embark upon other marketing initiatives designed to increase awareness of Cologuard.

We are focused on strengthening our Cologuard core business by increasing the size of our nationwide salesforce. We advanced this goal in August 2018 by entering into a Promotion Agreement with Pfizer. Under the terms of the Promotion Agreement, Pfizer will promote Cologuard 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 Cologuard. We agreed to pay Pfizer a service fee based on incremental gross profits over specified baselines and pay Pfizer royalties for Cologuard related revenues for a specified period after the expiration or termination of the Promotion Agreement. The initial term of the Promotion Agreement runs through December 31, 2021, but may be terminated by either party at any time on or after February 21, 2020 upon six months' written notice to the other party.

Payers

Successful commercialization of our Cologuard test depends, in large part, on adequate reimbursement from government insurance plans, managed care organizations and private insurance plans.

In October 2014, CMS issued a National Coverage Determination ("NCD") for Cologuard following a parallel review process with the FDA. Medicare covers approximately half of patients in the current screening population for Cologuard. Cologuard was the first screening test approved by the FDA and covered by CMS through a parallel process. As outlined in the NCD, Medicare Part B covers Cologuard 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).

The Clinical Laboratory Fee Schedule ("CLFS") for both 2018 and 2019 set the CMS reimbursement rate for Cologuard at $508.87. Under the Protecting Access to Medicare Act of 2014 ("PAMA"), payment rates for clinical diagnostic laboratory tests are calculated based on the volume-weighted median of private payer rates for each clinical diagnostic

laboratory test based on data submitted by certain applicable laboratories. The current CMS reimbursement rate was set based on the volume-weighted median of private payer rates for Cologuard for the period from January 1, 2016 to June 30, 2016. Based on current PAMA regulations, we expect that the current CMS reimbursement rate for Cologuard will remain in place until January 2021, and then will be reset based on the volume-weighted median of private payer rates for Cologuard during the data collection period from January 1, 2019 to June 30, 2019.

Pursuant to the Budget Control Act of 2011, Medicare payments, including Medicare's $508.87 reimbursement for Cologuard, became subject to a payment reduction of up to 2% due to implementation of the automatic expense reductions (i.e., a sequestration). The reduction is made to the total claims paid to plans and providers. Sequestration does not, however, rebase or re-establish the Medicare or Medicaid reimbursement rates.

In addition to Medicare reimbursement, we seek to secure favorable coverage and in-network reimbursement agreements from commercial payers. Most commercial payers have issued positive coverage decisions for Cologuard, and we have entered into contracts with several payers to include Cologuard as an in-network service. In-network agreements with payers have varying terms and conditions, including reimbursement rate, term and termination. From time to time in the ordinary course of our business, we may enter into new agreements, certain existing agreements may expire without renewal and certain other existing agreements may be terminated early by us or the third-party payer. We

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believe that commercial payers' reimbursement of Cologuard will depend on a number of factors, including payers' determination that it is: sensitive and specific for colorectal cancer; not experimental or investigational; approved or recommended by major organizations' guidelines; reliable, safe and effective; medically necessary; appropriate for the specific patient; and cost-effective. Reimbursement may also be affected by whether Cologuard is in-network for a given payer. Also, 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. Medical management, such as prior authorizations and post-payment review or audits, may require that we, patients, or physicians provide the payer with extensive medical records and other information.

Coverage of Cologuard 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 colorectal cancer screening services. For example, Section 2713 of the Patient Protection and Affordable Care Act ("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 Cologuard every three years without patient cost-sharing. While we believe the ACA Mandate will require most health insurers to cover Cologuard without patient cost-sharing certain health insurers have disagreed and determined not to cover Cologuard 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, overturned or significantly modified in the future. 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 been the subject of various legal challenges, which, if ultimately successful, could overturn the ACA Mandate. In December 2018, a federal district court in Texas held that the ACA is unconstitutional and unenforceable. The court's decision is subject to appeal.

Similarly, we believe the laws of approximately 30 states currently mandate coverage of Cologuard by certain health insurance plans. While some insurers have agreed with our interpretation regarding certain state mandates, other insurers have disagreed. In some cases, we have filed lawsuits in an effort to enforce state laws we believe require coverage of Cologuard, and we may file additional suits in the future. We may or may not be successful in any such lawsuit.

We are pursuing a variety of strategies to maximize commercial payer coverage for Cologuard, including providing cost effectiveness data to payers to make the case for Cologuard reimbursement. We are focusing our efforts on large national and regional insurers and health plans that have affiliated health systems.

We believe quality metrics may influence payers' coverage and contracting decisions, as well as physicians' cancer screening procedures. 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 HEDIS and CMS Star Ratings, to assess quality of care. We believe Cologuard's inclusion in the HEDIS measures and Star Ratings measures positively impacts payers' willingness to reimburse Cologuard, as well as on healthcare providers' willingness to prescribe the test.

Our Clinical Laboratory and Manufacturing Facilities

As part of our commercialization strategy, we established a state-of-the-art, highly automated lab facility that is certified pursuant to federal Clinical Laboratory Improvement Amendments ("CLIA") requirements to process Cologuard tests and provide patient results. Our commercial lab operation is housed in a 55,000 square foot facility in Madison, Wisconsin. At our lab, we currently have the capacity to process approximately three million tests per year.

During the fourth quarter of 2017 we began construction of a new clinical lab facility in Madison, Wisconsin that is expected to be completed mid-2019. After the new clinical laboratory is operational, we expect our total lab capacity at both facilities will be approximately seven million tests per year by the end of 2019.

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We currently manufacture the Cologuard test in a facility in Madison, Wisconsin. As we expand the commercialization of Cologuard, we believe it will be necessary to expand our manufacturing capacity. Accordingly, we are in the process of building an additional manufacturing facility which we expect to complete in 2019. 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.

Future Product Opportunities

Enhance Cologuard

In May 2018, the ACS updated its guidelines to recommend colorectal cancer screening beginning at age 45, rather than 50, for people at average risk of the disease due to the rising incidence rate within the 45-49 year-old population. There are nearly 21 million people who are between the ages of 45-49, and we estimate approximately 19 million of them are at average risk for colorectal cancer and would be eligible for screening under the ACS guidelines. We plan to conduct clinical and other necessary work to gain FDA approval to expand Cologuard's indication to people between the ages of 45 and 49 who are at average risk for colorectal cancer.

In addition, we are seeking opportunities to improve upon Cologuard's performance characteristics. For example, we are evaluating whether new biomarkers would increase specificity while maintaining sensitivity. If we could increase the specificity of Cologuard, we believe that would enhance its adoption as a front-line screening test. We are also evaluating ways that we might make Cologuard even easier for patients to use and opportunities for lowering the cost of providing Cologuard.

The timing of any expansion of Cologuard's indication or of any such enhancements to Cologuard is unknown and would be subject to FDA approval.

Advance Liquid Biopsy

We also are focusing our research and development efforts on building a pipeline of potential future products and services with a focus on blood-based ("liquid biopsy") tests. We will continue to advance liquid biopsy through biomarker discovery and validation in tissue and blood. We have identified proprietary biomarkers for several cancers, including liver cancer and lung cancer. We have successfully performed validation studies on tissue samples for thirteen cancers and on blood samples for eight cancers.

The ACS estimates that liver cancer will be diagnosed in 42,000 Americans and cause 32,000 deaths in 2019, three-fourths of which will be hepatocellular carcinoma ("HCC"). Incidence and mortality rates are both increasing at approximately 3 percent per year. People who have been diagnosed with cirrhosis of the liver or Hepatitis B are at high risk of developing HCC. Evidence shows that HCC testing in these high-risk groups leads to earlier detection and improved outcomes. The NCCN and American Association for the Study of Liver Diseases ("AASLD") guidelines recommend that these two groups be tested for HCC every six months using ultrasound and the blood-based biomarker alpha-fetoprotein ("AFP"). However, ultrasound and AFP are documented to have poor sensitivity for early

stage cancer, which is the primary target of testing. We are currently seeking to develop a blood-based biomarker test to serve as an alternative to ultrasound and AFP for use in HCC testing, and our goal is to develop a patient-friendly test that performs better than this current standard of care. We are currently enrolling a case control study of at least 1,500 patients to finalize the development of our liver cancer test.

The ACS estimates that, in the U.S. in 2019, lung cancer will be diagnosed in 228,000 people and cause 143,000 deaths. Currently, more than half of lung cancer cases are diagnosed at an advanced stage, after symptoms appear, when the five-year survival rate is in the low single digits. We are currently seeking to develop a blood-based biomarker test to aid in the early detection of lung cancer in individuals with lung nodules discovered through a computerized tomography (“CT”)

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or other scan. Such a test may help reduce the number of follow-up procedures, and thereby reduce costs and improve health outcomes.

Research and Development

Research and development costs account for a material portion of our operating expenses. As we seek to enhance Cologuard 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.

Competition

The U.S. market for colorectal cancer and pre-cancer screening is large, consisting of more than 85 million individuals between the ages of 50 and 85. If the screening population includes 45-49 year olds, as recommended by the ACS, the colorectal cancer screening market would increase by approximately 19 million people to approximately 104 million people. Given the large market for colorectal cancer screening, we face numerous competitors, some of which possess significantly greater financial and other resources and development capabilities than us. 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 ("FOBT") and the fecal immunochemical test ("FIT"), and newer screening technologies such as 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. Our competitors may also be developing additional methods of detecting colorectal cancer and pre-cancer that have not yet been announced.

In addition, some companies and institutions are developing liquid biopsy tests based on the detection of proteins, tumor cells, nucleic acids, epigenetic markers, or other biomarkers in the blood. These tests could represent significant competition for Cologuard and other tests we may develop. We are aware of at least 13 companies—Epigenomics AG, EDP Biotech Corporation, Freenome Inc., GRAIL, Inc., CellMax, Inc., Volition Diagnostics, Cambridge Epigenetix Limited, Nucleix Ltd., Singlera Genomics, DiaCarta, Genomictree, Bioprognos, and PapGene, Inc. — that have developed, or are developing, liquid biopsy tests for the detection of colorectal cancer. Epigenomics AG received FDA approval for its liquid biopsy screening test for colorectal cancer, Epi proColon, in April 2016, and began offering the test commercially in May 2016. We also are aware of at least two companies, DiaTech and Geneoscopy, that have launched outside the U.S., or are seeking to develop, stool-based colorectal cancer tests based on the detection of nucleic acids.

We believe other companies are also working on liquid biopsy tests using next generation sequencing or other technologies, and these tests could represent significant competition for Cologuard and other tests we may develop.

Notwithstanding that the market for colorectal cancer screening is highly competitive, we believe that Cologuard, 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 compliance, 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 seven out of 10 people age 50 and older who were told they should get a colonoscopy did not do so primarily due to fears. 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 cancers. 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 three out of every 1,000 patients studied adhered to fecal test screening guidelines during a continuous 10-year observation period.

Beyond our Cologuard test, as we seek to develop other tests to detect cancer and pre-cancer, 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:

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

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. We have limited experience developing tests for detecting non-colorectal cancers and cannot guarantee that our research and development activities will be successful in developing any marketable testing products or services. Furthermore, even if we do develop new marketable products or services, our current and future competitors may develop products and services that are more commercially attractive than ours, and they may bring those products and services to market earlier or more effectively than us.

Seasonality

We are in the early stages of Cologuard's commercialization and 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 physicians, 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 for preventive care such as colorectal cancer screening, and other factors relating to the timing of patient deductibles and co-insurance limits.

Government 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 and state 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

The FDA granted premarket approval ("PMA") for Cologuard in August 2014. Devices subject to FDA regulation must undergo premarket review prior to commercialization unless the device is exempt from such review. The regulations governing Cologuard's approval place substantial restrictions on how Cologuard is marketed and sold, specifically, by prescription only. In addition, as a condition of our FDA approval, we are required to conduct a post-approval study. A final report on this study is due to FDA in 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 Cologuard.

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.

We may develop new diagnostic products and services that are 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

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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.

We may also develop diagnostic products or services that, under today's laws, would be regulated as laboratory developed tests ("LDTs") under CLIA. However, as noted below, the regulation of LDTs may be in flux, as the FDA retracted a proposal for increased LDT oversight in January 2017 and continues to apply enforcement discretion.

Laboratory Developed Tests ("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 disease and uncommon conditions.

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. It is unclear at this time if or when the FDA end 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.

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

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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. Beginning in 2020 we will also need to comply with the California Consumer Privacy Act of 2018, which protects personal information other than health information covered by HIPAA. In the E.U., the General Data Protection Regulation ("GDPR") took effect in May 2018 and imposes increasingly stringent data protection and privacy rules. All of these laws may impact our business and may change periodically, which could have an effect on our business operations if compliance becomes substantially costlier than under current requirements. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain stool, blood and other patient samples and associated patient information could significantly impact our business and our future business plans.

Federal and State Billing and Fraud and Abuse Laws

Antifraud Laws/Overpayments. We are subject to numerous federal and state antifraud and abuse laws, including the Federal False Claims Act. Many of these antifraud 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 antifraud 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 may identify overpayments and be required to refund those amounts 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”

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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.

Self Referral Law. The federal "self referral" law, commonly referred to as the "Stark" law, provides that physicians 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 physicians 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 physicians 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, or CHIP, to report annually to CMS any payments or other transfers of value made to physicians and teaching hospitals, unless an exception applies. Manufacturers must also disclose to CMS any physician 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.

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 for Cologuard subject us to regulations of the Department of Transportation, the United States 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, 2018, and there are no material expenditures planned for such purposes for the year ended December 31, 2019.

Intellectual Property

We have intellectual property rights pertaining to sample type, sample preparation, sample preservation, biomarkers, and related methods and formulations.

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Our success depends to a significant degree upon our ability to protect our technologies through patent coverage. As of December 31, 2018, we owned 43 issued patents and 42 pending patent applications in the United States, and 87 issued patents and 67 pending patent applications in foreign jurisdictions.

As further described in the "License Agreements" section below, we acquired certain patents related to Cologuard from MDxHealth ("MDx") on April 25, 2017 as part of a royalty buy-out agreement and patent purchase agreement.

In December 2017, we entered into an asset purchase agreement (the "Armune Purchase Agreement") with Armune BioScience, Inc. ("Armune"), pursuant to which we acquired intellectual property and certain other assets underlying Armune's APIFINY®, APIFINY® PRO and APIFINY® ACTIVE SURVEILLANCE prostate cancer diagnostic tests. The portfolio of Armune assets we acquired is expected to complement our product pipeline. The total consideration was comprised of an up-front cash payment of $12.0 million and $17.5 million in contingent payment obligations that will become payable upon our achievement of development and commercial milestones using the acquired intellectual property. In connection with the Armune Purchase Agreement, Armune terminated a license agreement pursuant to which it licensed certain patent rights and know-how from the Regents of the University of Michigan ("University of Michigan"), and we entered into a license agreement with the University of Michigan with respect to such patent rights and know-how, as well as certain additional intellectual property rights. Pursuant to our agreement with the University of Michigan, we are required to pay the University of Michigan a low single-digit royalty on our net sales of products using the licensed intellectual property.

Each of our patents generally has a term of 20 years from its respective priority filing date. Of our issued patents referenced above, the earliest is set to expire in 2020 and the last of these will expire in 2035.

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 Foundation for Medical Education and Research ("Mayo"). Our license agreement with Mayo was amended and restated in February 2015 and further amended in January 2016, October 2017, and in December 2018. 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 tests or tools 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.

Mayo has agreed to make available personnel through January 2020 to provide us product development and research and development assistance.

Pursuant to our agreement with Mayo, we are required to pay Mayo a low single-digit royalty on our net sales of products using the licensed Mayo intellectual property, with minimum annual royalty fees of $25,000 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 our net sales of Cologuard increased, but the rate remained a low single-digit percentage of net sales.

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In addition to the royalty rates 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 February 2015 amendment and restatement of the license agreement, we agreed to pay Mayo an additional $5.0 million, payable in five annual installments, through 2019.

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 2033 (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 of the licensed patents 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.

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 cancers 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.

MDx Health

In July 2010, we entered into a technology license and royalty agreement (“MDx License Agreement”) with MDx Health (formerly Oncomethylome Sciences, S.A.) (“MDx”). Under the MDx License Agreement, MDx granted us a royalty bearing, exclusive, worldwide license to certain patents. Under the MDx License Agreement, we were obligated to make commercially reasonable efforts to bring products covered by the license agreement to market. We were required to pay MDx a low-single digit royalty fee, subject to an annual minimum, as well as various milestone payments.

Effective April 2017, we and MDx entered into a Royalty Buy-Out Agreement, which terminated the MDx License Agreement. Pursuant to the Royalty Buy-Out Agreement, we paid MDx a one-time fee of $8.0 million in exchange for an assignment of certain patents covered by the MDx License Agreement and the elimination of all ongoing royalties and other payments by us to MDx under the MDx License Agreement. Also included in the Royalty Buy-Out

Agreement is a mutual release of liabilities, which includes all amounts previously accrued under the MDx License Agreement. Concurrently with entering into the Royalty Buy-Out Agreement, we entered into a Patent Purchase Agreement with MDx under which we paid MDx an additional $7.0 million in exchange for the assignment of certain other patent rights that were not covered by the MDx License Agreement.

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Acquisitions

In October 2018, we completed the acquisition of Biomatrica, Inc. (“Biomatrica”), a privately held company specializing in the collection and preservation of biological materials. In the acquisition, we acquired all of the outstanding equity interests for an aggregate purchase price of $20.0 million net of cash received, debt repaid and certain other adjustments. Contingent consideration for up to an additional $20.0 million could be earned based upon certain revenue milestones being met.

Employees

As of December 31, 2018, we had 1,977 full time employees. None of our employees are represented by a labor union. We consider our relationship with our employees generally to be good.

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 441 Charmany Drive, 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, 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.

We may never become profitable.

We have incurred losses since we were formed and only began generating revenue from Cologuard, our only product, in 2014. From our date of inception on February 10, 1995 through December 31, 2018, we have accumulated a total deficit of approximately $1.0 billion. We expect to continue investing significantly toward development and commercialization of our colorectal cancer screening technology 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 Cologuard 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

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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 certain of 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.

For at least the next 12 months, our ability to generate revenues will depend very substantially on the commercial success of our Cologuard test. There can be no assurance that we will develop or commercialize any other product or service that will generate significant revenue. The commercial success of our Cologuard test and our ability to generate revenues will depend on a variety of factors, including the following:

- acceptance in the medical community;
- inclusion of Cologuard in healthcare guidelines and recommendations, such as those developed by ACS and USPSTF;
- inclusion of Cologuard in quality measures including the HEDIS measures and the CMS Medicare Advantage Star Ratings;
- recommendations and studies regarding Cologuard specifically or colorectal cancer screening generally that may be published by government agencies, professional organizations, academic or medical journals or other key opinion leaders;
- patient acceptance of and demand for the Cologuard test;
- patient compliance with orders for the Cologuard test by healthcare providers, and patient adherence over time to recommendations regarding periodic re-screening;
- 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 Cologuard for that purpose;
- sufficient coverage and reimbursement by third-party payers, which may depend in whole or in part on multiple factors, including federal or state laws that mandate coverage for colorectal cancer screening, the extent to which those laws mandate coverage of Cologuard and the enforcement of those laws;
- the amount and nature of competition from other colorectal cancer or pre-cancer screening products and procedures;
- maintaining FDA marketing approval of Cologuard;
- the ease of use of our ordering process for physicians;
- maintaining and defending patent protection for the intellectual property relevant to Cologuard; and
- our ability to establish and maintain adequate commercial manufacturing, distribution, sales and CLIA laboratory testing capabilities.

If we are unable to develop and maintain substantial sales of our Cologuard test or if we are significantly delayed or limited in doing so, our business prospects, financial condition and results of operation would be adversely affected.

Our quarterly 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:

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our success in marketing and selling, and changes in demand for, our Cologuard test, and the level of reimbursement and collection obtained for Cologuard;

- seasonal variations affecting physician recommendations for colorectal cancer screenings and patient compliance with physician recommendations, including without limitation holidays, weather events, and circumstances such as the outbreak of influenza that may limit patient access to medical practices for preventive services such as colorectal cancer screening;

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- 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 Cologuard test, including potential changes in CMS or other reimbursement rates;
- circumstances affecting our ability to provide our Cologuard test, including weather events, supply shortages, or regulatory or other circumstances that adversely affect our ability to manufacture our Cologuard test or process Cologuard tests in our clinical laboratory;
- 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, including our Cologuard test, less competitive or obsolete.

The U.S. market for colorectal cancer and pre-cancer screening is large, consisting of more than 85 million individuals between the ages of 50 and 85. If the screening population includes 45-49 year olds, as recommended by the ACS, the colorectal cancer screening market would increase by approximately 19 million people to approximately 104 million people. Given the large market for colorectal cancer screening, we face numerous competitors, some of which possess significantly greater financial and other resources and development capabilities than us. 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 (“FOBT”) and the fecal immunochemical test (“FIT”), and newer screening technologies such as 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. Our competitors may also be developing additional methods of detecting colorectal cancer and pre-cancer that have not yet been announced.

In addition, some companies and institutions are developing liquid biopsy tests based on the detection of proteins, tumor cells, nucleic acids, epigenetic markers, or other biomarkers in the blood. These tests could represent significant competition for Cologuard and other tests we may develop. We are aware of at least 13 companies—Epigenomics AG, EDP Biotech Corporation, Freenome Inc., GRAIL, Inc., CellMax, Inc., Volition Diagnostics, Cambridge Epigenetix Limited, Nucleix Ltd., Singlera Genomics, DiaCarta, Genomictree, Bioprognos, and PapGene, Inc. — that have developed, or are developing, liquid biopsy tests for the detection of colorectal cancer. Epigenomics AG received FDA approval for its liquid biopsy screening test for colorectal cancer, Epi proColon, in April 2016, and began offering the test commercially in May 2016. We also are aware of at least two companies, DiaTech and Geneoscopy, that have launched outside the U.S., or are seeking to develop, stool-based colorectal cancer tests based on the detection of nucleic acids.

Beyond our Cologuard test, as we seek to develop other tests to detect cancer and pre-cancer, 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.

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. We have limited experience developing tests for detecting non-colorectal cancers and cannot guarantee that our research and development activities will be successful in developing any marketable testing products or services. Furthermore, even if we do develop new marketable products or services, our current and future competitors may develop products and services that are more commercially attractive than ours, and they may bring those products and services to market earlier or more effectively than us.

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We may not be successful expanding Cologuard's indication to include people from 45 to 49 years old at average risk for colorectal cancer or in commercializing Cologuard for use in this patient population.

We plan to seek FDA approval to expand Cologuard's indication to people age 45 and older who are at average risk for colorectal cancer and to undertake any clinical work required to support such approval, so that we can market Cologuard to that population. The efforts necessary to support FDA approval of this label expansion may be expensive and time consuming and may require us to perform clinical trials. There can be no assurance that we will obtain FDA approval for the expanded indication.

Even if the FDA approves Cologuard for use by people from 45-49 years old at average risk for colorectal cancer, we may not be able to successfully commercialize Cologuard to this patient population unless Government and other third-party payers, including managed care organizations, approve reimbursement for our Cologuard test for such patients at adequate reimbursement rates. We expect that securing a favorable recommendation from the U.S. Preventative Services Task Force, as well as other influential recommendations, inclusion in healthcare guidelines and inclusion in quality metrics will be keys to payers' willingness to cover, and healthcare providers' willingness to prescribe, Cologuard for people in this expanded population. However, there can be no assurance that these guidelines and quality metrics will support the expanded use of Cologuard. Further, we cannot be sure that payers will be willing to cover, that healthcare providers will be willing to prescribe the test to patients in this population, or that 45-49 year-old patients will be willing to use Cologuard. If we are unable to successfully commercialize Cologuard to people age 45 to 49, our financial results and our business prospects may be materially and adversely affected.

We face uncertainty related to healthcare reform, pricing, coverage and reimbursement, which could reduce our revenue.

Healthcare reform laws, including the Patient Protection and Affordable Care Act (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 substantially 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 held that the ACA is unconstitutional and unenforceable. The court's decision is subject to appeal, but if this case, or any other case challenging the ACA is ultimately successful, insurance coverage for Cologuard 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.

The CLFS for both 2018 and 2019 set the CMS reimbursement rate for Cologuard at $508.87. Under PAMA, payment rates for clinical diagnostic laboratory tests are calculated based on the volume-weighted median of private payer rates for each clinical diagnostic laboratory test based on data submitted by certain applicable laboratories. The current

CMS reimbursement rate for Cologuard was based on the volume-weighted median of private payer rates for Cologuard from January 1, 2016 through June 30, 2016. Based on current regulations, we expect that the CMS reimbursement rate for Cologuard will remain in place until January 2021 and then will be reset based on the volume-weighted median of private payer rates for Cologuard during the data collection period from January 1, 2019 to June 30, 2019. PAMA presents significant uncertainty for future CMS reimbursement rates for Cologuard. Because Medicare currently covers approximately half of the patients in the current screening population for Cologuard, any reduction in the CMS reimbursement rate for Cologuard would negatively affect our revenues and our business prospects. There can be no assurance under PAMA that adequate CMS reimbursement rates will continue to be assigned to 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

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payable to us. Any such action could have a negative impact on our revenues.

Coverage of Cologuard and other 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 colorectal 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 Cologuard every three years without patient cost-sharing. While we believe the ACA Mandate requires most health insurers to cover Cologuard for most patients between the ages of 50 and 75, without patient cost-sharing some health insurers have disagreed and determined not to cover Cologuard 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. Not all of these laws apply to Cologuard, however. 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 Cologuard.

If third-party payers, including managed care organizations, do not approve and maintain reimbursement for our Cologuard test at adequate reimbursement rates, we may be unable to successfully commercialize our Cologuard test which, we expect, would limit or slow our revenue generation and likely have a material adverse effect on our business.

Successful commercialization of our Cologuard test 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. 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 whether Cologuard and any new test we may develop, will be eligible for coverage by third-party payers or, if eligible for coverage, what the reimbursement rates will be. Reimbursement of sDNA colorectal cancer screening by a third-party payer may depend on a number of factors, including a payer's determination that tests using our technologies are: sensitive and specific for colorectal cancer and pre-cancer; 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.

If we are unable to obtain positive decisions from third-party payers, including managed care organizations, approving reimbursement for our Cologuard test at adequate levels, its commercial success will be compromised and our revenues would be significantly limited. Healthcare providers may be reluctant to prescribe Cologuard if they believe that a significant number of their patients will not be reimbursed for the test.

We may also experience material delays in obtaining such reimbursement decisions and payment for our Cologuard test that are beyond our control. Further, there can be no assurance that CMS and commercial payers who initially decide to cover Cologuard will continue to do so. We are pursuing a variety of strategies to increase commercial payer coverage and reimbursement of Cologuard. In certain situations, where we believe payers are obligated to cover Cologuard under federal and state laws that mandate coverage for certain colorectal cancer screening tests, we have sued to enforce coverage obligations. We may pursue similar litigation or other tactics in the future. Such litigation and tactics may be costly, may divert management attention from other responsibilities, may cause payers, including those not directly involved in any litigation, to resist contracting with us, and may ultimately prove unsuccessful.

As noted above, federal and state coverage mandates may be deemed not to apply to Cologuard, may be interpreted in a manner unfavorable to us, may be difficult to enforce and are subject to repeal or modification. For example, the ACA may be repealed or materially modified, in whole or in part, or replaced with an alternative legal framework

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governing healthcare matter. Such repeal, modification or replacement may eliminate or modify the coverage mandate for preventive services, and any such elimination or modification may have an adverse effect on our business prospects.

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

Even where a third-party payer agrees to cover Cologuard, other factors may have a significant impact on the actual reimbursement we receive for a Cologuard test 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 Cologuard 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 Cologuard is out of network for a given payer, physicians may be less likely to prescribe Cologuard 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 Cologuard 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 physicians 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 physicians less likely to prescribe Cologuard for their patients, and may make patients less likely to comply with physician orders for Cologuard, all or any of which may have an adverse effect on our revenues.

If our clinical studies do not satisfy providers, payers, patients and others as to the reliability, effectiveness and superiority of our Cologuard test or any future test we may develop and seek to commercialize, we may experience reluctance or refusal on the part of physicians to order, and third-party payers to pay for, such test.

Although we have received FDA approval for our Cologuard test, if the results of our research and clinical studies and our sales and marketing activities relating to communication of these results, do not convince guidelines organizations, physicians and other healthcare providers, third-party payers and patients that our Cologuard test is reliable, effective and superior to alternative screening methods, we may experience reluctance or refusal on the part of physicians to order, and third-party payers to pay for, our Cologuard test, which could adversely affect our business prospects. Likewise, if the results of our research and clinical studies and our sales and marketing activities relating to new tests we may develop in the future do not convince FDA and other regulators, guidelines organizations, physicians and other healthcare providers, third-party payers and patients that other tests we may develop and seek to commercialize in the future are safe, effective, reliable and superior to alternative tests, those tests may not receive or sustain necessary regulatory approvals and we may experience reluctance or refusal on the part of physicians to order, and third-party payers to pay for, those tests, which could adversely affect our business prospects.

We have finite selling and marketing resources and only limited sales, marketing, customer support, manufacturing, distribution and commercial laboratory experience, which may restrict our success in commercializing Cologuard and other products we may develop, 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 Cologuard test. Also, in connection with the launch of Cologuard in late 2014, we began operating a CLIA certified lab facility to process Cologuard tests and provide patient results. We have limited experience managing a sales force, customer support operation and operating a manufacturing operation and clinical lab facility and 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. In August 2018, we entered into a Promotion Agreement with Pfizer, pursuant to which Pfizer agreed to promote Cologuard and provide certain sales, marketing, analytical and other commercial operations

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support services. The Promotion Agreement, and any other future partnership arrangement, may not perform as expected or the arrangements may otherwise prove to be detrimental to our short and long term results. For example, certain third party arrangements may cause us to forego or defer the development or acquisition of internal capabilities. If a third party arrangement fails to perform as expected or if it is terminated prematurely for any reason, our business may be harmed not only by such failure or termination itself, but also by the opportunity cost associated with not timely developing or acquiring necessary for useful capabilities internally.

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 test and our future products and services, we must continue to develop and grow our sales, marketing and medical affairs organizations and our sales, marketing and medical affairs organizations must effectively explain to healthcare providers the reliability, effectiveness and benefits of Cologuard and our 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 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 test or any future products or services.

The success of our Cologuard test and any other screening or diagnostic product or service we may develop will depend on the degree of market acceptance by physicians, patients, healthcare payers and others in the medical community.

Our Cologuard test and our future products and services may not gain market acceptance by physicians, healthcare payers and others in the medical community. The degree of market acceptance of our Cologuard test and our future products and services will depend on a number of factors, including:

- its demonstrated sensitivity and specificity;
- its price;
- the availability and attractiveness of alternative screening methods;
- the willingness of physicians to prescribe our products and services;
- the ease of use of our ordering process for physicians; and
- adequate third-party coverage or reimbursement.

Use of a stool-based DNA colorectal cancer screening test requires people to collect a stool sample, which some people may be reluctant to do. If our Cologuard test does not achieve an adequate level of acceptance, we may not generate the substantial revenues we need to generate to become profitable.

Our assumptions regarding the market opportunity for Cologuard may not prove true. We estimate the potential market opportunity for Cologuard 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 Cologuard and CMS has determined that Medicare will cover the test at this interval, the label for Cologuard does not specify a three-year interval and physicians, 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.

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Recommendations, guidelines and quality metrics issued by various organizations, including the U.S. Preventative Services Task Force, the American Cancer Society and the National Committee for Quality Assurance, may significantly affect payers' willingness to cover, and physicians' willingness to prescribe, our products.

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

The USPSTF, a panel of primary care physicians 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, the 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 Cologuard). USPSTF updates its screening recommendations periodically, approximately every five to eight years. USPSTF distributed a draft research plan for public comment on January 3, 2019. The research plan, once finalized, will be used to guide a systematic review of the evidence by researchers at an evidence-based practice center. The resulting evidence review will form the basis of the next update to the USPSTF recommendation statement regarding colorectal cancer screening. 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 continue to include FIT-DNA, whether updated recommendations may take a different format, including by ranking different methodologies and positioning FIT-DNA below other methodologies, or whether updated recommendations will include new technologies that are competitive with Cologuard and that may have greater appeal to physicians, 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.

The 2016 USPSTF recommendation statement 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 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 Cologuard every three years without patient cost-sharing. While we believe the ACA Mandate requires certain health insurers to cover Cologuard 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 Cologuard 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 been the subject of various legal challenges and in December 2018, a federal district court in Texas held that the ACA is unconstitutional and unenforceable. The court's decision is subject to appeal, but if this case, or any other case challenging the ACA is ultimately successful, insurance coverage for Cologuard 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 Cologuard, 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 Cologuard, our business prospects may be adversely affected.

In addition, 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 National Committee for Quality Assurance ("NCQA"), Healthcare Effectiveness Data and Information Set ("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. In October 2016, the NCQA included Cologuard testing on a three-year interval in the final published 2017 HEDIS measures. In April 2017, CMS released final details for the 2018 Medicare Advantage Star Ratings program and included Cologuard. If for some reason Cologuard was removed from, or not included in, HEDIS, the Star Ratings or other quality metrics, payers may be less inclined to

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reimburse our Cologuard test at adequate levels, if at all, which could adversely impact our business. Additionally, if Cologuard was removed from, or not included in, HEDIS, the Star Ratings or other quality metrics, physicians may not earn quality credit for prescribing Cologuard and therefore may be less inclined to do so. If Cologuard fails to maintain its current position within any updated USPSTF colorectal cancer screening recommendations, Cologuard 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 screening and diagnostic tools, which may not be successful.

In addition to commercializing our Cologuard test, we are seeking to increase Cologuard's specificity by substituting new biomarkers and to develop a pipeline for future products and services, including screening and diagnostic tests for liver, 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 screening or diagnostic tools 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. 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.

We may need to explore a number of different marker 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.

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, which could adversely affect our ability to develop and commercialize our products and services.

The development and commercialization of our products and services rely, directly or indirectly, upon strategic collaborations and licensing agreements with third parties. We currently have a collaborative and licensing arrangement with Mayo Foundation for Medical Education and Research. In addition, we have licensing agreements with Hologic and others. Such arrangements provide us with intellectual property crucial to our product development and commercialization, including technology that we have incorporated into our Cologuard test. 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.

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

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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. Even if we successfully establish new collaborations, these relationships may never result in the successful commercialization of any product or service.

We have entered into a Promotion Agreement with Pfizer regarding the commercialization of Cologuard. If we or Pfizer fail to adequately perform under the Promotion Agreement, or if the Promotion Agreement is terminated prior to its full term, our business, prospects, financial condition and results of operation could be adversely affected.

In August 2018 we entered into a Promotion Agreement ("Promotion Agreement") with Pfizer, Inc. ("Pfizer"), pursuant to which Pfizer will promote Cologuard 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 Cologuard. We agreed to pay Pfizer a service fee based on incremental gross profits over specified baselines and pay Pfizer royalties for Cologuard-related revenues for a specified period after the expiration or termination of the Promotion Agreement.

The initial term of the Promotion Agreement is scheduled to run through December 31, 2021, but may be terminated by either party at any time on or after February 21, 2020 upon six months' written notice to the other party.

We have dedicated significant time and resources to negotiating and implementing our Promotion Agreement. The growth in Cologuard 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 Cologuard or otherwise fails to perform under the Promotion Agreement, if Pfizer prioritizes the promotion of its own, or other partners', products or services over Cologuard, 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 Cologuard (for example, reimbursement, competition, or seasonal factors). Our relationship with Pfizer is new, 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 Cologuard 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 Cologuard or for any other reason, our business, prospects, financial condition and results of operation may be adversely affected.

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 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 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.

We must maintain FDA approval for Cologuard and compliance with applicable FDA requirements; failure to maintain compliance with FDA requirements may prevent or delay the development, marketing or manufacturing of our Cologuard test.

As a condition of the FDA approval of our Cologuard test, we are required to conduct a post-approval study. We anticipate that the post-approval study will require significant funding and resources to reach its conclusion. There is a

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risk that the FDA may modify or withdraw the approval of Cologuard if the results of this post-approval study are not satisfactory or are inconsistent with previous studies. We rely on third parties, such as contract research organizations, medical institutions and clinical investigators to conduct the post-approval study. We have limited control over the activities of these third parties and the post-approval study may be delayed or halted prior to its completion for reasons outside our control.

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.

Our inability to obtain without delay any necessary 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 diagnostic test candidates 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. 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 or service 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 and services 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.

In the future, we may develop tests that could be regulated as LDTs. If the FDA begins to actively regulate LDTs, we may need to obtain additional FDA or other regulatory approvals, which may prevent, delay, or adversely impact our

commercialization of these diagnostic tests.

We may develop products or services that would be regulated as LDTs under CLIA. LDTs are clinical laboratory tests that are developed, validated and manufactured 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 most LDTs performed by CLIA-certified laboratories. The FDA has historically chosen not to exercise its authority to regulate LDTs because LDTs were limited in number, were relatively simple tests, and typically were used to diagnose rare disease and uncommon conditions.

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In October 2014, the FDA published two draft guidance documents describing a proposed risk-based framework under which it 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 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. We cannot predict the timing, content or form of any legislation, regulation or guidance, or the potential effect on our existing molecular diagnostic tests or our tests in development, or the potential impact of such guidance or regulation on our business, financial condition or results of operation.

Our business could be materially affected if the FDA begins to actively regulate LDTs. We may be required to change business plans regarding the development and commercialization of new diagnostic tests. New laws and regulations may significantly slow the time it would take us to bring LDTs to market, may materially increase the costs of developing, and decrease the profitability of providing, LDTs, and may prevent us from commercializing certain products or services. We cannot provide any assurance that FDA clearance or approval will not be required in the future for any of our tests, whether as a result of additional guidance or regulations issued by the FDA, new enforcement policies adopted by the FDA or new legislation adopted by Congress. It is possible that legislation will be enacted into law, regulations could be promulgated or guidance could be issued by the FDA that may result in increased regulatory burdens for us to continue to offer molecular diagnostic tests or to develop and introduce new tests. Moreover, if pre-market review is required by the FDA or if we decide to voluntarily pursue the FDA's pre-market review for any of our tests, there can be no assurance that they will be cleared or approved on a timely basis, if at all, nor can there be assurance that labeling claims will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our tests. If pre-market review is required, our business could be negatively impacted as a result of commercial delay that may be caused by any new requirements.

We currently manufacture our Cologuard test predominantly in one facility and perform our Cologuard test in one laboratory facility. If demand for our Cologuard test grows, we may lack adequate facility space and capabilities to meet increased processing requirements. Moreover, if these or any future facilities or our 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 a single laboratory facility 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 Cologuard and increase the number of tests processed by our laboratory facility, we believe it will be necessary to both expand our existing laboratory facility 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 existing laboratory facility to approximately three million tests per year. Also, during the fourth quarter of 2017, we purchased real property in Madison, Wisconsin and began construction of a new clinical laboratory facility. The new laboratory facility is expected to increase our annual capacity by approximately four million tests per year. Construction of the new facility is expected to be completed near mid 2019. We are also in the process of building an additional manufacturing facility and additional warehouse and office space on the recently-acquired real property, which are expected to be completed in 2019. Manufacturing in the new facility is expected commence during 2020. We have also contracted with a third party regarding the construction and lease of a new headquarters facility in Madison, Wisconsin, which is expected to be completed in the first quarter of 2020. Failure to complete, or timely complete, these expansion projects, may significantly delay our Cologuard processing times and capabilities, or other operations, which may adversely affect our business, financial

condition and results of operation. In addition, our financial condition may be adversely affected if we are unable to complete these expansion projects on budget and otherwise on terms and conditions acceptable to us. 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.

If our present, or any future facilities, were to be damaged, destroyed or otherwise unable to operate, whether due to fire, floods, storms, tornadoes, other inclement weather events or natural disasters, employee malfeasance, terrorist

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acts, power outages, or otherwise, our business could be severely disrupted. If our present and/or future Madison, Wisconsin, manufacturing facility or laboratory is disrupted, we may not be able to produce or perform our Cologuard test or generate test reports as promptly as patients and healthcare providers require or expect, or possibly not at all. If we are unable to perform our Cologuard test or generate test reports within a timeframe that meets patient and healthcare provider expectations, our business, financial results and reputation could be materially harmed.

We currently maintain insurance against damage to our property and equipment and against business interruption, subject to deductibles and other limitations. If we have underestimated our insurance needs with respect to an interruption, or if an interruption is not subject to coverage under our insurance policies, we may not be able to cover our losses.

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 Cologuard test, 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 Cologuard test or future products or services. Moreover, we may become dependent on other single-source suppliers as we expand and develop our product 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, which could adversely impact our revenues, as well as our research, development and commercialization 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 laboratory, and our research and development efforts. We are substantially dependent on our IT systems to receive and process Cologuard test orders, securely store patient health records and deliver the results of our Cologuard 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 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. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our IT systems, sustained or repeated system failures that interrupt our ability to generate and maintain data, and in particular to operate our clinical laboratory, could adversely affect our ability to operate our business. Any interruption in the operation of IT systems could have an adverse effect on our operations. Furthermore, any breach in our IT systems could lead to the unauthorized access, disclosure and use of non-public information, including protected health information, which is protected by HIPAA and other laws. 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, and damage to our reputation.

System upgrades and enhancements require significant expenditures and allocation of valuable employee resources. We are currently in the process of upgrading our systems with SAP SE. Additionally we continuously upgrade our

customer facing software applications. On November 12, 2018, we entered into an agreement with Epic Systems Corporation (“Epic”) pursuant to which we will use Epic’s software to handle multiple components of our information technology system, from order entry all the way through revenue cycle and customer care. Delays in integration or disruptions to our business from implementation of these 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

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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 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 facility for analysis, by 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 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.

Due to billing complexities in the diagnostic and laboratory service industry, we may not be able to collect payment for the Cologuard 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 Cologuard tests. If we are unsuccessful, we may not receive payment for Cologuard 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 colorectal cancer screening 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 Cologuard 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 Cologuard 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 Cologuard could be adversely affected. To the extent patients express dissatisfaction with our billing practices to their physicians, those physicians may be less likely to prescribe Cologuard for other patients, and our business would be adversely affected.

Even if payers do agree to cover Cologuard, 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 physicians to provide complete and correct billing information.

Sometimes, when we have a contract with a commercial payer to cover Cologuard, 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 Cologuard 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 Cologuard test and complex laboratory billing processes could negatively affect our business and our operating results.

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We may be subject to substantial costs and liability, or be prevented from using technologies incorporated in our Cologuard test, 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 colorectal cancer and pre-cancer 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. 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 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 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 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 you 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. To the extent third parties are

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able to develop or commercialize competing products and services that do not infringe our patents, our business will be adversely impacted.

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.

Our business is subject to various complex laws and regulations. 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 and local laws and regulations governing various aspects of our business. In particular, the clinical laboratory industry is subject to significant governmental certification and licensing regulations, as well as federal and state laws regarding:

- test ordering and billing practices;
- marketing, sales and pricing practices;
- health information privacy and security, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and comparable state laws;
- insurance;
- 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. 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.

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 Cologuard test 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.

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 physicians, 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 physicians or others either to refer patients or

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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, physicians, 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. 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.

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 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

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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.

While we believe we currently have adequate internal control over financial reporting, 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 in our financial reports 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 or not 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. 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.

The success of our business is substantially dependent upon the efforts of our senior management team.

Our success depends largely on the skills, experience and performance of key members of our senior management team including Kevin Conroy, our Chairman, President and Chief Executive Officer, Mark Stenhouse, our President of Cologuard, Scott Coward, our Senior Vice President, General Counsel and Chief Administrative Officer, Scott Johnson, our Senior Vice President of Research & Development, and Jeff Elliott, our Chief Financial Officer. These 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. While our management team has experience in developing and securing FDA approvals for diagnostic products, we have considerably less experience in commercializing products or services. The efforts of our management team will be critical to us as we develop our technologies and seek to commercialize our Cologuard test and other products and services.

Our success depends on our ability to retain our managerial personnel and to attract additional personnel.

Our success depends in large part on our ability to attract and retain managerial personnel. 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. The failure to maintain management or to attract sales and marketing personnel as we commercialize our Cologuard test could materially adversely affect our business, financial condition and 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.

As of December 31, 2018, we had $1.1 billion in combined cash and marketable securities. Our management currently expects to deploy these resources primarily to expand our Cologuard operation and commercialization activities, to fund our product development efforts and for general corporate and working capital purposes. However, our management has broad discretion to pursue other objectives and we may use these funds for other purposes. Our management might not effectively deploy our cash and marketable securities which could have an adverse effect on our business.

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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 Cologuard test.

Inherent risks are involved in providing and marketing cancer screening and diagnostic tests, such as our Cologuard test, 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 Cologuard test 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. Performance defects, incomplete or improper process controls, excessively slow turnaround times, unanticipated uses of Cologuard or mishandling of stool samples or Cologuard 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 Cologuard or our laboratory facility and could result in the removal of Cologuard from the market or the suspension of our laboratory's 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 Cologuard and payers' willingness to cover our Cologuard test. 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 Cologuard test could lead to product or professional liability claims. Such 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.

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 do not have the ability to independently conduct the clinical or other studies that will be required to obtain FDA or other regulatory approvals or clearances for future products we may develop or the approval of foreign regulatory bodies that may be required for such future products or for our Cologuard test to the extent we seek to market products internationally. Accordingly, we expect to rely on third parties such as contract research organizations, medical institutions and clinical investigators to conduct any such studies, including the post-approval study 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.

Our inability to manage growth could harm our business.

In connection with the commercialization of our Cologuard test, we have added, and expect to continue to add, additional 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 736, as of December 31, 2016, to 1,268, as of December 31, 2017, and to 1,977, as of December 31, 2018. 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 Cologuard test, we will also need to effectively manage our growing

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manufacturing, laboratory operations and sales and marketing needs. We are presently seeking to add facilities to support anticipated demand for our Cologuard test and anticipated associated growth in our personnel. We are expanding the capacity of our existing clinical laboratory, and have started construction of a second clinical laboratory, both in Madison, Wisconsin. We have begun construction on new manufacturing, warehouse and office facilities. 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.

International operations could subject us to risks and expenses that could adversely impact our business and results of operations.

To date, we have not undertaken substantial commercial activities outside the United States. We have evaluated the commercialization of Cologuard in several European, Middle Eastern and Asian countries. After undertaking preliminary preparatory activities, we determined to cease those efforts and we do not have present plans to expand Cologuard internationally. If we seek to expand Cologuard internationally, or launch other products or services internationally, in the future, those efforts would expose us to risks from the failure to comply with foreign laws and regulations that differ from those under which we operate in the U.S., as well as U.S. rules and regulations that govern foreign activities such as the U.S. Foreign Corrupt Practices Act. In addition, we could be adversely affected by other risks associated with operating in foreign countries. Economic uncertainty in some of the geographic regions in which we might operate, including developing regions, could result in the disruption of commerce and negatively impact cash flows from our operations in those areas. Also, if we choose to pursue international expansion efforts, it may be necessary or desirable to contract with third parties, such as laboratories, distributors or others. We may not be able to enter into such agreements on commercially acceptable terms, or at all, such arrangements may not perform to our expectations, we may be exposed to various risks as a result of the activities of our partners, and we may be exposed to contractual or other liabilities to our partners if the arrangements prove non beneficial for them or if we seek to terminate them early.

These and other factors may have a material adverse effect on any international operations we may seek to undertake and, consequently, on our financial condition and results of operations.

Delaware law, our charter 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 $690 million and $218.5 million of convertible notes we issued in January 2018 and June 2018, respectively, 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

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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. 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.

We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders and reduce our financial resources.

We have recently undertaken certain acquisition activities. In 2018, we acquired the stock of Biomatrica, Inc. We could incur losses resulting from yet undiscovered liabilities of these acquired business that are not covered by any indemnification or other contractual remedies. In addition, we may not be able to successfully integrate these businesses into our existing operations in an effective, timely and non disruptive manner.

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 small 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. 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 could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by any indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and non-disruptive manner. Acquisitions may also divert management from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results.

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

As of December 31, 2018, we had federal and state net operating loss carryforwards ("NOLs") of approximately $937.4 million and $403.5 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.

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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 $82.85 and a low of $37.36 in the twelve-month period ended December 31, 2018. 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. 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 retain any earnings 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 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 we incurred $908.5 million of indebtedness, and we have a construction loan outstanding of $24.3 million as of December 31, 2018. 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

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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 $908.5 million aggregate principal amount of 1.0% convertible senior notes due 2025 depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to 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 on terms that may be onerous or 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, 2018, we occupied approximately 437,000 square feet of space at our significant facilities in the Madison, Wisconsin area, a 10,000 square foot facility in San Diego California, a 6,000 square foot facility in Ann Arbor, Michigan, and a 5,000 square foot facility in Salt Lake City, Utah. See Note 7 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, 2018, our facilities are as follows:

Location	Primary Function	Total Square Feet (approx.)	Leased or Owned
Madison, Wisconsin	Research and development	48,000	Leased
Madison, Wisconsin	Corporate offices	160,000	Owned
Madison, Wisconsin	Operations	35,000	Leased
Madison, Wisconsin	Operations	66,000	Leased
Madison, Wisconsin	Clinical laboratory	55,000	Leased
Madison, Wisconsin	Corporate offices	45,000	Leased
Salt Lake City, Utah	Corporate offices	5,000	Leased
San Diego, California	Corporate offices	10,000	Leased

Ann Arbor, Michigan	Research and development	6,000	Leased
Madison, Wisconsin	Corporate offices	2,000	Leased
Middleton, Wisconsin	Corporate offices	26,000	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. We are not currently a party to any pending litigation that we believe is likely to have a material adverse effect on our business operations or financial condition.

Item 4. Mine Safety Disclosures

Not applicable.

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PART II

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

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

As of February 20, 2019, there were 125,760,907 shares of our common stock outstanding held by approximately 85 holders of record.

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

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Item 6. Selected Financial Data

The selected historical financial data for the five years ended December 31, 2018 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,				
	2018	2017	2016	2015	2014
	(Amounts in thousands, except per share data)				
Statements of Operations Data:					
Revenue:	$ 454,462	$ 265,989	$ 99,376	$ 39,437	$ 1,798
Cost of sales(1)	117,982	79,196	45,195	24,501	4,325
Gross margin	336,480	186,793	54,181	14,936	(2,527)
Operating expenses:					
Research and development(1)	68,210	42,139	33,473	33,914	28,669
General and administrative(1)	178,293	109,040	76,898	57,950	30,435
Sales and marketing(1)	249,448	153,924	112,826	82,140	38,908
	495,951	305,103	223,197	174,004	98,012
Loss from operations	(159,471)	(118,310)	(169,016)	(159,068)	(100,539)
Investment income	21,203	3,932	2,018	1,271	542
Interest expense	(36,789)	(206)	(213)	(6)	(51)
Net loss before tax	(175,057)	(114,584)	(167,211)	(157,803)	(100,048)
Income tax benefit (expense)	(92)	187	—	—	—
Net loss	$ (175,149)	$ (114,397)	$ (167,211)	$ (157,803)	$ (100,048)
Net loss per share:					
Basic and diluted	$ (1.43)	$ (0.99)	$ (1.63)	$ (1.71)	$ (1.25)
Weighted average common shares outstanding:					
Basic and diluted	122,207	115,684	102,335	92,135	80,232
Balance Sheet Data:					
Cash and cash equivalents	$ 160,430	$ 77,491	$ 48,921	$ 41,135	$ 58,131
Marketable securities	963,752	347,224	262,179	265,744	224,625
Total assets	1,524,022	598,560	377,040	364,030	312,824
Convertible notes, net	664,749	—	—	—	—
Long-term debt	24,073	4,269	4,633	4,789	1,000
Other long-term liabilities	9,475	5,633	5,734	4,601	3,599
Total liabilities	843,081	78,142	41,745	37,174	23,840
Stockholders' equity	680,941	520,418	335,295	326,856	288,984

(1) Non cash stock based compensation expense included in these amounts are as follows:

	2018	2017	2016	2015	2014
Cost of sales	$ 3,531	$ 1,783	$ 1,064	$ 876	$ 279
Research and development	10,189	6,836	4,014	3,744	4,149
General and administrative	34,181	20,221	14,597	9,358	5,575

Sales and marketing	12,363	6,672	4,057	4,072	1,517

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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.

Overview

Exact Sciences Corporation (together with its subsidiaries, "Exact," "we," "us," "our" or the "Company") is a molecular diagnostics company focused on the early detection and prevention of some of the deadliest forms of cancer. We have developed an accurate, non-invasive, patient-friendly screening test called Cologuard® for the early detection of colorectal cancer and pre-cancer, and we are currently working on the development of additional tests for other types of cancer, with the goal of becoming a leader in cancer screening and diagnostics.

Our Cologuard Test

Colorectal cancer is the second leading cause of cancer deaths in the U.S. and the leading cause of cancer deaths in the U.S. among non-smokers. Each year in the U.S. there are approximately:

- 146,000 new cases of colorectal cancer
- 51,000 deaths from colorectal cancer

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. Of the more than 85 million people between the ages of 50 and 85, who are at average-risk for colorectal cancer in the U.S., 38 percent have not been screened according to current guidelines. Internal studies have shown that approximately 50% of Cologuard users were previously unscreened for colorectal cancer. Poor compliance with screening guidelines has meant that nearly two-thirds of colorectal cancer diagnoses are made in the disease's late stages. The five-year survival rates for stages 3 and 4 are 70 percent and 13 percent, respectively. We believe the large underserved population of unscreened and inadequately screened patients represents a significant opportunity for a patient-friendly screening test.

Our Cologuard test is a non-invasive 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.

Changes in DNA methylation, and the occurrence of mutations, alter gene expression and other mechanisms for cell cycle regulation and differentiation. As a result, the affected cells continue to proliferate, often resulting in malignancies associated with colorectal cancer and pre-cancer. Hemoglobin is the protein complex responsible for

transporting oxygen in red blood cells. During the progression of cancer, the probability of bleeding into the colon increases. The presence of hemoglobin, released from red blood cells, can be detected in the stool. Using sDNA Cologuard purifies, amplifies and detects increased levels of methylation, and presence of mutations, in specific genes. By combining these DNA indicators with a test for hemoglobin, Cologuard produces a multi-marker result effective for the detection of colorectal cancer and pre-cancerous adenomas.

In August 2014, the FDA granted PMA to Cologuard for use as a colorectal cancer screening test in adults 50 years of age and older who are at a typical average-risk for colorectal cancer. Upon approval, Cologuard became the first and only FDA-approved sDNA non-invasive colorectal cancer screening test. Our original PMA submission to the FDA for Cologuard included the results of our pivotal DeeP-C clinical trial that had over 10,000 patients enrolled at 90 sites in the U.S. and Canada. The results of our DeeP-C clinical trial for Cologuard were published in the New England Journal of Medicine in April 2014. The peer-reviewed study, “Multi-target Stool DNA Testing for Colorectal-Cancer Screening,” highlighted the performance of Cologuard in the trial population:

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

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

We believe the competitive advantages of sDNA screening may provide a significant market opportunity. There are 85 million people in the U.S. between the ages of 50-85 who are at average risk for colorectal cancer. At a three-year screening interval and an average revenue per test of $500 this represents a potential $14 billion market for Cologuard, of which our current share is approximately four percent.

We are also seeking to develop a pipeline of potential future products and services with a focus on liquid biopsy tests.

Our Clinical Laboratory and Manufacturing Facilities

As part of our commercialization strategy, we established a state-of-the-art, highly automated lab facility that is certified pursuant to federal CLIA requirements to process Cologuard tests and provide patient results. Our commercial lab operation is housed in a 55,000 square foot facility in Madison, Wisconsin. At our lab, we currently have the capacity to process approximately three million tests per year.

During the fourth quarter of 2017 we began construction of a new clinical lab facility in Madison, Wisconsin that is expected to be completed mid-2019. After the new clinical laboratory is operational, we expect our total lab capacity at both facilities will be approximately seven million tests per year by the end of 2019.

We currently manufacture the Cologuard test in a facility in Madison, Wisconsin. As we expand the commercialization of Cologuard, we believe it will be necessary to expand our manufacturing capacity. Accordingly, we are in the process of building an additional manufacturing facility which we expect to complete in 2019. 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.

How We Recognize Revenue

We recognize revenue on the delivery of a test result to an ordering healthcare provider for tests performed where based on our estimate of the amount that we will ultimately collect at the time delivery is complete. 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 on a per-payer or per-agreement basis, 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, the existence of secondary payers and claim denials. 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 recognize revenue from claims on an accrual basis and later determine the judgments underlying estimated collections change, our financial results could be negatively impacted in future quarters. Historically, a portion of our revenue was recognized upon cash receipt, because we were unable to reasonably estimate the amount that would ultimately be collected from certain payers. Effective during the first quarter of 2017, we determined that we had the ability to reasonably estimate the amount that will ultimately be collected from all payers, including the impact of patient cost-share collections. Accordingly, as noted above, we now recognize revenue for all billed claims at the time the test results are delivered to the customer.

Our average reimbursement per test, as further defined below, was approximately $476 and $438 through December 31, 2018 and 2017, respectively. This cumulative average Cologuard reimbursement rate will change over time due to a number of factors, such as medical coverage decisions by payers, changes in the payer mix, the effects of contracts signed with payers, non-renewal or termination of payer contracts, changes in allowed amounts by payers, our ability to successfully win appeals for payment, settlements reached with payers regarding previously denied claims and our ability to collect cash payments from payers and individual patients. Historical average reimbursement is not necessarily indicative of future average reimbursement.

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We calculate the average Cologuard reimbursement per test on a trailing twelve-month basis for all tests that are at least six months old, since it can take that long, or in some cases longer, to collect from some payers and patients. Thus, the average reimbursement per test at December 31, 2018 and December 31, 2017, respectively, represents the total cash collected through such dates for tests performed during the twelve-month periods ended June 30, 2018 and June 30, 2017, respectively, divided by the number of tests performed during those same periods.

Acquisitions

In October 2018, we completed the acquisition of Biomatrica, a privately held company specializing in the collection and preservation of biological materials. In the acquisition, we acquired all of the outstanding equity interests for an aggregate purchase price of $20.0 million net of cash received, debt repaid and certain other adjustments. Contingent consideration for an additional $20.0 million could be earned based upon certain revenue milestones being met.

2019 Priorities

Our top priorities for 2019 are to (1) power our partnership with Pfizer, (2) enhance Cologuard through label expansion and product improvements, and (3) advance liquid biopsy.

Power the Partnership

In August 2018, we entered into a Promotion Agreement with Pfizer. Under the terms of the Promotion Agreement, Pfizer agreed to promote Cologuard and provide certain other sales and marketing services. We and Pfizer committed in the Promotion Agreement to invest specified amounts in the advertising and promotion of Cologuard. Pfizer has a large primary care sales team that has extensive experience with large health system organizations and enhances our physician and consumer marketing capabilities. A priority for 2019 is executing on the Pfizer partnership in order to grow the Cologuard brand and get more patients screened with Cologuard.

Enhance Cologuard

In May 2018, the ACS updated its guidelines to recommend colorectal cancer screening beginning at age 45, rather than 50, for people at average risk of the disease due to the rising incidence rate within the 45-49 year-old population. There are nearly 21 million people who are between the ages of 45-49, and we estimate approximately 19 million of them are at average risk for colorectal cancer and would be eligible for screening under the ACS guidelines. We plan to conduct clinical and other necessary work to gain FDA approval to expand Cologuard's indication to people between the ages of 45 and 49 who are at average risk for colorectal cancer.

In addition, we are seeking opportunities to improve upon Cologuard's performance characteristics. For example, we are evaluating whether new biomarkers would increase specificity while maintaining sensitivity. If we could increase the specificity of Cologuard, we believe that would enhance its adoption as a front-line screening test. We are also evaluating ways that we might make Cologuard even easier for patients to use and opportunities for lowering the cost of providing Cologuard.

The timing of any expansion of Cologuard's indication or of any such enhancements to Cologuard is unknown and would be subject to FDA approval.

Advance Liquid Biopsy

We also are focusing our research and development efforts on building a pipeline of potential future products and services with a focus on liquid biopsy tests. We will continue to advance liquid biopsy through biomarker discovery and validation in tissue and blood. We have identified proprietary biomarkers for several cancers, including liver cancer and lung cancer. We have successfully performed validation studies on tissue samples for thirteen cancers and on blood samples for eight cancers.

The ACS estimates that liver cancer will be diagnosed in 42,000 Americans and cause 32,000 deaths in 2019, three-fourths of which will be hepatocellular carcinoma ("HCC"). Incidence and mortality rates are both increasing at approximately 3 percent per year. People who have been diagnosed with cirrhosis of the liver or Hepatitis B are at high

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risk of developing HCC. Evidence shows that HCC testing in these high-risk groups leads to earlier detection and improved outcomes. The NCCN and American Association for the Study of Liver Diseases ("AASLD") guidelines recommend that these two groups be tested for HCC every six months using ultrasound and the blood-based biomarker alpha-fetoprotein ("AFP"). However, ultrasound and AFP are documented to have poor sensitivity for early stage cancer, which is the primary target of testing. We are currently seeking to develop a blood-based biomarker test to serve as an alternative to ultrasound and AFP for use in HCC testing, and our goal is to develop a patient-friendly test that performs better than this current standard of care. We are currently enrolling a case control study of at least 1,500 patients to finalize the development of our liver cancer test.

The ACS estimates that, in the U.S. in 2019, lung cancer will be diagnosed in 228,000 people and cause 143,000 deaths. Currently, more than half of lung cancer cases are diagnosed at an advanced stage, after symptoms appear, when the five-year survival rate is in the low single digits. We are currently seeking to develop a blood-based biomarker test to aid in the early detection of lung cancer in individuals with lung nodules discovered through a CT or other scan. Such a test may help reduce the number of follow-up procedures, and thereby reduce costs and improve health outcomes.

Results of Operations

Our top priorities for 2018 were to (1) continue to strengthen our core Cologuard business by increasing the size of our nationwide sale force, (2) prepare for future demand including by continuing to invest in people, processes, technology and systems to build capacity, and (3) expand our product pipeline by developing additional cancer screening and diagnostic tests.

During 2018, we completed approximately 934,000 Cologuard tests, and generated $454.5 million of revenue compared to 2017 when we completed 571,000 tests and generated $266.0 million of revenue. We believe that the increase in revenues and tests completed from the prior year was primarily driven by sales force execution, our patient advertising campaign, and the increase in commercial coverage for Cologuard. As of December 31, 2018, nearly 147,000 health care providers have ordered Cologuard compared to nearly 102,000 health care providers as of December 31, 2017. In August 2018, we entered into a Promotion Agreement with Pfizer, Inc. Pfizer is promoting Cologuard to both physicians and health systems and will also actively participate in extending and deepening the Cologuard marketing campaign.

During 2018, we made investments in our technical systems, manufacturing capabilities, customer care center, and our sales force in order to enhance our infrastructure and position our operations and processes for continued growth. Additionally, we continued to focus on cost containment throughout the business which, along with the increase in test volume, helped drive improvements in our gross margin from 70 percent for 2017 to 74 percent for 2018.

In 2018, we continued to invest in research and development and focused on the development of additional cancer diagnostic tests as outlined in the "Advance Liquid Biopsy" section above.

In order to support the commercialization of Cologuard and to achieve our goals for 2018, our selling, general, and administrative costs increased by $164.8 million during the year. In addition, our efforts in 2018 to develop our pipeline products and improvements to Cologuard led to an increase in research and development costs of

$26.1 million during the year. We ensured that we were well capitalized to meet our future goals by raising $671.1 million and $225.3 million, net of issuance costs, through an underwritten public offering of convertible notes completed in January 2018 and June 2018, respectively, and finished the year with $1.1 billion in cash, cash equivalents, and marketable securities.

Comparison of the years ended December 31, 2018 and 2017

Revenue. Our revenue is primarily generated by performing screening services using our Cologuard test. For the years ended December 31, 2018 and 2017, we completed approximately 934,000 and 571,000 Cologuard tests, respectively, and generated revenue of $454.5 million and $266.0 million, respectively. The increase in revenue was primarily due to an increase in completed Cologuard tests and an increase in average revenue recognized per test during the current period due to increased commercial insurance coverage for our Cologuard test.

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.

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Cost of sales includes costs related to inventory production and usage, shipment of test collection kits, royalties and the cost of services to process tests and provide results to physicians. We incur expenses for tests in the period in which the activities occur, therefore, gross margin as a percentage of revenue may vary due to costs being incurred in one period that relate to revenues recognized in a later period.

We expect that gross margin for our services will continue to fluctuate and be affected by Cologuard test volume, our operating efficiencies, patient compliance rates, payer mix, the levels of reimbursement, and payment patterns of payers and patients.

Cost of sales. Cost of sales increased to $118.0 million for the year ended December 31, 2018 from $79.2 million for the year ended December 31, 2017. The increase in cost of sales is primarily due to the increases in completed Cologuard tests. The Company completed approximately 934,000 and 571,000 Cologuard tests for the years ended December 31, 2018 and 2017, respectively.

Amounts in millions	2018	2017	Change
Production costs	$ 82.8	$ 57.3	$ 25.5
Facility and support services	11.1	8.3	2.8
Personnel expenses	20.3	11.6	8.7
Stock-based compensation	3.5	1.8	1.7
Other cost of sales expenses	0.3	0.2	0.1
Total cost of sales expense	$ 118.0	$ 79.2	$ 38.8

Research and development expenses. Research and development expenses increased to $68.2 million for the year ended December 31, 2018 compared to $42.1 million for the year ended December 31, 2017. The increase in research and development expenses was primarily due to an increase in direct research and development expenses for our pipeline as well as personnel costs due to increased headcount.

Amounts in millions	2018	2017	Change
Personnel expenses	$ 19.3	$ 13.9	$ 5.4
Direct research and development expenses	28.3	16.8	11.5
Professional and legal fees	5.3	2.1	3.2
Stock-based compensation	10.2	6.8	3.4
Other research and development expenses	5.1	2.5	2.6
Total research and development expenses	$ 68.2	$ 42.1	$ 26.1

General and administrative expenses. General and administrative expenses increased to $178.3 million for the year ended December 31, 2018 compared to $109.0 million for the year ended December 31, 2017. The increase in general and administrative expenses was primarily a result of increased costs in the areas outlined in the table below to support the overall growth of the Company.

Amounts in millions	2018	2017	Change
Personnel expenses	$ 67.8	$ 42.7	$ 25.1
Facility and support services	37.8	21.1	16.7
Stock-based compensation	34.2	20.2	14.0
Professional and legal fees	30.9	20.1	10.8
Other general and administrative	7.6	4.9	2.7
Total general and administrative expenses	$ 178.3	$ 109.0	$ 69.3

Sales and marketing expenses. Sales and marketing expenses increased to $249.4 million for the year ended December 31, 2018 compared to $153.9 million for the year ended December 31, 2017. The increase in sales and marketing expenses was a result of hiring additional sales and marketing personnel and increasing our advertising and

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patient marketing efforts as part of the ongoing commercialization of our Cologuard test.

Amounts in millions	2018	2017	Change
Personnel expenses	$ 105.6	$ 70.4	$ 35.2
Direct marketing costs and professional fees	127.7	75.4	52.3
Stock-based compensation	12.4	6.7	5.7
Other sales and marketing expenses	3.7	1.4	2.3
Total sales and marketing expenses	$ 249.4	$ 153.9	$ 95.5

Investment income. Investment income increased to $21.2 million for the year ended December 31, 2018 compared to $3.9 million for the year ended December 31, 2017. This increase in investment income was due to an increase in the average cash and marketable securities balance and an increase in the average rate of return on investments due to an increase in market interest rates for the year ended December 31, 2018 when compared to the same period in 2017.

Interest expense. Net interest expense increased to $36.8 million for the year ended December 31, 2018 compared to $0.2 million for the year ended December 31, 2017. We issued $690.0 million and $218.5 million of convertible debt in January 2018 and June 2018, respectively, which collectively resulted in $36.4 million in interest expense during the year ended December 31, 2018. $28.6 million of interest expense relates to amortization of debt discount and debt issuance costs for the year ended December 31, 2018. The remaining $7.8 million of interest expense for the year ended December 31, 2018 relates to the stated interest that was paid in cash during the year. There was minimal interest expense for the year ended December 31, 2018 related to the mortgage on one of our facilities in Madison, Wisconsin that was entered into in June 2015. The interest expense for the year ended December 31, 2017 is related solely to the mortgage on one of our facilities in Madison, Wisconsin that was entered into in June 2015.

Comparison of the years ended December 31, 2017 and 2016

Revenue. Our revenue is generated by performing screening services using our Cologuard test. For the years ended December 31, 2017 and 2016, the Company completed approximately 571,000 and 244,000 Cologuard tests, respectively, and generated revenue of $266.0 million and $99.4 million, respectively. The increase in revenue was primarily due to an increase in completed Cologuard tests during the period.

Cost of sales. Cost of sales increased to $79.2 million for the year ended December 31, 2017 from $45.2 million for the year ended December 31, 2016. The increase in cost of sales is primarily due to the increase in completed Cologuard tests. The company completed approximately 571,000 and 244,000 Cologuard tests for the years ended December 31, 2017 and 2016, respectively.

Amounts in millions	2017	2016	Change
Production costs	$ 57.3	$ 30.0	$ 27.3
Personnel expenses	11.6	6.8	4.8
Facility and support services	8.3	7.2	1.1
Stock-based compensation	1.8	1.1	0.7
Other cost of sales expenses	0.2	0.1	0.1

Total cost of sales expenses	$ 79.2	$ 45.2	$ 34.0

Research and development expenses. Research and development expenses increased to $42.1 million for the year ended December 31, 2017 from $33.5 million for the year ended December 31, 2016. The increase in research and development expenses was primarily due to an increase in personnel costs due to increased headcount and an increase in

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direct research and development expenses for our pipeline.

Amounts in millions	2017	2016	Change
Personnel expenses	$ 13.9	$ 11.5	$ 2.4
Stock-based compensation	6.8	4.0	2.8
Direct research and development expenses	16.8	13.8	3.0
Professional and legal fees	2.1	1.9	0.2
Other research and development expenses	2.5	2.3	0.2
Total research and development expenses	$ 42.1	$ 33.5	$ 8.6

General and administrative expenses. General and administrative expenses increased to $109.0 million for the year ended December 31, 2017 from $76.9 million for the year ended December 31, 2016. The increase in general and administrative expenses was primarily a result of increased personnel costs, facility and support costs, legal and professional fees, and stock-based compensation expense to support the overall growth of the Company.

Amounts in millions	2017	2016	Change
Personnel expenses	$ 42.7	$ 31.8	$ 10.9
Professional and legal fees	20.1	11.9	8.2
Stock-based compensation	20.2	14.6	5.6
Other general and administrative expenses	4.9	2.9	2.0
Facility and support services	21.1	15.7	5.4
Total general and administrative expenses	$ 109.0	$ 76.9	$ 32.1

Sales and marketing expenses. Sales and marketing expenses increased to $153.9 million for the year ended December 31, 2017 from $112.8 million for the year ended December 31, 2016. The increase in sales and marketing expense was a result of hiring additional sales and marketing personnel and increasing our advertising and patient marketing efforts as part of the ongoing commercialization of Cologuard test.

Amounts in millions	2017	2016	Change
Direct marketing costs and professional fees	$ 75.4	$ 50.6	$ 24.8
Personnel expenses	70.4	57.4	13.0
Stock-based compensation	6.7	4.1	2.6
Other sales and marketing expenses	1.4	0.7	0.7
Total sales and marketing expenses	$ 153.9	$ 112.8	$ 41.1

Investment income. Investment income increased to $3.9 million for the year ended December 31, 2017 from $2.0 million for the year ended December 31, 2016. This increase in investment income was due to a higher average

balance and return on investments for the year ended December 31, 2017 when compared to the same period in 2016.

Interest expense. Net interest expense of $0.2 million was realized for each of the years ended December 31, 2017 and 2016. Interest expense is related to the mortgage on one of our facilities in Madison, Wisconsin that was entered into in June 2015.

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 Cologuard. As of December 31, 2018, we had approximately $160.4 million in unrestricted cash and cash equivalents and approximately $963.8 million in marketable securities.

All 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.

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Net cash used in operating activities was $69.3 million, $71.7 million, and $130.1 million for the years ended December 31, 2018, 2017 and 2016, respectively. The principal use of cash in operating activities for each of the years ended December 31, 2018, 2017 and 2016 was to fund our net loss. The decrease in use of cash in operating activities for the year ended December 31, 2018 when compared to the same period in 2017 and 2016 is primarily due to increased Cologuard revenue and an increase in non-cash expenses such as amortization and stock-based compensation.

Net cash used in investing activities was $781.9 million, $160.8 million, and $11.5 million for the years ended December 31, 2018, 2017, and 2016, respectively. The increase in cash used in investing activities for the year ended December 31, 2018 when compared to the same period in 2017 and 2016 was primarily the result of the timing of purchases and maturities of marketable securities following our convertible debt offerings. Excluding the impact of purchases and maturities of marketable securities, net cash used in investing activities was $168.6 million, $75.2 million, and $14.9 million for the years ended December 31, 2018, 2017, and 2016, respectively. The increase in investing activities from 2017 to 2018, excluding the impact of purchases and maturities of marketable securities, was primarily due to an increase in purchases of property and equipment during the year ended December 31, 2018 from increased laboratory equipment purchases, computer equipment and computer software purchases, and assets under construction in order to continue to scale-up our operations for future expected growth of our Cologuard business. Additionally, the increase for 2018 was driven by the acquisition of Biomatrica for $17.9 million compared to 2017 when we completed an acquisition of Sampleminded, Inc. (“Sampleminded”) for $3.0 million. The increase in investing activities from 2016 to 2017, excluding the impact of purchases and maturities of marketable securities was primarily due to an increase in purchases of property and equipment during the year ended December 31, 2018. Additionally, the increase for 2017 was driven by the purchase of intangible assets for $20.7 million and the acquisition of Sampleminded for $3.0 million compared to 2016 when we had no activity in these areas.

Net cash provided by financing activities was $934.1 million, $261.0 million, and $149.6 million for the years ended December 31, 2018, 2017, and 2016, respectively. The increase in cash provided by financing activities for the year ended December 31, 2018 when compared to the same period in 2017 was primarily the result of proceeds from our offerings of convertible debt in January 2018 and June 2018. The increase in cash provided by financing activities for the year ended December 31, 2017 when compared to the same period in 2016 was primarily the result of an increase in proceeds from the sale of common stock from $144.2 million in 2016 to $253.4 million in 2017.

We expect that cash and cash equivalents and marketable securities on hand at December 31, 2018 will be sufficient to fund our current operations for at least the next twelve months, based on current operating plans. However, we may need to raise additional capital to fully fund our current strategic plan, which includes successfully commercializing Cologuard 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, we cannot assure that our business will ever generate sufficient cash flow from operations to become profitable.

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, 2018:

	Payments Due by Period		
	Less Than		More Than

(In thousands)	Total	One Year	1 - 3 Years	3 - 5 Years	5 Years
Convertible notes(1)	$ 908,500	$ —	$ —	$ —	$ 908,500
Long-term debt obligations(2)	43,054	943	2,085	26,035	13,991
Other long-term liabilities(3)	1,200	—	—	1,200	—
Operating lease obligations(4)	68,450	3,861	10,130	10,173	44,286
Total	$ 1,021,204	$ 4,804	$ 12,215	$ 37,408	$ 966,777

(1) Senior convertible notes were issued in January and June 2018 and are treated as a single series of securities with a maturity date of January 15, 2025. The table excludes expected interest payments related to the Notes. See Note 10 in the Notes to Consolidated Financial Statements for further information.

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(2) Includes obligations associated with outstanding credit and loan agreements. The table excludes expected interest payments related to long term debt obligations. See Note 9 in the Notes to Consolidated Financial Statements for further information.

(3) Includes fixed or minimum commitments associated with a land purchase option agreement with the owner of the land adjacent to one of our current Madison, Wisconsin facilities. See Note 12 in the Notes to Consolidated Financial Statements for further information.

(4) Operating leases reflect remaining obligations associated with the leased facilities at our headquarters, operations and lab facilities in Madison, Wisconsin, San Diego, California, Salt Lake City, Utah, and Ann Arbor, Michigan. This also includes the lease payments associated with the research and development facility, which was recorded under the financing method. See Note 7 and Note 9 in the Notes to Consolidated Financial Statements for further information.

Net Operating Loss Carryforwards

As of December 31, 2018, we had federal, state, and foreign net operating loss carryforwards of approximately $937.4 million, $403.5 million, $78.0 million, respectively. We also had federal and state research tax credit carryforwards of approximately $17.4 million and $7.5 million, respectively. The net operating loss and tax credit carryforwards will expire at various dates through 2038, 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 limit 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. 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. The deferred tax assets are still available for us to use in the future to offset taxable income, which would result in the recognition of tax benefit and a reduction to our effective tax rate.

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 United States (“GAAP”). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, tax positions, and stock based compensation. 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 2 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.

Revenue. Our revenue is primarily generated by performing screening services using our Cologuard test, and the service is completed upon delivery of a patient's test result to the ordering physician. We account for revenue in accordance with Accounting Standards Codification Topic 606, Revenue from Contracts with Customers ("ASC 606"),

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which we adopted on January 1, 2018, using the modified retrospective method, which we elected to apply to all contracts. Application of the modified retrospective method did not impact amounts previously reported by us, nor did it require a cumulative effect adjustment upon adoption, as our method of recognizing revenue under ASC 606 was analogous to the method utilized immediately prior to adoption. Accordingly, there is no need for us to disclose the amount by which each financial statement line item was affected as a result of applying the new standard and an explanation of significant changes.

The core principle of ASC 606 is that we recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. We recognize revenue from our Cologuard test in accordance with that core principle, and key aspects considered include the following:

Contracts

Our customer is the patient. However, we do not enter into a formal reimbursement contract with a patient, as formal reimbursement contracts, including national coverage determination, are established with payers. Accordingly, we establish a contract with a patient in accordance with other customary business practices.

- Approval of a contract is established via the order submitted by the patient's physician and the return of a sample by the patient.
- We are obligated to perform our laboratory services upon receipt of a sample from a patient, and the patient and/or applicable payer are obligated to reimburse us for services rendered based on the patient's insurance benefits.
- Payment terms are a function of a patient's existing insurance benefits, including the impact of coverage decisions with CMS and applicable reimbursement contracts established between us and payers, unless the patient is a self-pay patient, whereby we require payment from the patient prior to us shipping a collection kit to the patient.
    - Once we deliver a patient's test result to the ordering physician, we are legally able to collect payment and bill an insurer and/or patient, depending on payer contract status or patient insurance benefit status.
- Our consideration is deemed to be variable, and we consider collection of such consideration to be probable to the extent that it is unconstrained.

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. Our contracts have a single performance obligation, which is satisfied upon rendering of services, which culminates in the delivery of a patient's Cologuard test result to the ordering physician. The duration of time between sample receipt and delivery of a valid test result to the ordering physician is typically less than two weeks. Accordingly, we elect the practical expedient and therefore, we do not disclose the value of unsatisfied performance obligations.

Transaction price

The transaction price is the amount of consideration that we expect 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 from a contract with a customer may include fixed amounts, variable amounts, or both.

The consideration derived from our contracts is deemed to be variable, though the variability is not explicitly stated in any contract. Rather, the implied variability is due to several factors, such as the amount of contractual adjustments, any patient co-payments, deductibles or compliance incentives, the existence of secondary payers and claim denials.

We estimate 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.

We limit the amount of variable consideration included in the transaction price to the unconstrained portion of such consideration. In other words, we recognize revenue up to the amount of variable consideration that is not subject to a

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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 $15.0 million for the year ended December 31, 2018.

We monitor our estimates of transaction price to depict conditions that exist at each reporting date. If we subsequently determine that we will collect more consideration than we originally estimated for a contract with a patient, we will account for the change as an increase in the estimate of the transaction price (i.e., an upward revenue adjustment) in the period identified. Similarly, if we subsequently determine that the amount we expect to collect from a patient is less than we originally estimated, we will generally account for the change as a decrease in the estimate of the transaction price (i.e., a downward revenue adjustment), provided that such downward adjustment does not result in a significant reversal of cumulative revenue recognized.

When we do 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 delivery of a patient's Cologuard test result to the ordering physician, with recognition generally occurring at the date of cash receipt. Since the first quarter of 2017, we determined that our historical experience has sufficient predictive value, such that there are no longer any contracts for which no revenue is recognized upon delivery of a Cologuard test result to an ordering physician under both legacy accounting principles, which were effective in 2017, and ASC 606, which was adopted in 2018 as discussed above. Of the revenue recognized in the twelve months ended December 31, 2017, approximately $4.3 million relates to the one-time impact of certain payers meeting our revenue recognition criteria for accrual-basis revenue recognition beginning with the period ended March 31, 2017. Approximately $1.0 million of this one-time impact relates to tests completed in the prior year and for which our accrual revenue recognition criteria were not met until 2017.

Allocate transaction price

The entire transaction price is allocated to the single performance obligation contained in a contract with a patient.

Point in time recognition

Our single performance obligation is satisfied at a point in time, and that point in time is defined as the date a patient's successful test result is delivered to the patient's ordering physician. We consider this date to be the time at which the patient obtains control of the promised Cologuard test service.

Disaggregation of Revenue

The following table presents our revenues disaggregated by revenue source for the years ended December 31, 2018, 2017 and 2016, respectively:

	Year Ended December 31,		
(In thousands)	2018	2017	2016
Medicare Parts B & C	$ 254,431	$ 172,255	$ 81,976
Commercial	184,538	84,842	16,017
Other	15,493	8,892	1,383
Total	$ 454,462	$ 265,989	$ 99,376

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 delivery of a patient's test result to the ordering physician, resulting in an account receivable. However, we sometimes receive advance payment from a patient, particularly a self-pay patient, before a Cologuard test result is completed, resulting in deferred revenue. The deferred revenue balance is relieved upon delivery of the applicable patient's test result to the ordering physician. Changes in accounts receivable and deferred revenue were not materially impacted by any other factors.

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Deferred revenue balances are reported in other short-term liabilities on our consolidated balance sheets and were $0.5 million and $0.2 million as of December 31, 2018 and December 31, 2017, respectively.

Revenue recognized for the year ended December 31, 2018 and 2017, which was included in the deferred revenue balance at the beginning of each period was $0.1 million and $44,000, respectively.

Practical expedients

We do not adjust the transaction price for the effects of a significant financing component, as at contract inception we expect the collection cycle to be one year or less.

We expense sales commissions when incurred because the amortization period would have been one year or less. These costs are recorded within sales and marketing expenses on our consolidated statements of operations.

We incur 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. compliance reminder letters). These costs are expensed as incurred and recorded within general and administrative expenses on our consolidated statements of operations.

Inventory. Inventory is stated at the lower of cost or market value (net realizable value). We determine the cost of inventory using the first-in, first out method (“FIFO”). We estimate the recoverability of inventory by reference to internal estimates of future demands and product life cycles, including expiration. We periodically analyze our inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated realizable value and record a charge to cost of sales for such inventory as appropriate. In addition, our products are subject to strict quality control and monitoring which we perform throughout the manufacturing process. If certain batches or units of product no longer meet quality specifications or become obsolete due to expiration, we record a charge to cost of sales to write down such unmarketable inventory to its estimated realizable value.

Direct and indirect manufacturing costs incurred during process validation and for other research and development activities, which are not permitted to be sold, have been expensed to research and development.

Stock Based Compensation. In accordance with GAAP, all stock-based payments, including grants of employee stock options, restricted stock and restricted stock units, market measure-based awards and shares purchased under an employee stock purchase plan (“ESPP”) (if certain parameters are not met), are recognized in the financial statements based on their fair values. The grant date fair value of market measure-based share-based compensation plans are calculated using a Monte Carlo simulation pricing model. The following assumptions are used in determining fair value for stock options, restricted stock and ESPP shares:

· Valuation and Recognition—The fair value of each option award is estimated on the date of grant using the Black Scholes option pricing model. The fair value of each market measure-based award is estimated on the date of grant using a Monte Carlo simulation pricing model. 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. For awards issued to non-employees, the measurement date is the date when the performance is complete or when the award vests, whichever is the earliest. Accordingly, non-employee awards are re-measured at each reporting period until the final measurement date. The fair value of the award is recognized as stock-based compensation expense over the requisite service period, generally the vesting period. The Black-Scholes and Monte Carlo pricing models utilize the following assumptions:

· Expected Term—Expected term is based on our historical life data and is determined using the average of the vesting period and the contractual life of the stock options granted. Expected life of a market measure-based award is based on the applicable performance period.

· Expected Volatility—Expected volatility is based on our historical stock volatility data over the expected term of the awards.

· Risk Free Interest Rate—We base the risk free interest rate used in the Black Scholes and Monte Carlo valuation models on the implied yield currently available on U.S. Treasury zero coupon issues with an equivalent expected term.

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· Forfeitures—Effective January 1, 2017, we adopted Accounting Standards Update ("ASU") No. 2016-09, Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting ("Update 2016-09"). With the adoption of Update 2016-09, forfeiture estimates are no longer required, and the effects of actual forfeitures are recorded at the time they occur. The impact on the consolidated balance sheet was a cumulative-effect adjustment of $0.4 million, increasing opening accumulated deficit and additional paid-in capital.

The fair value of service-based awards for each restricted stock award and restricted stock unit is determined on the date of grant using the closing stock price on that day. The fair value of market measure-based share-based compensation plans are calculated using a Monte Carlo simulation pricing model. The fair value of each option award is estimated on the date of grant using the Black Scholes option pricing model based on the assumptions noted above and as further described in Note 6 in the Notes to Consolidated Financial Statements.

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 $209.9 million and $214.3 million valuation allowance at December 31, 2018 and 2017 is necessary to reduce the tax assets to the amount that is more likely than not to be realized. The change in valuation allowance for 2018 and 2017 was a decrease of $4.4 million and $45.8 million, respectively. 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. In January 2018 and June 2018, we issued $690.0 million and $218.5 million, respectively, in aggregate principal amount of 1.0% Convertible Notes with a maturity date of January 15, 2025 (the "Notes"). We determined the carrying amount of the liability component of the Notes by using assumptions that market participants would use in pricing a debt instrument, including market interest rates, credit standing, yield curves and volatilities. Determining the fair value of the debt component requires the use of accounting estimate 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.

For the January 2018 offering, we allocated $194.9 million to the equity component of the convertible debt instrument. That equity component is treated as a discount on the liability component of the Notes, which is amortized over the seven-year term of the Notes using the effective interest rate method. For the June 2018 offering, we allocated $73.0 million to the equity component of the convertible debt instrument. That equity component, less the $14.2 million premium, is treated as a discount on the liability component of the Notes, which is amortized over the remaining six-and-a-half-year term of the Notes using the effective interest rate method. In addition, debt issuance costs related to the Notes were $18.9 million and $7.4 million for the January 2018 and June 2018 offerings, respectively. We allocated the costs to the liability and equity components of the Notes based on their relative values. The debt issuance costs allocated to the liability component are being amortized over the life of the Notes 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.

Goodwill. In 2017, we recognized goodwill of $2.0 million from the acquisition of Sampleminded. During the fourth quarter of 2018, we recognized goodwill of $15.3 million from the acquisition of Biomatrica. We evaluate goodwill impairment on an annual basis or more frequently should an event or change in circumstance occur that indicates that the carrying amount is in excess of the fair value. There were no impairment losses for the years ended December 31, 2018, 2017, and 2016. Refer to Note 2 and 14 for further discussion of the goodwill recorded.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). We adopted this guidance on January 1, 2018. See Note 2 for additional discussion.

In January 2016, the Financial Accounting Standards Board issued ASU No. 2016-01, Financial Instruments – Overall: Recognition and Measurement of Financial Assets and Financial Liabilities (“Update 2016-01”). Update 2016-01 modifies how entities will have to measure equity investments and present changes in the fair value of financial

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liabilities. Under the new guidance, entities will have to measure equity investments that do not result in consolidation and are not accounted for under the equity method at fair value and recognize any changes in fair value in net income unless the investments qualify for the new practicality exception. A practicality exception will apply to those equity investments that do not have readily determinable fair value and do not qualify for the practical expedient to estimate fair value under ASC 820, "Fair Value Measurements," and as such these investments may be measured at cost. Update 2016-01 will be effective for the Company's fiscal year beginning January 1, 2018, and subsequent interim periods. Update 2016-01 was further amended in February 2018 by ASU No. 2018-03, Technical Corrections and Improvements to Financial Instruments – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities, ("Update 2018-03"). Update 2018-03 clarifies certain aspects of the guidance issued in Update 2016-01. Public business entities with fiscal years beginning between December 15, 2017 and June 15, 2018, are not required to adopt these amendments until the interim period beginning after June 15, 2018. We adopted Update 2016-01 on January 1, 2018, and it did not have an impact on our consolidated financial statements.

In February 2016, the Financial Accounting Standards Board issued ASU No. 2016-02, Leases (Topic 842), ("Update 2016-02") to increase transparency and comparability among organizations by requiring the recognition of right-of-use ("ROU") assets and lease liabilities on the balance sheet. The most noteworthy change in the standard is the recognition of ROU assets and lease liabilities by lessees for those leases classified as operating leases under current U.S. GAAP. The standard requires disclosures to meet the objective of enabling users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases.

We will adopt the standard on January 1, 2019 with initial application on the effective date as permitted under ASU No. 2018-11. We will recognize and measure leases existing at the initial application date of January 1, 2019 through a cumulative-effect adjustment recorded at the beginning of fiscal year 2019. We intend to elect the package of practical expedients and accordingly, we will not reassess the lease classification or whether expired or existing contracts contain leases under the new definition of a lease. Additionally, we will elect not to separate the lease components from the non-lease components for all classes of underlying assets. Our ability to adopt the new standards depends on system readiness, including software procured from a third-party provider. We remain on schedule and have implemented key system functionality to enable preparation of financial statements in accordance with the new standard.

We anticipate this standard will have a material impact on our consolidated balance sheets; however, we do not expect adoption to have a material impact on our consolidated statements of operations. We expect the most significant impact to be the recognition of ROU assets and lease liabilities for operating leases. Adoption of the standard is expected to result in the recognition of ROU assets and lease liabilities for operating leases of approximately $17.0 million to $18.0 million and $19.5 million to $20.5 million as of December 31, 2018, respectively. We are not party to any capital lease agreements as of December 31, 2018.

Based on our analysis, the sale-lease back transaction detailed within Note 9, the buyer-lessor has not obtained control of the underlying asset as the present value of the lease payments is substantially all of the fair value of the underlying asset. As such, the underlying asset and related financing obligation will continue to be included in our consolidated balance sheets upon adoption.

At December 31, 2018, we included $7.3 million as an asset under construction, including $2.1 million that is funded by the landlord, with a corresponding financing obligation related to a build-to-suit construction project. See Note 9 in the Notes to Consolidated Financial Statements for further information. Based on our analysis, upon adoption of Topic 842, we do not control the asset under construction and, as such, the asset and corresponding financing obligation will be de-recognized at adoption of ASC 842 on January 1, 2019.

In August 2016, the Financial Accounting Standards Board issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, ("Update 2016-15"). Current GAAP either is unclear or does not include specific guidance on the eight cash flow classification issues included in the amendments in Update 2016-15. The amendments are an improvement to GAAP because they provide guidance for each of the eight issues, thereby reducing the current and potential future diversity in practice. We adopted this guidance on January 1, 2018, and it did not have an impact on our consolidated statements of cash flows.

In October 2016, the Financial Accounting Standards Board issued ASU No. 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory, ("Update 2016-16"). This amendment improves the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. We adopted this guidance on

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January 1, 2018, and it did not have an impact on our consolidated financial statements.

In November 2016, the Financial Accounting Standards Board issued ASU No. 2016-18, Statement of Cash Flows: Restricted Cash, (“Update 2016-18”). Update 2016-18 provides guidance on the classification of restricted cash in the statement of cash flows. We adopted this guidance on January 1, 2018, and it did not have an impact on our consolidated financial statements, as we do not have restricted cash.

In May 2017, the Financial Accounting Standards Board issued ASU No. 2017-09, Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting, (“Update 2017-09”). Update 2017-09 provides guidance on determining which changes to the terms and conditions of share-based payment awards require an entity to apply modification accounting under Topic 718. We adopted this guidance on January 1, 2018, and it did not have an impact on our consolidated financial statements.

In June 2018, the Financial Accounting Standards Board issued ASU No. 2018-07 (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting, (“Update 2018-07”). Update 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for certain exemptions specified in the amendment. The guidance is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that fiscal year. Early adoption is permitted, but no earlier than an entity’s adoption of Topic 606. We will adopt this guidance on January 1, 2019, and we do not anticipate it will have an impact on our consolidated financial statements.

In July 2018, the Financial Accounting Standards Board issued ASU No. 2018-09, Codification Improvements, ("Update 2018-09"). Update 2018-09 provided various minor codification updates and improvements to address comments that the FASB had received regarding unclear or vague accounting guidance. The guidance is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that fiscal year. We will adopt this guidance on January 1, 2019, and we do not anticipate it will have an impact on our consolidated financial statements.

In August 2018, the Financial Accounting Standards Board issued ASU No. 2018-13, Fair Value Measurement (Topic 820); Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement, ("Update 2018-13"). Update 2018-13 provided an update to the disclosure requirements for fair value measurements under the scope of ASC 820. The guidance is effective for fiscal years beginning after December 15, 2019. We are currently evaluating the impact of the guidance on our consolidated financial statements.

In August 2018, the Financial Accounting Standards Board issued ASU No. 2018-15, Intangibles – Goodwill and Other – Internal-Use Software, (“Update 2018-15”). Update 2018-15 provided guidance for evaluating the accounting for fees paid by a customer in a cloud computing arrangement that is a service contract. The guidance is effective for fiscal years beginning after December 15, 2019. We are currently evaluating the impact of the guidance on our consolidated

financial statements.

In November 2018, the Financial Accounting Standards Board issued ASU No. 2018-18, Collaborative Arrangements (Topic 808), ("Update 2018-18"). Update 2018-18 provided additional guidance regarding the interaction between Topic 808 on Collaborative Arrangements and Topic 606 on Revenue Recognition. The guidance is effective for fiscal years beginning after December 15, 2019. We are currently evaluating the impact of the guidance on our consolidated financial statements.

Off-Balance Sheet Arrangements

As of December 31, 2018, 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

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bonds, which as of December 31, 2018 and December 31, 2017 were classified as available for sale. We place our cash equivalents 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, 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, 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 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

We have no significant operations outside the United States and we do not expect to be impacted significantly by foreign currency fluctuations.

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Item 8. Consolidated Financial Statements and Supplementary Data

EXACT SCIENCES CORPORATION

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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 sheets of Exact Sciences Corporation (the “Company”) and subsidiaries as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, stockholders’ equity, and cash flows for each of the three years in the period ended December 31, 2018, 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 and subsidiaries at December 31, 2018 and 2017, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) and our report dated February 21, 2019 expressed an unqualified opinion thereon.

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 United States 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 since 2012.

Madison, Wisconsin

February 21, 2019

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Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors

Exact Sciences Corporation

Madison, Wisconsin

Opinion on Internal Control over Financial Reporting

We have audited Exact Sciences Corporation's (the "Company's") internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of the Company and subsidiaries as of December 31, 2018 and 2017, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and our report dated February 21, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A, Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with United States federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit of internal control over financial reporting in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit 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 opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance

with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ BDO USA, LLP

Madison, Wisconsin

February 21, 2019

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EXACT SCIENCES CORPORATION

Consolidated Balance Sheets

(Amounts in thousands, except share data)

	December 31, 2018	December 31, 2017
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 160,430	$ 77,491
Marketable securities	963,752	347,224
Accounts receivable, net	44,239	26,419
Inventory, net	39,148	26,027
Prepaid expenses and other current assets	20,498	10,055
Total current assets	1,228,067	487,216
Long-term Assets:		
Property, plant and equipment, net	245,259	79,986
Goodwill and intangibles, net	46,281	24,205
Other long-term assets, net	4,415	7,153
Total assets	$ 1,524,022	$ 598,560
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 28,141	$ 16,135
Accrued liabilities	100,644	49,126
Accrued interest	4,593	—
Debt, current portion	8	182
Other short-term liabilities	3,204	2,681
Total current liabilities	136,590	68,124
Convertible notes, net	664,749	—
Long-term debt, less current portion	24,073	4,269
Other long-term liabilities	9,475	5,749
Lease incentive obligation, less current portion	8,194	—
Total liabilities	843,081	78,142
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.01 par value Authorized—5,000,000 shares issued and outstanding—no shares at December 31, 2018 and December 31, 2017	—	—
Common stock, $0.01 par value Authorized—200,000,000 shares issued and outstanding—123,192,540 and 120,497,426 shares at December 31, 2018 and December 31, 2017	1,232	1,205
Additional paid-in capital	1,716,894	1,380,577
Accumulated other comprehensive loss	(1,422)	(750)
Accumulated deficit	(1,035,763)	(860,614)
Total stockholders' equity	680,941	520,418
Total liabilities and stockholders' equity	$ 1,524,022	$ 598,560

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

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EXACT SCIENCES CORPORATION

Consolidated Statements of Operations

(Amounts in thousands, except per share data)

	Year Ended December 31,		
	2018	2017	2016
Revenue	$ 454,462	$ 265,989	$ 99,376
Cost of sales	117,982	79,196	45,195
Gross margin	336,480	186,793	54,181
Operating expenses:			
Research and development	68,210	42,139	33,473
General and administrative	178,293	109,040	76,898
Sales and marketing	249,448	153,924	112,826
Total operating expenses	495,951	305,103	223,197
Loss from operations	(159,471)	(118,310)	(169,016)
Other income (expense)			
Investment income	21,203	3,932	2,018
Interest expense	(36,789)	(206)	(213)
Total other income (expense)	(15,586)	3,726	1,805
Net loss before tax	(175,057)	(114,584)	$ (167,211)
Income tax benefit (expense)	(92)	187	—
Net loss	$ (175,149)	$ (114,397)	$ (167,211)
Net loss per share—basic and diluted	$ (1.43)	$ (0.99)	$ (1.63)
Weighted average common shares outstanding—basic and diluted	122,207	115,684	102,335

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

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EXACT SCIENCES CORPORATION

Consolidated Statements of Comprehensive Loss

(Amounts in thousands)

	Year Ended December 31,		
	2018	2017	2016
Net loss	$ (175,149)	$ (114,397)	$ (167,211)
Other comprehensive loss, net of tax:			
Unrealized gain (loss) on available-for-sale investments	(708)	(475)	230
Foreign currency translation gain (loss)	36	143	(215)
Comprehensive loss	$ (175,821)	$ (114,729)	$ (167,196)

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

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EXACT SCIENCES CORPORATION

Consolidated Statements of Stockholders' Equity

(Amounts in thousands, except share data)

	Common Stock Number of Shares	$0.01 Par Value	Additional Paid In Capital	Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance, January 1, 2016	96,674,786	$ 967	$ 904,932	$ (433)	$ (578,610)	$ 326,856
Issuance of common stock, net of issuance costs of $7.3 million	9,775,000	98	144,144	—	—	144,242
Exercise of common stock options	2,254,384	23	3,388	—	—	3,411
Issuance of common stock to fund the Company's 2015 401(k) match	341,507	3	2,148	—	—	2,151
Compensation expense related to issuance of stock options and restricted stock awards	833,627	8	23,724	—	—	23,732
Purchase of employee stock purchase plan shares	356,823	3	2,096	—	—	2,099
Net loss	—	—	—	—	(167,211)	(167,211)
Accumulated other comprehensive income	—	—	—	15	—	15
Balance, December 31, 2016	110,236,127	$ 1,102	$ 1,080,432	$ (418)	$ (745,821)	$ 335,295
Cumulative-effect adjustment - ASU 2016-09 adoption	—	—	396	—	(396)	
Issuance of common stock, net of issuance costs of $7.4 million	7,450,000	74	253,314	—	—	253,388
Exercise of common stock	1,067,047	11	5,092	—	—	5,103

options						
Issuance of common stock to fund the Company's 2016 401(k) match	158,717	2	3,006	—	—	3,008
Compensation expense related to issuance of stock options and restricted stock awards	1,162,112	12	35,500	—	—	35,512
Purchase of employee stock purchase plan shares	423,423	4	2,837	—	—	2,841
Net loss	—	—	—	—	(114,397)	(114,397)
Accumulated other comprehensive loss		—	—	(332)	—	(332)
Balance, December 31, 2017	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 loss		—	—	(672)	—	(672)
Balance, December 31, 2018	123,192,540	$ 1,232	$ 1,716,894	$ (1,422)	$ (1,035,763)	$ 680,941

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

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EXACT SCIENCES CORPORATION

Consolidated Statements of Cash Flows

(Amounts in thousands, except share data)

	Year Ended December 31,		
	2018	2017	2016
Cash flows from operating activities:			
Net loss	$ (175,149)	$ (114,397)	$ (167,211)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of property and equipment	20,482	14,500	11,309
Loss on disposal of property and equipment	353	954	151
Loss on preferred stock investment	765	—	—
Deferred tax benefit	—	(115)	—
Stock-based compensation	60,264	35,512	23,732
Amortization of debt discount	26,291	—	—
Amortization of debt issuance costs	2,273	—	—
Amortization of other liabilities	(2,500)	(1,674)	(1,013)
Amortization of deferred financing costs	106	54	52
Amortization of premium on short-term investments	(3,901)	65	463
Amortization of intangible assets	2,602	1,055	200
Proceeds from refundable tax credits	—	—	800
Changes in assets and liabilities, net of effects of acquisition:			
Accrued interest	4,593	—	—
Accounts receivable, net	(17,292)	(17,529)	(3,593)
Inventory, net	(12,729)	(19,194)	(156)
Prepaid expenses and other current assets	(9,076)	(995)	761
Accounts payable	11,332	15,383	(2,598)
Accrued liabilities	21,744	15,154	7,349
Other short-term liabilities	172	119	—
Lease incentive obligation	345	(616)	(312)
Net cash used in operating activities	(69,325)	(71,724)	(130,066)
Cash flows from investing activities:			
Purchases of marketable securities	(1,192,506)	(357,051)	(189,989)
Maturities of marketable securities	579,171	271,466	193,321
Purchases of property and equipment	(150,093)	(48,480)	(14,851)
Business acquisition, net of cash acquired	(17,908)	(2,980)	—
Investment in privately-held company	—	(3,000)	—
Purchases of intangible assets	—	(20,690)	—
Internally developed software	(578)	(70)	—
Net cash used in investing activities	(781,914)	(160,805)	(11,519)
Cash flows from financing activities:			
Proceeds from issuance of convertible notes, net	896,430	—	—
Proceeds from financing obligation	6,762	—	—
Proceeds from exercise of common stock options	6,636	5,103	3,411
Proceeds from sale of common stock, net of issuance costs	—	253,388	144,242

Proceeds in connection with the Company's employee stock purchase plan	4,895	2,841	2,099
Payments of deferred financing costs	(24)	(202)	—
Proceeds from construction loan	24,260	—	—
Payments on mortgage payable	(4,678)	(174)	(166)
Payments on capital lease	(139)	—	—
Net cash provided by financing activities	934,142	260,956	149,586
Effects of exchange rate changes on cash and cash equivalents	36	143	(215)
Net increase in cash and cash equivalents	82,939	28,570	7,786
Cash and cash equivalents, beginning of period	77,491	48,921	41,135
Cash and cash equivalents, end of period	$ 160,430	$ 77,491	$ 48,921
Supplemental disclosure of non-cash investing and financing activities:			
Property and equipment acquired but not paid	$ 33,452	$ 8,818	$ 655
Property acquired under build-to-suit lease	$ 2,092	$ —	—
Unrealized loss on available-for-sale investments	$ (708)	$ (475)	$ 230
Issuance of 86,882, 158,717, and 341,507 shares of common stock to fund the Company’s 401(k) matching contribution for 2017, 2016, and 2015, respectively	$ 4,303	$ 3,008	$ 2,151
Business acquisition contingent consideration liability	$ 3,060	$ —	$ —
Interest paid	$ 4,638	$ 201	$ 209

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

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements

(1) ORGANIZATION

Exact Sciences Corporation (together with its subsidiaries, "Exact," or the "Company") was incorporated in February 1995. Exact is a molecular diagnostics company currently focused on the early detection and prevention of some of the deadliest forms of cancer. The Company has developed an accurate, non-invasive, patient friendly screening test called Cologuard for the early detection of colorectal cancer and pre-cancer, and is currently working on the development of additional tests for other types of cancer, with the goal of becoming a leader in cancer screening and diagnostics.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company's wholly owned subsidiaries and variable interest entities. See Note 12 for the discussion of financing arrangements involving certain entities that are variable interest entities that are included in the Company's consolidated financial statements. All significant intercompany transactions and balances have been eliminated in consolidation.

References to "Exact", "we", "us", "our", or the "Company" refer to Exact Sciences Corporation and its wholly owned subsidiaries.

Use of Estimates

The preparation of 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. Actual results could differ from those estimates.

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. The Company had no restricted cash at December 31, 2018 and 2017.

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. Marketable equity securities and debt securities not classified as held to maturity are classified as available for sale. Available for sale securities are carried at fair value, with the unrealized gains and losses, net of tax, reported in other comprehensive income. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity computed under the straight line method. Such amortization is included in investment income. Realized

gains and losses and declines in value judged to be other than temporary on available for sale securities are included in investment income. 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 investment income.

At December 31, 2018 and 2017, the Company's marketable securities were comprised of fixed income investments, and all were deemed available for sale. The objectives of the Company's investment strategy are to provide liquidity and safety of principal while striving to achieve the highest rate of return consistent with these two objectives. The Company's investment policy limits investments to certain types of instruments issued by institutions with

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

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. All of the Company's investments are considered current. Realized gains were $0.4 million, $23,000, and $24,000, net of insignificant realized losses, for the years ended December 31, 2018, 2017, and 2016, respectively and are included in investment income.

The Company periodically reviews investments in unrealized loss positions for other-than-temporary impairments. This evaluation includes, but is not limited to, significant quantitative and qualitative assessments and estimates regarding credit ratings, collateralized support, the length of time and significance of a security's loss position, the Company's intent not to sell the security, and whether it is more likely than not that the Company will have to sell the security before recovery of its cost basis. For the year ended December 31, 2018, no investments were identified with other-than-temporary declines in value.

Available for sale securities at December 31, 2018 consist of the following:

	December 31, 2018			
(In thousands)	Amortized Cost	Gains in Accumulated Other Comprehensive Income (Loss)	Losses in Accumulated Other Comprehensive Income (Loss)	Estimated Fair Value
Corporate bonds	$ 392,973	$ 33	$ (719)	$ 392,287
Asset backed securities	277,537	30	(568)	276,999
U.S. government agency securities	250,606	43	(178)	250,471
Commercial paper	12,158	—	(7)	12,151
Certificates of deposit	31,875	—	(31)	31,844
Total available-for-sale securities	$ 965,149	$ 106	$ (1,503)	$ 963,752

Available for sale securities at December 31, 2017 consist of the following:

	December 31, 2017			
(In thousands)	Amortized Cost	Gains in Accumulated Other Comprehensive Income (Loss)	Losses in Accumulated Other Comprehensive Income (Loss)	Estimated Fair Value
Corporate bonds	$ 181,639	$ 10	$ (344)	$ 181,305
Asset backed securities	94,700	—	(185)	94,515
U.S. government agency securities	54,974	—	(162)	54,812

Commercial paper	9,953	—	(7)	9,946
Certificates of deposit	6,647	1	(2)	6,646
Total available-for-sale securities	$ 347,913	$ 11	$ (700)	$ 347,224

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Changes in Accumulated Other Comprehensive Income (Loss)

The amount recognized in accumulated other comprehensive income (loss) ("AOCI") for the years ended December 31, 2018, 2017 and 2016 were as follows:

(In thousands)	Cumulative Translation Adjustment	Unrealized Gain (Loss) on Securities	Accumulated Other Comprehensive Income (Loss)
Balance at January 1, 2016	$ 11	$ (444)	$ (433)
Other comprehensive income (loss) before reclassifications	(215)	117	(98)
Amounts reclassified from accumulated other comprehensive loss	—	113	113
Net current period change in accumulated other comprehensive income (loss)	(215)	230	15
Balance at December 31, 2016	$ (204)	$ (214)	$ (418)
Other comprehensive income (loss) before reclassifications	143	(530)	(387)
Amounts reclassified from accumulated other comprehensive loss	—	55	55
Net current period change in accumulated other comprehensive income (loss)	143	(475)	(332)
Balance at December 31, 2017	$ (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)	36	(708)	(672)
Balance at December 31, 2018	$ (25)	$ (1,397)	$ (1,422)

Amounts reclassified from accumulated other comprehensive loss for the years ended December 31, 2018, 2017 and 2016 were as follows:

Details about AOCI Components (In thousands)	Affected Line Item in the Statements of Operations	Year Ended December 31, 2018	2017	2016
Change in value of available-for-sale investments				
Sales and maturities of available-for-sale investments	Investment income	$ 317	$ 55	$ 113
Total reclassifications		$ 317	$ 55	$ 113

Allowance for Doubtful Accounts

The Company estimates an allowance for doubtful accounts against accounts receivable based on estimates of expected collections consistent with historical cash collection experience. 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, 2018 and 2017 there was no allowance for doubtful accounts recorded. For the years ended December 31, 2018, 2017 and 2016, there was no bad debt expense written off against the allowance and charged to operating expense.

Inventory

Inventory is stated at the lower of cost or market value (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 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. In addition, the Company's products are subject to strict quality control and monitoring which the Company performs throughout the manufacturing process. If

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certain batches or units of product no longer meet quality specifications or become obsolete due to expiration, the Company records a charge to cost of sales to write down such unmarketable inventory to its estimated realizable value.

Direct and indirect manufacturing costs incurred during process validation and 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.

Inventory consisted of the following:

(In thousands)	December 31, 2018	December 31, 2017
Raw materials	$ 12,761	$ 10,344
Semi-finished and finished goods	26,387	15,683
Total inventory	$ 39,148	$ 26,027

Property, Plant and Equipment

Property 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. Maintenance and repairs are expensed when incurred; additions and improvements are capitalized. The estimated useful lives of property and equipment are as follows:

(In thousands)	Estimated Useful Life	December 31, 2018	December 31, 2017
Property, plant and equipment			
Land	(1)	$ 4,466	$ 4,466
Leasehold and building improvements	(2)	38,895	17,629
Land improvements	15 years	1,530	1,419
Buildings	30 years	7,928	7,928
Computer equipment and computer software	3 years	36,969	30,148
Laboratory equipment	3 - 10 years	37,518	23,296
Furniture and fixtures	3 years	8,353	4,531
Assets under construction	(3)	167,462	28,655
Property, plant and equipment, at cost		303,121	118,072
Accumulated depreciation		(57,862)	(38,086)
Property, plant and equipment, net		$ 245,259	$ 79,986

(1) Not depreciated.
(2) Lesser of remaining lease term, building life, or useful life.
(3) Not depreciated until placed into service.

Depreciation expense for the years ended December 31, 2018, 2017, and 2016 was $20.5 million, $14.5 million, and $11.3 million, respectively.

At December 31, 2018, the Company had $167.5 million of assets under construction which consisted of $130.8 million related to building and leasehold improvements, $5.2 million of capitalized costs related to software projects, and $31.5 million of costs related to laboratory equipment under construction. Depreciation will begin on these assets once they are placed into service. The Company expects to incur an additional $184.9 million to complete the building projects and leasehold improvements, $7.5 million of costs to complete the computer software projects, $7.2 million to complete the laboratory equipment, and minimal costs to complete the computer equipment. These projects are expected to be completed in 2019 and 2020. The Company assesses its long-lived assets, consisting primarily of

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property and equipment, for impairment when material events and changes in circumstances indicate that the carrying value may not be recoverable. There were no impairment losses for the years ended December 31, 2018, 2017 or 2016.

Software Capitalization Policy

Software development costs related to internal use software are incurred in three stages of development: 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.

Patent Costs, Intangible Assets and Goodwill

Goodwill and intangible assets consisted of the following:

(In thousands)	December 31, 2018	December 31, 2017
Finite-lived intangible assets		
Finite-lived intangible assets	$ 33,058	$ 23,726
Less: Accumulated amortization	(4,107)	(1,500)
Finite-lived intangible assets, net	28,951	22,226
Internally developed technology in process	51	—
Total finite-lived intangible assets, net	29,002	22,226
Goodwill	17,279	1,979
Goodwill and intangible assets, net	$ 46,281	$ 24,205

Finite-Lived Intangible Assets

The following table summarizes the net-book-value and estimated remaining life of the Company’s finite-lived intangible assets as of December 31, 2018:

(In thousands)	Net Balance at December 31, 2018	Weighted Average Remaining Life (Years)
Trade name	$ 689	14.8

Customer relationships	2,666	14.8
Patents	18,979	9.6
Acquired developed technology	6,086	13.8
Internally developed technology	531	2.7
Total	$ 28,951	

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As of December 31, 2018, 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)	
2019	$ 3,193
2020	3,193
2021	3,092
2022	2,956
2023	2,953
Thereafter	13,564
	$ 28,951

The Company reviews long-lived assets, including property and equipment and identifiable intangibles for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be 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. There were no impairment losses for the years ended December 31, 2018, 2017, and 2016.

Patent costs, which have historically consisted of related legal fees, 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. Other than the transactions discussed below, the Company determined that all patent costs incurred during the year ended December 31, 2018, 2017 and 2016 should be expensed and not capitalized as the future economic benefit derived from the transactions cannot be determined.

Under a technology license and royalty agreement entered into with MDx Health ("MDx"), dated July 26, 2010 (as subsequently amended, the "MDx License Agreement"), the Company was required to pay MDx milestone-based royalties on sales of products or services covered by the licensed intellectual property. Once the achievement of a milestone occurred or was considered probable, an intangible asset and corresponding liability was reported in goodwill and intangible assets and accrued liabilities, respectively. The liability was relieved once the milestone was achieved and payment made. The intangible asset is being amortized over the estimated ten-year useful life of the licensed intellectual property through 2024, and such amortization is reported in cost of sales. Payment for all remaining milestones under the License Agreement was made as part of the Royalty Buy-Out agreement outlined below.

Effective April 2017, the Company and MDx entered into a royalty buy-out agreement ("Royalty Buy-Out Agreement"), which terminated the MDx License Agreement. Pursuant to the Royalty Buy-Out Agreement, the Company paid MDx a one-time fee of $8.0 million in exchange for an assignment of certain patents covered by the MDx License Agreement and the elimination of all ongoing royalties and other payments by the Company to MDx under the MDx License Agreement. Also included in the Royalty Buy-Out Agreement is a mutual release of liabilities, which includes all amounts previously accrued under the MDx License Agreement. Concurrently with entering into the Royalty Buy-Out Agreement, the Company entered into a patent purchase agreement ("Patent Purchase Agreement") with MDx under which it paid MDx an additional $7.0 million in exchange for the assignment of certain other patent rights that were not covered by the MDx License Agreement. The total $15.0 million paid by the Company pursuant to the Royalty Buy-Out Agreement and Patent Purchase Agreement, net of liabilities relieved of $6.6 million, was recorded as an intangible asset and is being amortized over the estimated remaining useful life of the licensed intellectual property

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through 2024, and such amortization is reported in cost of sales. The $6.6 million of liabilities relieved were related to historical milestones and accrued royalties under the License Agreement.

As of December 31, 2018 and 2017, an intangible asset of $7.7 million and $9.0 million, respectively, related to historical milestone payments made under the MDx License Agreement and intangible assets acquired as part of the Royalty Buy-Out Agreement and Patent Purchase Agreement is reported in intangible assets. Amortization expense for the years ended December 31, 2018, 2017, and 2016 was $1.3 million, $1.0 million, and $0.2 million, respectively.

In December 2017, the Company entered into an asset purchase agreement (the “Armune Purchase Agreement”) with Armune BioScience, Inc. (“Armune”), pursuant to which the Company acquired intellectual property and certain other assets underlying Armune’s APIFINY®, APIFINY® PRO and APIFINY® ACTIVE SURVEILLANCE prostate cancer diagnostic tests. The portfolio of Armune assets the Company acquired is expected to complement its product pipeline. The total consideration was comprised of an up-front cash payment of $12.0 million and $17.5 million in contingent payment obligations that will become payable upon the Company’s achievement of development and commercial milestones using the acquired intellectual property. The satisfaction of these milestones is subject to many risks and is therefore uncertain. The Company will not record the contingent consideration until it is probable that the milestones will be met. There is no other consideration due to Armune beyond the milestone payments and the Company is not subject to future royalty obligations should a product be developed and commercialized. In connection with the Armune Purchase Agreement, Armune terminated a license agreement pursuant to which it licensed certain patent rights and know-how from the Regents of the University of Michigan (“University of Michigan”), and the Company entered into a license agreement with the University of Michigan with respect to such patent rights and know-how, as well as certain additional intellectual property rights. Pursuant to the Company’s agreement with the University of Michigan, it is required to pay the University of Michigan a low single-digit royalty on its net sales of products using the licensed intellectual property.

The Company accounted for the transaction as an asset acquisition under GAAP. The asset is comprised of a portfolio of biomarkers, related technology and know-how, which is a group of complementary assets concentrated in a single identifiable asset. The transaction costs directly related to the asset acquisition were added to the asset in accordance with GAAP. As such, the collective asset value from the acquisition resulted in an intangible asset of $12.2 million. The intellectual property asset, which includes related transaction costs, is being amortized on a straight-line basis over the period the Company expects to be benefited, which is consistent with the legal life of the patents acquired. The Company capitalized these costs as there is a reasonable expectation that the assets acquired will be used in an alternative manner in the future, that is not contingent on future development subsequent to acquisition, and the Company anticipates there to be economic benefit from these alternative uses. For the years ended December 31, 2018 and 2017, the Company recorded amortization expense of $0.9 million and $40,000, respectively. At December 31, 2018 and 2017, the net balances of $11.3 million and $12.2 million, respectively are reported in net goodwill and intangible assets in the Company’s consolidated balance sheet.

As a result of the Sampleminded, Inc. (“Sampleminded”) acquisition discussed in Note 14, the Company recorded an intangible asset of $1.0 million which was comprised of acquired developed technology of $0.9 million, customer relationships of $0.1 million, and non-compete agreements of $32,000. The intangible assets acquired are being amortized over the remaining useful life which was determined to be eight years for acquired developed technology, three years for customer relationships, and five years for non-compete agreements. For the years ended December 31, 2018 and 2017, the Company recorded amortization expense of $0.1 million and $52,000, respectively, and the net balances of $0.8 million and $0.9 million, respectively, are reported in net goodwill and intangible assets in the Company’s consolidated balance sheet.

As a result of the Biomatrica Acquisition discussed in Note 14, the Company recorded an intangible asset of $8.8 million which was comprised of acquired developed technology of $5.4 million, customer relationships of $2.7 million, and trade names of $0.7 million. The intangible assets acquired are being amortized over the remaining useful life which was determined to be fifteen years for the acquired developed technology, fifteen years for the customer relationships,

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and fifteen years for the trade names. For the year ended December 31, 2018, the Company recorded amortization expense of $0.1 million and the net balance of $8.7 million is reported in net goodwill and intangible assets in the Company's consolidated balance sheet.

In 2017, the Company recognized goodwill of $2.0 million from the acquisition of Sampleminded, Inc. During the fourth quarter of 2018, the Company recognized goodwill of $15.3 million from the acquisition of Biomatrica, Inc. Goodwill is reported in net goodwill and intangible assets in the Company's consolidated balance sheet. The Company will evaluate goodwill impairment on an annual basis or more frequently should an event or change in circumstance occur that indicates that the carrying amount is in excess of the fair value. There were no impairment losses for the years ended December 31, 2018, 2017, and 2016. Refer to Note 14 for further discussion of the goodwill recorded.

The change in the carrying amount of goodwill for the years ended December 31, 2018 and 2017 is as follows:

(In thousands)	
Balance, December 31, 2016	$ —
Sampleminded acquisition	1,979
Balance, December 31, 2017	1,979
Biomatrica acquisition	15,300
Balance, December 31, 2018	$ 17,279

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)	2018	2017	2016
Shares issuable upon exercise of stock options	2,532	3,360	3,505
Shares issuable upon the release of restricted stock awards	6,246	6,149	5,601
Shares issuable upon conversion of convertible notes	12,044	—	—
	20,822	9,509	9,106

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 and shares purchased under an employee stock purchase plan (if certain parameters are not met), to be recognized in the financial statements based on their fair values.

Revenue Recognition

The Company's revenue is primarily generated by screening services using its Cologuard test, and the service is completed upon delivery of a patient's test result to the ordering physician. The Company accounts for revenue in accordance with Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers ("ASC 606"), which it adopted on January 1, 2018, using the modified retrospective method, which it elected

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to apply to all contracts. Application of the modified retrospective method did not impact amounts previously reported by the Company, nor did it require a cumulative effect adjustment upon adoption, as the Company's method of recognizing revenue under ASC 606 was analogous to the method utilized immediately prior to adoption. Accordingly, there is no need for the Company to disclose the amount by which each financial statement line item was affected as a result of applying the new standard and an explanation of significant changes.

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 be entitled in exchange for those goods or services. The Company recognizes revenue from its Cologuard test in accordance with that core principle, and key aspects considered by the Company include the following:

Contracts

The Company's customer is the patient. However, the Company does not enter into a formal reimbursement contract with a patient, as formal reimbursement contracts, including national coverage determination for Cologuard, are established with payers. Accordingly, the Company establishes a contract with a patient in accordance with other customary business practices.

- Approval of a contract is established via the order submitted by the patient's physician and the return of a sample by the patient.
- The Company is obligated to perform its laboratory services upon receipt of a sample from a patient, and the patient and/or applicable payer are obligated to reimburse the Company for services rendered based on the patient's insurance benefits.
- Payment terms are a function of a patient's existing insurance benefits, including the impact of coverage decisions with CMS and applicable reimbursement contracts established between the Company and payers, unless the patient is a self-pay patient, whereby the Company requires payment from the patient prior to the Company shipping a collection kit to the patient.
- Once the Company delivers a patient's test result to the ordering physician, the contract with a patient has commercial substance, as the Company is legally able to collect payment and bill an insurer and/or patient, depending on payer contract status or patient insurance benefit status.
- The Company's consideration is deemed to be variable, and the Company considers collection of such consideration to be probable to the extent that it is unconstrained.

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 delivery of a patient's Cologuard test result to the ordering physician. The duration of time between sample receipt and delivery of a valid test result to the ordering physician is typically less than two weeks. Accordingly, the Company elects the practical expedient and therefore, the Company does not disclose the value of unsatisfied performance obligations.

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 from a contract with a customer may include fixed amounts, variable amounts, or both.

The consideration derived from the Company's contracts is deemed to be variable, though the variability is not explicitly stated in any contract. Rather, the implied variability is due to several factors, such as the amount of

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contractual adjustments, any patient co-payments, deductibles or patient compliance 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 $15.0 million for the year ended December 31, 2018.

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 consideration than it originally estimated for a contract with a patient, it will account for the change as an increase in the estimate of the transaction price (i.e., an upward revenue adjustment) in the period identified. Similarly, if the Company subsequently determines that the amount it expects to collect from a patient is less than it originally estimated, it will generally account for the change as a decrease in the estimate of the transaction price (i.e., a downward revenue adjustment), provided that such downward adjustment does not result in a significant reversal of cumulative revenue recognized.

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 delivery of a patient’s Cologuard test result to the ordering physician, with recognition, generally occurring at the date of cash receipt. Since the first quarter of 2017, the Company has determined that its historical experience has sufficient predictive value, such that there are no longer any contracts for which no revenue is recognized upon delivery of a Cologuard test result to an ordering physician. Of the revenue recognized in the twelve months ended December 31, 2017, approximately $4.3 million relates to the one-time impact of certain payers meeting the Company’s revenue recognition criteria for accrual-basis revenue recognition beginning with the period ended March 31, 2017. Approximately $1.0 million of this one-time impact relates to tests completed in the prior year and for which the Company’s accrual revenue recognition criteria were not met until 2017.

Allocate transaction price

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

Point in time recognition

The Company’s single performance obligation is satisfied at a point in time, and that point in time is defined as the date a patient’s successful test result is delivered to the patient’s ordering physician. The Company considers this date to be the time at which the patient obtains control of the promised Cologuard test service.

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Disaggregation of Revenue

The following table presents our revenues disaggregated by revenue source for the years ended December 31, 2018, 2017 and 2016, respectively:

	Year Ended December 31,		
(In thousands)	2018	2017	2016
Medicare Parts B & C	$ 254,431	$ 172,255	$ 81,976
Commercial	184,538	84,842	16,017
Other	15,493	8,892	1,383
Total	$ 454,462	$ 265,989	$ 99,376

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 delivery of a patient's test result to the ordering physician, resulting in an account receivable. However, the Company sometimes receives advance payment from a patient, particularly a self-pay patient, before a Cologuard test result is completed, resulting in deferred revenue. The deferred revenue balance is relieved upon delivery of the applicable patient's test result to the ordering physician. Changes in accounts receivable and deferred revenue were not materially impacted by any other factors.

Deferred revenue balances are reported in other short-term liabilities in the Company's consolidated balance sheets and were $0.5 million and $0.2 million as of December 31, 2018 and 2017, respectively.

Revenue recognized for the years ended December 31, 2018 and 2017, which was included in the deferred revenue balance at the beginning of each period was $0.1 million and $44,000, 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. compliance reminder letters). These costs are expensed as incurred and recorded within general and administrative expenses in the Company's consolidated statements of operations.

Advertising Costs

The Company expenses the costs of media advertising at the time the advertising takes place. The Company expensed approximately $93.7 million, $58.0 million, and $38.1 million of media advertising during the years ended December 31, 2018, 2017, and 2016, respectively.

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

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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.

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.

Fixed income securities are valued using a third-party pricing agency. The valuation is based on observable inputs including pricing for similar assets and other observable market factors. There has been no material pricing change from period to period. The estimated fair value of the Company's long-term debt represents a Level 2 measurement. When determining the estimated fair value of the Company's long-term debt, the Company used market-based risk measurements, such as credit risk. See Note 9 and Note 10 for further detail on the Company's long-term debt. The fair value 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 assesses the fair value of expected contingent consideration and the corresponding liability each reporting period using the Monte Carlo Method, which is consistent with the initial measurement of the expected earn out liability. This fair value measurement is considered a Level 3 measurement because 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. The contingent earn out liability is classified as a component of other long-term liabilities in the Company's consolidated balance sheets. There were no changes in the fair value assessed between the acquisition date and December 31, 2018. See Note 14 for further detail on the Biomatrica Acquisition.

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The following table presents the Company's fair value measurements as of December 31, 2018 along with the level within the fair value hierarchy in which the fair value measurements, in their entirety, fall.

		Fair Value Measurement at December 31, 2018 Using:		
(In thousands)	Fair Value at December 31, 2018	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	$ 86,375	$ 86,375	$ —	$ —
U.S. government agency securities	49,985	—	49,985	—
Commercial paper	24,070	—	24,070	—
Available-for-sale Marketable securities				
Corporate bonds	392,287	—	392,287	—
Asset backed securities	276,999	—	276,999	—
U.S. government agency securities	250,471	—	250,471	—
Certificates of deposit	31,844	—	31,844	—
Commercial paper	12,151	—	12,151	—
Contingent consideration	(3,060)	—	—	(3,060)
Total	$ 1,121,122	$ 86,375	$ 1,037,807	$ (3,060)

The following table presents the Company's fair value measurements as of December 31, 2017 along with the level within the fair value hierarchy in which the fair value measurements, in their entirety, fall.

		Fair Value Measurement at December 31, 2017 Using:		
(In thousands)	Fair Value at December 31, 2017	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	$ 61,297	$ 61,297	$ —	$ —
Commercial paper	10,995	—	10,995	—
Certificates of deposit	1,499	—	1,499	—

U.S. government agency securities	3,700	—	3,700	—
Available-for-sale				
Marketable securities				
Corporate bonds	181,305	—	181,305	—
Asset backed securities	94,515	—	94,515	—
U.S. government agency securities	54,812	—	54,812	—
Commercial paper	9,946	—	9,946	—
Certificates of deposit	6,646	—	6,646	—
Total	$ 424,715	$ 61,297	$ 363,418	$ —

The Company monitors investments for other-than-temporary impairment. It was determined that unrealized gains and losses at December 31, 2018 and 2017 are temporary in nature because the change in market value for those securities has resulted from fluctuating interest rates rather than a deterioration of the credit worthiness of the issuers. So long as the Company holds these securities to maturity, it is unlikely to experience gains or losses. In the event that the Company disposes of these securities before maturity, it is expected that realized gains or losses, if any, will be immaterial.

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Notes to Consolidated Financial Statements (Continued)

The following table summarizes the gross unrealized losses and fair values of investments in an unrealized loss position as of December 31, 2018, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position:

	December 31, 2018					
	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	$ 340,287	$ (638)	$ 35,773	$ (81)	$ 376,060	$ (719)
U.S. government agency securities	201,036	(178)	—	—	201,036	(178)
Asset backed securities	243,846	(501)	18,335	(67)	262,181	(568)
Certificates of deposit	31,843	(31)	—	—	31,843	(31)
Commercial paper	12,151	(7)	—	—	12,151	(7)
Total	$ 829,163	$ (1,355)	$ 54,108	$ (148)	$ 883,271	$ (1,503)

The following table summarizes the gross unrealized losses and fair value of investments in an unrealized loss position as of December 31, 2017, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position:

	December 31, 2017					
	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	$ 158,790	$ (340)	$ 4,715	$ (4)	$ 163,505	$ (344)
Asset backed securities	85,906	(179)	8,609	(6)	94,515	(185)
U.S. government agency securities	24,878	(90)	29,934	(72)	54,812	(162)
Commercial paper	19,944	(7)	—	—	19,944	(7)
Certificates of deposit	2,997	(2)	—	—	2,997	(2)
Total	$ 292,515	$ (618)	$ 43,258	$ (82)	$ 335,773	$ (700)

The following table summarizes contractual underlying maturities of the Company's available for sale investments at December 31, 2018:

	Due one year or less		Due after one year through four years	
(In thousands)	Cost	Fair Value	Cost	Fair Value
Marketable securities				
Corporate bonds	$ 282,910	$ 282,437	$ 110,062	$ 109,850
U.S. government agency securities	201,116	200,961	49,491	49,510
Asset backed securities	70,859	70,681	206,678	206,318
Certificates of deposit	25,485	25,471	6,390	6,373
Commercial paper	12,158	12,151	—	—
Total	$ 592,528	$ 591,701	$ 372,621	$ 372,051

Concentration of Credit Risk

In accordance with GAAP, the Company is required to disclose any significant off balance sheet risk and credit risk concentration. The Company has no significant off balance sheet risk, such as foreign exchange contracts or other

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Notes to Consolidated Financial Statements (Continued)

hedging arrangements. Financial instruments that subject the Company to credit risk consist of cash, cash equivalents and marketable securities. As of December 31, 2018, 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 $43.6 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, 2018, the Company's revenues have been primarily derived from the sale of Cologuard. 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	2018	2017	2016	2018	2017	2016
Centers for Medicare and Medicaid Services	36%	44%	60%	32%	39%	63%
UnitedHealthCare	13%	11%	(1)	10%	10%	(1)

(1) Payer was less than 10 percent of revenue for the year.

As the number of payers reimbursing for Cologuard increases, the percentage of revenue derived from major payers will continue to change as a percentage of revenue and accounts receivable.

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 $209.9 million and $214.3 million valuation allowance at December 31, 2018 and 2017 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, 2018 and 2017 was a decrease of $4.4 million and $45.8 million, respectively. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact the Company's effective tax rate.

Subsequent Events

The Company evaluates events that occur through the filing date and discloses those events or transactions that provide additional evidence with respect to conditions that existed at the date of the balance sheet. In addition, the financial statements are adjusted for any changes in estimates resulting from the use of such evidence.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). The Company adopted this guidance on January 1, 2018. See Note 2 for additional discussion.

In January 2016, the Financial Accounting Standards Board issued ASU No. 2016-01, Financial Instruments – Overall: Recognition and Measurement of Financial Assets and Financial Liabilities ("Update 2016-01"). Update 2016-01 modifies how entities will have to measure equity investments and present changes in the fair value of financial liabilities. Under the new guidance, entities will have to measure equity investments that do not result in consolidation and are not accounted for under the equity method at fair value and recognize any changes in fair value in net income unless the investments qualify for the new practicality exception. A practicality exception will apply to those equity investments that do not have readily determinable fair value and do not qualify for the practical expedient to estimate fair value under ASC 820, "Fair Value Measurements," and as such these investments may be measured at cost. Update 2016-01 will be effective for the Company's fiscal year beginning January 1, 2018, and subsequent interim periods. Update 2016-01 was further amended in February 2018 by ASU No. 2018-03, Technical Corrections and Improvements

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to Financial Instruments – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities, ("Update 2018-03"). Update 2018-03 clarifies certain aspects of the guidance issued in Update 2016-01. Public business entities with fiscal years beginning between December 15, 2017 and June 15, 2018, are not required to adopt these amendments until the interim period beginning after June 15, 2018. The Company adopted Update 2016-01 on January 1, 2018, and it did not have an impact on its consolidated financial statements.

In February 2016, the Financial Accounting Standards Board issued ASU No. 2016-02, Leases (Topic 842) ("Update 2016-02"), to increase transparency and comparability among organizations by requiring the recognition of right-of-use ("ROU") assets and lease liabilities on the balance sheet. The most noteworthy change in the standard is the recognition of ROU assets and lease liabilities by lessees for those leases classified as operating leases under current U.S. GAAP. The standard requires disclosures to meet the objective of enabling users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases.

The Company will adopt the standard on January 1, 2019 with initial application on the effective date as permitted under ASU No. 2018-11. The Company will recognize and measure leases existing at the initial application date of January 1, 2019 through a cumulative-effect adjustment recorded at the beginning of fiscal year 2019. The Company intends to elect the package of practical expedients and accordingly, the Company will not reassess the lease classification or whether expired or existing contracts contain leases under the new definition of a lease. Additionally, we will elect not to separate the lease components from the non-lease components for all classes of underlying assets. The Company's ability to adopt the new standards depends on system readiness, including software procured from a third-party provider. The Company remains on schedule and have implemented key system functionality to enable preparation of financial statements in accordance with the new standard.

The Company anticipates this standard will have a material impact on its consolidated balance sheets; however, the Company does not expect adoption to have a material impact on its consolidated statements of operations. The Company expects the most significant impact to be the recognition of ROU assets and lease liabilities for operating leases. Adoption of the standard is expected to result in the recognition of ROU assets of approximately $17.0 million to $18.0 million and lease liabilities of $19.5 million to $20.5 million as of December 31, 2018. The Company is not party to any capital lease agreements as of December 31, 2018.

Based on the Company's analysis, the sale-lease back transaction detailed within Note 9, the buyer-lessor has not obtained control of the underlying asset as the present value of the lease payments is substantially all of the fair value of the underlying asset. As such, the underlying asset and related financing obligation will continue to be included in the Company's consolidated balance sheets upon adoption.

At December 31, 2018, the Company included $7.3 million as an asset under construction, including $2.1 million that is funded by the landlord, with a corresponding financing obligation related to a build-to-suit construction project. See Note 9 to the Company's consolidated financial statements for further information. Based on the Company's analysis, upon adoption of Topic 842, the Company does not control the asset under construction and as such, the asset and corresponding financing obligation will be de-recognized at adoption of ASC 842 on January 1, 2019.

In August 2016, the Financial Accounting Standards Board issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, ("Update 2016-15"). Current GAAP either is unclear or does not include specific guidance on the eight cash flow classification issues included in the amendments in Update 2016-15. The amendments are an improvement to GAAP because they provide guidance for each of the eight issues, thereby reducing the current and potential future diversity in practice. The Company adopted this guidance on January 1, 2018, and it did not have an impact on its consolidated statements of cash flows.

In October 2016, the Financial Accounting Standards Board issued ASU No. 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory, ("Update 2016-16"). This amendment improves the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. The Company adopted this guidance

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Notes to Consolidated Financial Statements (Continued)

on January 1, 2018, and it did not have an impact on its consolidated financial statements.

In November 2016, the Financial Accounting Standards Board issued ASU No. 2016-18, Statement of Cash Flows: Restricted Cash, (“Update 2016-18”). Update 2016-18 provides guidance on the classification of restricted cash in the statement of cash flows. The Company adopted this guidance on January 1, 2018, and it did not have an impact on its consolidated financial statements, as we do not have restricted cash.

In May 2017, the Financial Accounting Standards Board issued ASU No. 2017-09, Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting, (“Update 2017-09”). Update 2017-09 provides guidance on determining which changes to the terms and conditions of share-based payment awards require an entity to apply modification accounting under Topic 718. The Company adopted this guidance on January 1, 2018, and it did not have an impact on its consolidated financial statements.

In June 2018, the Financial Accounting Standards Board issued ASU No. 2018-07 (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting, (“Update 2018-07”). Update 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for certain exemptions specified in the amendment. The guidance is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that fiscal year. Early adoption is permitted, but no earlier than an entity’s adoption of Topic 606. The Company will adopt this guidance on January 1, 2019, and it does not anticipate it will have an impact on its consolidated financial statements.

In July 2018, the Financial Accounting Standards Board issued ASU 2018-09, Codification Improvements, ("Update 2018-09"). Update 2018-09 provided various minor codification updates and improvements to address comments that the FASB had received regarding unclear or vague accounting guidance. The guidance is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that fiscal year. The Company will adopt this guidance on January 1, 2019, and it does not anticipate it will have an impact on its consolidated financial statements.

In August 2018, the Financial Accounting Standards Board issued ASU 2018-13, Fair Value Measurement (Topic 820); Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement, ("Update 2018-13"). Update 2018-13 provided an update to the disclosure requirements for fair value measurements under the scope of ASC 820. The guidance is effective for fiscal years beginning after December 15, 2019. The Company is

currently evaluating the impact of the guidance on its consolidated financial statements.

In August 2018, the Financial Accounting Standards Board issued ASU 2018-15, Intangibles – Goodwill and Other – Internal-Use Software, ("Update 2018-15"). Update 2018-15 provided guidance for evaluating the accounting for fees paid by a customer in a cloud computing arrangement that is a service contract. The guidance is effective for fiscal years beginning after December 15, 2019. The Company is currently evaluating the impact of the guidance on its consolidated financial statements.

In November 2018, the Financial Accounting Standards Board issued ASU 2018-18, Collaborative Arrangements (Topic 808), ("Update 2018-18"). Update 2018-18 provided additional guidance regarding the interaction between Topic 808 on Collaborative Arrangements and Topic 606 on Revenue Recognition. The guidance is effective for fiscal years beginning after December 15, 2019. The Company is currently evaluating the impact of the guidance on its consolidated financial statements.

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Notes to Consolidated Financial Statements (Continued)

Foreign Currency Translation

For the Company's international subsidiaries, the local currency is the functional currency. Assets and liabilities of these subsidiaries are translated into United States dollars at the period-end exchange rate or historical rates, as appropriate. Consolidated statements of operations amounts are translated at average exchange rates for the period. The cumulative translation adjustments resulting from changes in exchange rates are included in the consolidated balance sheet as a component of accumulated other comprehensive loss in total Exact Sciences Corporation's shareholders' equity. Transaction gains and losses are included in the consolidated statements of operations.

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.

(3) MAYO LICENSE AGREEMENT

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 amended and restated in February 2015 and further amended in January 2016, October 2017 and December 2018. 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, as amended, 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 markers, sample processing, analytical testing and data analysis associated with nucleic 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. In addition to granting the Company a license to the covered Mayo intellectual property, Mayo agreed to make available personnel to provide the Company product development and research and development assistance. 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.

Mayo has agreed to make available personnel through January 2020 to provide the Company product development and research and development assistance.

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 products using the licensed Mayo intellectual property, with minimum annual royalty fees of $25,000 each year through 2033, the year the last patent expires. 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 amendment, the royalty rate on the Company's net sales of Cologuard increased and, if in the future, improvements are made to the Cologuard product, the royalty rate may further increase,

but, pursuant to the terms of the January 2016 and October 2017 amendment, the rate remains a low-single-digit percentage of net sales.

In addition to royalties, the Company is required 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 February 2015 amendment and restatement of the license agreement, the Company agreed to pay Mayo an additional $5.0 million, payable in five annual installments, through 2019. The Company paid Mayo the annual installment of $1.0 million in the first quarter of each of 2015 through 2018.

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Notes to Consolidated Financial Statements (Continued)

In addition, the Company is paying Mayo for research and development efforts. As part of the Company's research collaboration with Mayo, the Company has incurred charges of $4.5 million and has made payments of $4.4 million for the year ended December 31, 2018. The Company has recorded an estimated liability in the amount of $1.9 million for research and development efforts as of December 31, 2018. The Company incurred charges of $3.8 million and made payments of $2.9 million for the year ended December 31, 2017. The Company recorded an estimated liability in the amount of $1.8 million for research and development efforts at December 31, 2017. The Company incurred charges of $3.6 million and made payments of $3.9 million for the year ended December 31, 2016.

The Mayo license agreement required, among other things, a $0.5 million milestone payment upon FDA approval of the Company's Cologuard test. The Company received this FDA approval, and paid the milestone payment, in August 2014.

Pursuant to the license agreement, the Company granted Mayo two common stock purchase warrants with an exercise price of $1.90 per share covering 1,000,000 and 250,000 shares of common stock, respectively. The warrant covering 1,000,000 shares was fully exercised as of September 2011. The warrant covering 250,000 shares was exercised at various dates in 2013 and 2014 and became fully exercised as of June 2014.

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 2033 (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.

(4) PFIZER PROMOTION AGREEMENT

In August 2018, the Company entered into a Promotion Agreement ("Promotion Agreement") with Pfizer, Inc. ("Pfizer"). Under the terms of the Promotion Agreement, Pfizer will promote Cologuard and provide certain sales, marketing, analytical and other commercial operations support services. The Company and Pfizer committed in the Promotion Agreement to invest specified amounts in the advertising and promotion of Cologuard. The Company agreed to pay Pfizer for promotion, sales and marketing costs incurred on behalf of the Company, a service fee based on incremental gross profits over specified baselines and royalties for Cologuard related revenues for a specified period after the expiration or termination of the Promotion Agreement. These costs are recorded in sales and marketing in the consolidated statements of operations. The initial term of the Promotion Agreement runs through December 31, 2021. The Company incurred charges of $5.8 million and made payments of $5.3 million for promotion, sales and marketing services performed by Pfizer on behalf of the Company in 2018. The Company recorded a liability of $0.5 million for promotion, sales and marketing services performed by Pfizer on behalf of the Company in accrued liabilities in the Company's consolidated balance sheet as of December 31, 2018. The Company recorded a liability of $4.8 million for the promotion fee earned by Pfizer as of December 31, 2018 in accrued liabilities in the Company's consolidated

balance sheet.

(5) ISSUANCES OF EQUITY

Underwritten Public Offerings

In August 2016 the Company completed an underwritten public offering of 9.8 million shares of common stock at a price of $15.50 per share to the public. The Company received approximately $144.2 million of net proceeds from the offering after deducting $7.3 million for the underwriting discount and commissions and other stock issuance costs paid by the Company.

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Notes to Consolidated Financial Statements (Continued)

In June 2017, the Company completed an underwritten public offering of 7.0 million shares of common stock at a price of $35.00 per share to the public. On June 26, 2017, the underwriters partially exercised their over-allotment option in connection with the offering and purchased an additional 450,000 shares of common stock at $35.00 per share to the public. The Company received, in the aggregate, approximately $253.4 million of net proceeds from the offering, after deducting $7.3 million for the underwriting discount and commissions and other stock issuance costs paid by the Company.

(6) STOCK BASED COMPENSATION

Stock Based Compensation Plans

The Company maintains the 2010 Omnibus Long Term Incentive Plan (As Amended and Restated Effective July 27, 2017), the 2010 Employee Stock Purchase Plan, the 2015 Inducement Award Plan, the 2016 Inducement Award Plan and the 2000 Stock Option and Incentive Plan (collectively, the “Stock Plans”).

2000 Stock Option and Incentive Plan. The Company adopted the 2000 Stock Option and Incentive Plan (the “2000 Option Plan”) on October 17, 2000. The 2000 Option Plan expired October 17, 2010 and after such date no further awards could be granted under the plan. Under the terms of the 2000 Option Plan, the Company was authorized to grant incentive stock options, as defined under the Internal Revenue Code, non qualified options, restricted stock awards and other stock awards to employees, officers, directors, consultants and advisors. 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.

The 2000 Option Plan was administered by the compensation committee of the Company’s board of directors, which selected the individuals to whom equity based awards would be granted and determined the option exercise price and other terms of each award, subject to the provisions of the 2000 Option Plan. The 2000 Option Plan provides that upon an acquisition of the Company, all options to purchase common stock 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 options then outstanding under the 2000 Option Plan held by that employee will immediately become exercisable. At December 31, 2018, options to purchase 7,055 shares were 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. The 2010 Stock Plan will expire on July 16, 2020 and after such date no further awards may be granted under the plan. Under the terms of the 2010 Stock Plan, the Company is authorized to grant incentive stock options, as defined under the Internal Revenue Code, non qualified options, restricted stock awards and other stock awards to employees, officers, directors, consultants and advisors. 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.

The 2010 Stock Plan is administered by the compensation committee of the Company's board of directors, which selects the individuals to whom equity based awards will be granted and determines the option exercise price and other terms of each award, subject to the provisions of the 2010 Stock Plan. The 2010 Stock Plan provides that upon an acquisition of the Company, all equity will accelerate by a period of one year. In addition, upon the termination of an employee without cause or for good reason prior to the first anniversary of the completion of the acquisition, all equity awards then outstanding under the 2010 Stock Plan held by that employee will immediately vest. At December 31, 2018, options to purchase 2,524,506 shares were outstanding under the 2010 Stock Plan and 5,789,721 shares of restricted stock and restricted stock units were outstanding. At December 31, 2018, there were 9,071,346 shares available for future grant under the 2010 Stock Plan.

2015 Inducement Award Plan. The Company adopted the 2015 Inducement Award Plan (the "2015 Inducement Plan") on February 9, 2015. The 2015 Inducement Plan expired on July 27, 2015 and after such date no further awards could be granted under the plan. Under the terms of the 2015 Inducement Plan, the Company was authorized to grant

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incentive stock options, as defined under the Internal Revenue Code, non-qualified options, restricted stock awards and other stock awards to employees who were not previously an employee of the Company or any of its Subsidiaries. Options granted under the 2015 Inducement Plan expire ten years from the date of grant. Grants made from the 2015 Inducement Plan generally vest over a period of three to four years.

The 2015 Inducement Plan is administered by the compensation committee of the Company's board of directors, which selects the individuals to whom equity-based awards would be granted and determines the option exercise price and other terms of each award, subject to the provisions of the 2015 Inducement Plan. The 2015 Inducement Plan provides that upon an acquisition of the Company, all equity will accelerate by a period of one year. In addition, upon 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 2015 Inducement Plan held by that employee will immediately vest. At December 31, 2018, there were 38,572 shares of restricted stock and restricted stock units outstanding under the 2015 Inducement Award Plan. At December 31, 2018, there were no shares available for future grant under the 2015 Inducement Plan.

2016 Inducement Award Plan. The Company adopted the 2016 Inducement Award Plan (the "2016 Inducement Plan") on January 25, 2016. The 2016 Inducement Plan expired on July 27, 2017, and after such date no further awards could be granted under the plan. Under the terms of the 2016 Inducement Plan, the Company was authorized to grant incentive stock options, as defined under the Internal Revenue Code, non-qualified options, restricted stock awards and other stock awards to employees who were not previously an employee of the Company or any of its Subsidiaries. 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.

The 2016 Inducement Plan is administered by the compensation committee of the Company's board of directors, which selected the individuals to whom equity-based awards would be granted and determines the option exercise price and other terms of each award, subject to the provisions of the 2016 Inducement Plan. The 2016 Inducement Plan provides that upon an acquisition of the Company, all equity will accelerate by a period of one year. In addition, upon 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 2016 Inducement Plan held by that employee will immediately vest. At December 31, 2018, there were 417,881 shares of restricted stock and restricted stock units outstanding under the 2016 Inducement Award Plan. At December 31, 2018, 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. The 2010 Purchase Plan provides 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, 2020. On July 24, 2014, the Company's stockholders approved an amendment to the 2010 Employee Stock Purchase Plan to increase the number of shares available for purchase thereunder by 500,000 shares. On July 28, 2016 the Company's stockholders approved an amendment to the 2010 Employee Stock Purchase Plan to increase the number of shares available for purchase thereunder by 2,000,000 shares. At December 31, 2018, there were 1,236,537 shares of common stock available for purchase by participating employees under the 2010 Purchase Plan.

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The compensation committee of the Company's board of directors administers 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, 2018, there were 1,563,463 cumulative shares issued under the 2010 Purchase Plan, and 346,609 shares were issued in the year ended December 31, 2018, as follows:

Offering period ended	Number of Shares	Weighted Average price per Share
April 30, 2018	285,013	$ 9.32
October 31, 2018	61,596	$ 36.35

Stock Based Compensation Expense

The Company recorded approximately $60.3 million, $35.5 million, and $23.7 million in stock based compensation expense during the years ended December 31, 2018, 2017, and 2016, respectively, in connection with the amortization of restricted stock and restricted stock unit awards, stock purchase rights granted under the Company's employee stock purchase plan and stock options granted to employees, non employee consultants and non employee directors. Non cash stock based compensation expense by expense category for the years ended December 31, 2018, 2017, and 2016 are as follows:

	December 31,		
(In thousands)	2018	2017	2016
Cost of sales	$ 3,531	$ 1,783	$ 1,064
Research and development	10,189	6,836	4,014
General and administrative	34,181	20,221	14,597
Sales and marketing	12,363	6,672	4,057
Total stock-based compensation	$ 60,264	$ 35,512	$ 23,732

In connection with the November 2016 retirement of the Company's former Chief Financial Officer, the Company modified the vesting of 118,341 shares of his previously unvested restricted stock units whereby such restricted stock units vested on January 1, 2017. He forfeited all other unvested restricted stock units and stock option awards. In the fourth quarter of 2016, the Company recorded $1.5 million of non-cash stock-based compensation expense for the modified award.

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.

Determining Fair Value

Valuation and Recognition—The fair value of each option award is estimated on the date of grant using the Black Scholes option pricing model. The fair value of each market measure-based award is estimated on the date of

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Notes to Consolidated Financial Statements (Continued)

grant using a Monte Carlo simulation pricing model. 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. For awards issued to non-employees, the measurement date is the date when the performance is complete or when the award vests, whichever is earliest. Accordingly, non-employee awards are re-measured at each reporting period until the final measurement date. The fair value of the award is recognized as stock-based compensation expense over the requisite service period, generally the vesting period. The Black-Scholes and Monte Carlo pricing models utilize 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 life of a market measure-based award is based on the applicable performance period.

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 used in the Black Scholes and Monte Carlo valuation models on the implied yield currently available on U.S. Treasury zero coupon issues with an equivalent expected term.

Forfeitures—Effective January 1, 2017, the Company adopted Accounting Standards Update ("ASU") No. 2016-09, Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting ("Update 2016-09"). With the adoption of Update 2016-09, forfeiture estimates are no longer required, and the effects of actual forfeitures are recorded at the time they occur. The impact on the consolidated balance sheet was a cumulative-effect adjustment of $0.4 million, increasing opening accumulated deficit and additional paid-in capital.

The fair value of each option and market measure-based award is based on the assumptions in the following table:

	Year Ended December 31,		
Option Plan Shares	2018	2017	2016
Risk-free interest rates	2.73% - 2.79%	2.1% - 2.2%	1.5% - 1.7%
Expected term (in years)	5.45 - 6.44	6.51 - 6.59	6.25 - 6.74
Expected volatility	61.8% - 66.2%	62.1% - 62.9%	58.9% - 59.4%
Dividend yield	0 %	0 %	0 %
Weighted average fair value per share of options granted during the period	$ 24.55	$ 25.23	$ 3.17

Market Measure-Based Shares			
Risk-free interest rates	(1)	(1)	0.8% - 0.9%
Expected term (in years)	(1)	(1)	2.43 - 2.84
Expected volatility	(1)	(1)	68.3% - 79.6%
Dividend yield	(1)	(1)	0 %
Weighted average fair value per share of stock purchase rights granted during the period	(1)	(1)	$ 3.77
ESPP Shares			
Risk-free interest rates	2.1% - 2.8%	1% - 1.6%	0.4% - 0.8%
Expected term (in years)	0.5 - 2.0	0.5 - 2.0	0.5 - 2.0
Expected volatility	51.7% - 65.4%	45% - 85.5%	70.1% - 92.7%
Dividend yield	0 %	0 %	0 %
Weighted average fair value per share of stock purchase rights granted during the period	$ 20.47	$ 17.87	$ 3.30

(1) The Company did not issue market measure-based shares during the respective period.

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Notes to Consolidated Financial Statements (Continued)

Stock Option, Restricted Stock, and Restricted Stock Unit Activity

A summary of stock option activity under the Stock Plans during the years ended December 31, 2018, 2017 and 2016 is as follows:

Options (Aggregate intrinsic value in thousands)	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value(1)
Outstanding, January 1, 2016	4,936,594	$ 4.80	4.5	
Granted	883,889	5.48		
Exercised	(2,255,959)	1.52		
Forfeited	(59,043)	9.75		
Outstanding, December 31, 2016	3,505,481	$ 7.00	5.5	
Granted	953,097	21.97		
Exercised	(1,067,120)	4.78		
Forfeited	(30,997)	13.90		
Outstanding, December 31, 2017	3,360,461	$ 11.89	6.4	
Granted	343,566	44.37		
Exercised	(1,033,012)	6.42		
Forfeited	(139,454)	24.07		
Outstanding, December 31, 2018	2,531,561	$ 17.86	6.6	$ 114,524
Exercisable, December 31, 2018	1,147,872	$ 12.10	5.2	$ 58,536

(1) The aggregate intrinsic value of options outstanding at December 31, 2018 is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for the 2,531,561 options that had exercise prices that were lower than the $63.10 market price of our common stock at December 31, 2018. The aggregate intrinsic value of options exercisable at December 31, 2018 is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for the 1,147,872 options that had exercise prices that were lower than the $63.10 market price of our common stock at December 31, 2018. The total intrinsic value of options exercised during the years ended December 31, 2018, 2017 and 2016 was $53.0 million, $47.0 million, and $30.5 million, respectively, determined as of the date of exercise.

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Notes to Consolidated Financial Statements (Continued)

A summary of restricted stock and restricted stock unit activity under the Stock Plans during the years ended December 31, 2018, 2017 and 2016 is as follows:

	Restricted Shares	Weighted Average Grant Date Fair Value
Outstanding, January 1, 2016	3,444,694	$ 14.19
Granted	3,960,583	6.90
Released	(796,168)	16.95
Forfeited	(1,007,793)	9.57
Outstanding, December 31, 2016	5,601,316	$ 9.19
Granted	2,035,679	33.04
Released	(1,132,265)	14.24
Forfeited	(355,952)	19.68
Outstanding, December 31, 2017	6,148,778	$ 15.76
Granted	1,686,385	50.49
Released	(1,277,727)	21.66
Forfeited	(311,262)	24.39
Outstanding, December 31, 2018	6,246,174	$ 23.16

As of December 31, 2018, there was approximately $120.8 million of total unrecognized compensation cost related to non vested share based compensation arrangements granted under all equity compensation plans. Total unrecognized compensation cost will be adjusted for future changes in forfeitures. The Company expects to recognize that cost over a weighted average period of 2.8 years.

The Company received approximately $6.6 million, $5.1 million, and $3.4 million from stock option exercises during the years ended December 31, 2018, 2017 and 2016, respectively. During the years ended December 31, 2018, 2017 and 2016, 346,609, 423,423, and 356,823 shares of common stock, respectively, were issued under the Company's 2010 Purchase Plan, resulting in proceeds to the Company of $4.9 million, $2.8 million, and $2.1 million, respectively.

The following table summarizes information relating to currently outstanding and exercisable stock options as of December 31, 2018:

	Outstanding			Exercisable	
Exercise Price	Number of Options	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price

$0.00 - $10.00	973,527	5.4	$ 6.16	604,168	$ 6.57
$10.01 - $15.00	228,032	4.5	12.28	228,032	12.28
$15.01 - $20.00	18,477	5.6	16.52	18,477	16.52
$20.01 - $25.00	980,551	7.5	22.03	281,220	22.45
$25.01 - $30.00	12,608	6.1	26.98	12,608	26.98
$30.01 - $40.00	—	—	—	—	—
$40.01 - $45.00	308,266	8.9	44.37	—	—
$45.01- $49.33	10,100	8.8	49.33	3,367	49.33
	2,531,561	6.6	$ 17.86	1,147,872	$ 12.10

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Notes to Consolidated Financial Statements (Continued)

Shares Reserved for Issuance

The Company has reserved shares of its authorized common stock for issuance pursuant to its employee stock purchase and stock option plans, including all outstanding stock option grants noted above at December 31, 2018, as follows:

	Shares reserved for issuance
2010 Stock Plan	9,071,346
2010 Purchase Plan	1,236,537
	10,307,883

(7) COMMITMENTS AND CONTINGENCIES

Operating Leases

The Company leases a 35,000 square foot manufacturing and office facility in Madison, Wisconsin. This lease has been in effect since 2010. During September 2018, the Company entered into an amended lease agreement. The amended agreement extended the initial term of the lease and is subject to periodic rent escalation adjustments. The Company has two options to extend the term of the lease for one year each. The lease is in effect until February 2025 and is subject to periodic rent escalation adjustments.

The Company leases a 55,000 square foot facility which houses its commercial lab operations in Madison, Wisconsin. This lease has been in effect since 2013. The lease has been amended numerous times with the most recent amendment taking place in March 2018. The amended agreement extended the initial term of the lease and is subject to periodic rent escalation adjustments. The Company has two options to extend the term of the lease for five years each. As part of the lease agreements, the landlord agreed to pay for a portion of leasehold improvements constructed. These payments are recorded as a lease incentive obligation and are amortized over the remaining term of the lease as a reduction of rent expense. The lease is in effect until November 2027 and is subject to periodic rent escalation adjustments. As of December 31, 2018 and 2017, the lease incentive obligation was $0.1 million and $0.7 million, respectively.

The Company leases a 45,000 square foot facility in Madison, Wisconsin for administration purposes. This lease has been in effect since 2014. The lease has been amended several times with the most recent amendment taking place in June 2018. The amended agreement extended the initial term of the lease and is subject to periodic rent escalation adjustments. The Company has six options to extend the lease for up to three months each. The Company has already exercised three of those options. The lease is in effect until June 2020 and is subject to periodic rent escalation adjustments.

The Company leases a 66,000 square foot warehouse facility in Madison, Wisconsin. The lease has been in effect since 2015. The lease has been amended several times with the most recent amendment taking place in October 2017. The amended agreement increased the square footage of leased space and the landlord agreed to pay for a portion of leasehold improvements constructed. The lease is effective until May 2025 and is subject to periodic rent escalation adjustments. The lease includes an option to extend the lease to November 2027. As of December 31, 2018, the lease incentive obligation was $0.9 million.

The Company leases a 26,000 square foot facility which houses a portion of its sales operations in Middleton, Wisconsin. This lease has been in effect since February 2018. The lease is effective until March 2020 and is subject to periodic rent escalation adjustments.

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Notes to Consolidated Financial Statements (Continued)

The Company leases a 48,000 square foot facility in Madison, Wisconsin for research and development purposes. The lease has been in effect since September 2018. The lease is effective until March 2035 and is subject to periodic rent escalation adjustments. See Note 9 for further detail regarding this leased facility.

The Company leases a 5,000 square foot office facility in Salt Lake City, Utah. This lease was acquired as part of the Company's acquisition of Sampleminded. The lease is effective until February 2022 and is subject to periodic rent escalation adjustments.

The Company leases a 10,000 square foot facility in San Diego, California. This lease was acquired as part of the Company's acquisition of Biomatrica. The lease has been in effect since November 2017. The lease is effective until November 2024 and is subject to periodic rent escalation adjustments. As part of the lease agreement, the landlord agreed to pay for a portion of leasehold improvements constructed. These payments are recorded as a lease incentive obligation and are amortized over the remaining term of the lease as a reduction of rent expense. As of December 31, 2018, the lease incentive obligation was $0.6 million.

There is currently a building being constructed in Madison, Wisconsin which will serve as the Company's corporate headquarters. The building is expected to be completed in 2020, at which point the Company will begin leasing it from the landlord with an expected initial term from March 2020 to February 2035. The lease is subject to periodic rent escalation adjustments. See Note 9 for further detail regarding this lease and the Company's accounting considerations under build-to-suit lease accounting.

Future minimum payments under operating leases as of December 31, 2018 are as follows. Amounts included in the table are in thousands.

Year Ending December 31,	
2019	$ 3,861
2020	5,135
2021	4,995
2022	5,027
2023	5,146
Thereafter	44,286
Total lease obligations	$ 68,450

Rent expense included in the accompanying consolidated statements of operations was approximately $3.6 million, $2.6 million, and $2.1 million for the years ended December 31, 2018, 2017 and 2016, respectively.

License Agreements

The Company licenses certain technologies that are, or may be, incorporated into its technology under several license 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. See Note 3 for information related to the Mayo license agreement.

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 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 the Company with non exclusive, worldwide licenses to the Covered Hologic IP within the field of clinical diagnostic purposes relating to colorectal cancer (including cancer diagnosis, treatment, monitoring or staging) and

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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 received FDA approval for its Cologuard test in August 2014 and was required to make a milestone payment of $0.1 million to Hologic, which was expensed to research and development in August 2014. 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.

MDx Health. In July 2010, the Company entered into a technology license and royalty agreement ("MDx License Agreement") with MDx Health (formerly Oncomethylome Sciences, S.A.) ("MDx"). Under the MDx License Agreement, MDx granted the Company a royalty bearing, exclusive, worldwide license to certain patents. Under the MDx License Agreement, the Company was obligated to make commercially reasonable efforts to bring products covered by the license agreement to market. The MDx License Agreement required the Company to pay MDx a low single-digit royalty fee based on a certain percentage of the Company's net sales of the licensed products, including a minimum royalty fee of $0.1 million on each anniversary of the agreement for the life of the contract. The Company also agreed to pay various milestone payments:

- $0.1 million upon the first commercial sale of a licensed product after the receipt of the FDA approval, which the Company paid in 2014;
- $0.2 million after the Company has reached net sales of $10 million of a licensed product after receipt of the FDA approval, which the Company paid in 2015;
- $0.8 million after the Company reached cumulative net sales of $50 million, which the Company paid in 2016;
- $1.0 million after the Company reached net sales of $50 million in a single calendar year, which the Company paid in 2016.

Effective April 2017, the Company and MDx entered into a Royalty Buy-Out Agreement, which terminated the MDx License Agreement. Pursuant to the Royalty Buy-Out Agreement, the Company paid MDx a one-time fee of $8.0 million in exchange for an assignment of certain patents covered by the MDx License Agreement and the elimination of all ongoing royalties and other payments by the Company to MDx under the MDx License Agreement. Also included in the Royalty Buy-Out Agreement is a mutual release of liabilities, which includes all amounts previously accrued under the MDx License Agreement. Concurrently with entering into the Royalty Buy-Out Agreement, the Company entered into a Patent Purchase Agreement with MDx under which it paid MDx an additional $7.0 million in exchange for the assignment of certain other patent rights that were not covered by the MDx License Agreement. The total $15.0 million paid by the Company pursuant to the Royalty Buy-Out Agreement and Patent Purchase Agreement, net of liabilities relieved of $6.6 million, was recorded as an intangible asset and is being amortized over the estimated remaining useful life of the licensed intellectual property through 2024, and such amortization is reported in cost of sales. The $6.6 million of liabilities relieved were related to historical milestones and accrued royalties under the MDx License Agreement.

Armune BioScience & the University of Michigan

In December 2017, the Company entered into the Armune Purchase Agreement with Armune, pursuant to which the Company acquired intellectual property and certain other assets underlying Armune's APIFINY®, APIFINY® PRO

and APIFINY® ACTIVE SURVEILLANCE prostate cancer diagnostic tests. The portfolio of Armune assets the Company acquired is expected to complement its product pipeline. The total consideration was comprised of an up-front cash payment of $12.0 million and $17.5 million in contingent payment obligations that will become payable upon the Company's achievement of development and commercial milestones using the acquired intellectual property. The ability to meet these events is subject to many risks and is therefore uncertain. The Company will not record the contingent consideration until it is probable that the milestones will be met. There is no other consideration due to Armune beyond the milestone payments and the Company is not subject to future royalty obligations should a product be developed and commercialized. In connection with the Armune Purchase Agreement, Armune terminated a license agreement pursuant to which it licensed certain patent rights and know-how from the Regents of the University of

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

Michigan ("University of Michigan"), and the Company entered into a license agreement with the University of Michigan with respect to such patent rights and know-how, as well as certain additional intellectual property rights. Pursuant to the Company's agreement with the University of Michigan, it is required to pay the University of Michigan a low single-digit royalty on its net sales of products using the licensed intellectual property.

(8) ACCRUED LIABILITIES

Accrued liabilities at December 31, 2018 and 2017 consisted of the following:

	December 31,	
(In thousands)	2018	2017
Compensation	$ 37,133	$ 26,399
Assets under construction	32,021	8,797
Professional fees	19,143	5,304
Research and trial related expenses	6,245	3,466
Other	4,052	3,872
Licenses	2,050	1,288
	$ 100,644	$ 49,126

(9) LONG-TERM DEBT

Building Purchase Mortgage

During June 2015, the Company entered into a $5.1 million credit agreement with a third-party financial institution to finance the purchase of a research and development facility located in Madison, Wisconsin. The credit agreement was collateralized by the acquired building.

In September 2018, the Company entered into a Purchase and Sale Agreement with a third-party to sell its research and development facility. The Company also simultaneously entered into a Master Lease Agreement with the

third-party to lease the facility back. The sale-leaseback arrangement is recorded under the financing method of accounting, as the Company has continuing involvement in planned expansions of the facility and construction of the adjacent corporate headquarters facility. Under the financing method, the Company does not recognize the proceeds received from the third-party as a sale of the facility. The facility remains in property, plant and equipment on the Company's consolidated balance sheet, and the consideration of $6.8 million received in the sale is recorded as a financing obligation in other long-term liabilities on the Company's consolidated balance sheet as of December 31, 2018. A portion of the proceeds received from the sale were used to repay the mortgage on the facility, and as of December 31, 2018, the $4.5 million outstanding balance of the mortgage had been fully repaid in connection with the termination of the credit agreement. The remaining proceeds were utilized to fund the initial construction of the Company's corporate headquarters discussed in more detail below.

Prior to the repayment, borrowings under the credit agreement bore interest at 4.15 percent. The Company made interest-only payments on the outstanding principal balance for the period between July 12, 2015 and September 12, 2015. The credit agreement required the Company to make, beginning on October 12, 2015 and continuing through May 12, 2019, monthly principal and interest payments of $31,000, and a final principal and interest payment of $4.4 million would have been due on the maturity date of June 12, 2019.

Additionally, the Company previously recorded $73,000 in deferred financing costs, which were recorded as a direct deduction from the mortgage liability. The issuance costs were being amortized through June 12, 2019. The Company recorded $13,000, $18,000 and $18,000 in amortization of mortgage issuance costs during the years ended December, 31, 2018, 2017, and 2016, respectively. As of December 31, 2018, the outstanding balance of the mortgage issuance costs was written down to $0 due to the sale of the facility and the payoff of the mortgage.

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Revolving Loan Agreement

During December 2017 the Company entered into a revolving loan agreement (the "Revolving Loan Agreement") with MB Financial Bank, N.A. ("MB Bank"). The Revolving Loan Agreement provides the Company with a 24-month secured revolving credit facility of up to $15.0 million (the "Revolver"). The Revolver is collateralized by the Company's accounts receivable and inventory. The Revolver is available for general working capital purposes and all other lawful corporate purposes; provided that the Company may not use the Revolver to purchase or carry margin stock.

Borrowings under the Revolving Loan Agreement accrue interest at one of the following per annum rates, as elected by the Company (i) the sum of the 1-month LIBOR rate plus 2.00 percent, (ii) the sum of the 3-month LIBOR rate plus 2.00 percent, or (iii) the MB Bank Reference Rate minus 0.5 percent. Loans under the Revolving Loan Agreement may be prepaid at any time without penalty. The Revolver's maturity date is December 10, 2019.

The Company has agreed in the Revolving Loan Agreement to various financial covenants including minimum liquidity and minimum tangible net worth. At December 31, 2018, the Company is in compliance with all covenants.

As of December 31, 2018, the Company has not drawn funds from, nor are any amounts outstanding under, the Revolving Loan Agreement.

Construction Loan Agreement

During December 2017, the Company entered into a loan agreement with MB Bank (the "Construction Loan Agreement"), which provides the Company with a non-revolving construction loan (the "Construction Loan") of $25.6 million. The Company will use 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, MB 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 MB Bank’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 accordance with the Construction Loan Agreement, the Company will make monthly interest-only payments through November 2019. Starting in December 2019, the Company will make monthly payments towards the outstanding principal balance due plus accrued interest. As of December 31, 2018, the Company has drawn $24.7 million from the Construction Loan, including $0.4 million of interest incurred, which is included in accrued interest on the Company’s consolidated financial statements. The Company capitalized the $0.4 million to the construction project.

Additionally, the Company has recorded deferred financing costs of $0.2 million related to the Construction Loan. These deferred financing costs are recorded as a reduction to long-term debt in the consolidated balance sheets. The deferred financing costs are being amortized through December 10, 2022. The Company has recorded $45,000 in

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Notes to Consolidated Financial Statements (Continued)

amortization of deferred financing costs related to the Construction Loan for the year ended December 31, 2018. There was no amortization expense recorded for the year ended December 31, 2017.

The Company has agreed in the Construction Loan Agreement to various financial covenants including minimum liquidity and minimum tangible net worth. As of December 31, 2018, the Company is in compliance with all covenants.

The table below represents the future principal obligations as of December 31, 2018. Amounts included in the table are in thousands:

Year ending December 31,	
2019	$ 8
2020	96
2021	105
2022	24,051
	$ 24,260

Build-to-Suit Leases

The Company evaluates whether it is the accounting owner of leased assets during the construction period when the Company is involved in the construction of the leased asset. Due to funding provided by the Company for costs related to the construction of the Company's new Madison, WI, headquarters, as of December 31, 2018, the Company is considered, for accounting purposes only, the owner of the construction project in accordance with build-to-suit accounting. As of December 31, 2018, the Company has contributed $4.5 million towards the project. All project construction costs incurred over that amount are to be paid by the landlord, though the Company will account for those costs as assets under construction with a corresponding liability. As of December 31, 2018, the Company recorded a total of $7.3 million in construction costs related to this project, including $2.1 million funded by the landlord, which is included as a financing obligation and recorded in other long-term liabilities. An additional $0.7 million has been funded by the Company for leasehold improvements which are not considered part of the build-to-suit lease.

The construction project is expected to be completed in 2020.

(10) CONVERTIBLE NOTES

In January 2018, the Company issued and sold $690.0 million in aggregate principal amount of 1.0% Convertible Notes (the “January 2018 Notes”) with a maturity date of January 15, 2025 (the “Maturity Date”). The January 2018 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 2018 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 2018 Notes”). The June 2018 Notes were issued under the same indenture pursuant to which the Company previously issued the January 2018 Notes (the “Indenture”). The January 2018 Notes and the June 2018 Notes (collectively, the “Notes”) have identical terms and will be treated as a single series of securities. The net proceeds from the issuance of the June 2018 Notes were approximately $225.3 million, after deducting underwriting discounts and commissions and the offering expenses payable by the Company.

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Prior to July 15, 2024, the Notes are convertible only upon the occurrence of certain events and during certain periods, as set forth in the Indenture, and thereafter, until the close of business on the second scheduled trading day immediately preceding the Maturity Date. The Notes will be convertible into cash, shares of the Company's common stock (plus, if applicable, cash in lieu of any fractional share), or a combination of cash and shares of the Company's common stock, at the Company's election. On or after July 15, 2024, until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their Notes at any time.

It is the Company's intent and policy to settle all conversions through combination settlement. The initial conversion rate for the Notes is 13.2569 shares of common stock per $1,000 principal amount, which is equivalent to an initial conversion price of approximately $75.43 per share of the Company's common stock. 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.

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.

While the Notes are currently classified on the Company's consolidated balance sheets at December 31, 2018 as long-term, 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.

Under current accounting guidance, an entity must separately account for the liability and equity components of convertible debt instruments (such as the January 2018 Notes and June 2018 Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The liability component of the instrument was valued in a manner that reflects the market interest rate for a similar nonconvertible instrument at the date of issuance. On the January 2018 Notes, the initial carrying value of the liability component of $495.1 million was calculated using a 6.0% assumed borrowing rate. The equity component of $194.9 million, representing the conversion option, was determined by deducting the fair value of the liability component from the par value of the January 2018 Notes and is recorded in additional paid-in capital on the Company's consolidated balance sheet at the issuance date. That equity component is treated as a discount on the liability component of the January 2018 Notes, which is amortized over the seven-year term of the January 2018 Notes using the effective interest rate method. The equity component is not re-measured as long as it continues to meet the conditions for equity classification. On the June 2018 Notes, the initial carrying value of the liability component of $159.7 million was calculated using a 6.0% assumed borrowing rate. The equity component of $73.0 million, representing the conversion option, was determined by deducting the fair value of the liability component from the par value of the June 2018 Notes and adding in the premium at which the June 2018 Notes were sold. This is recorded in additional paid-in capital on the Company's consolidated balance sheet at the issuance date. That equity component, prior to adding in the premium, is treated as a discount on the liability component of the June 2018 Notes, which is amortized over the remaining term of six-and-a-half years of the June 2018 Notes using the effective interest rate method. The equity component is not re-measured as long as it continues to meet the conditions for equity classification.

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Notes to Consolidated Financial Statements (Continued)

The Company allocated the total transaction costs of approximately $18.8 million related to the issuance of the January 2018 Notes to the liability and equity components of the January 2018 Notes based on their relative values, with $13.1 million being allocated to the liability component of the January 2018 Notes. Transaction costs attributable to the liability component are amortized to interest expense over the seven-year term of the January 2018 Notes, and transaction costs attributable to the equity component are netted with the equity component in stockholders' equity.

The Company allocated the total transaction costs of approximately $7.4 million related to the issuance of the June 2018 Notes to the liability and equity components of the June 2018 Notes based on their relative values, with $5.1 million being allocated to the liability component of the June 2018 Notes. Transaction costs attributable to the liability component are amortized to interest expense over the remaining six-and-a-half-year term of the June 2018 Notes, and transaction costs attributable to the equity component are netted with the equity component in stockholders' equity.

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.

Convertible notes, net of discounts and deferred financing costs at December 31, 2018, consisted of the following:

(In thousands)	
Principal	$ 908,500
Debt discount, net	(227,403)
Deferred financing costs	(16,348)
Net carrying amount	$ 664,749

(11) EMPLOYEE BENEFIT PLAN

The Company maintains a qualified 401(k) retirement savings plan (the “401(k) Plan”) covering all employees. 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, 2018, 2017 and 2016 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 $7.4 million, $3.0 million, and $2.2 million, respectively, in the statements of operations for the years ended December 31, 2018, 2017 and 2016 in connection with 401(k) Plan matching contributions.

(12) 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. Through its participation in this program, the Company has secured low interest financing and the potential for future debt forgiveness related to the Madison, Wisconsin facility. Upon closing of this transaction, the Company provided an aggregate of approximately $5.1 million to the Investor, in the form of a loan receivable, with a term of seven years, bearing an interest rate of 2.74 percent per annum. This $5.1 million in proceeds plus $2.4 million of capital from the Investor was used to make an aggregate $7.5 million loan to a subsidiary of the Company. This financing arrangement is not secured by any assets of the Company. On December 1, 2021, the Company would receive a repayment of its approximately $5.1 million loan. The $5.1 million is eliminated in the consolidation of the financial statements. This transaction also includes a put/call feature

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

that becomes enforceable at the end of the seven-year compliance period. The Investor may exercise its put option or the Company can exercise the call, both of which will serve to trigger forgiveness of the debt. The value attributable to the put/call is nominal. The $2.4 million was recorded in other long-term liabilities on the Company's balance sheet. The benefit of this net $2.4 million contribution will be recognized as a decrease in expenses, included in cost of sales, as the Company amortizes the contribution liability over the seven-year compliance period as it is being earned through the Company's on-going compliance with the conditions of the NMTC program. The Company recorded $0.3 million as a decrease of expenses for the years ended December 31, 2018, 2017, and 2016. At December 31, 2018, the remaining balance of $1.0 million is included in other long-term liabilities. The Company incurred approximately $0.2 million of debt issuance costs related to the above transactions, which are being amortized over the life of the agreements.

The Investor is subject to 100 percent recapture of the NMTC it receives for a period of seven years as provided in the Internal Revenue Code and applicable U.S. Treasury regulations. The Company is required to be in compliance 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 underling 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.

Also in December 2014, in connection with the NMTC transaction, the Company entered into a land purchase option agreement with the owner of certain real property (land) adjacent to certain of the Company's current Madison,

Wisconsin facilities. The option is renewable annually in exchange for a fee. If the Company exercises its land purchase option, it will pay a fixed amount for the land. That fixed amount approximates the then-current fair value of the land. If the Company decides not to exercise its option, then on December 31, 2021 (which is after the seven-year compliance period of the NMTC program), the Company must pay $1.2 million to the community development entity. As discussed below, the community development entity is a variable interest entity consolidated into the Company. The community development entity would then distribute this money to its members. The majority member of the community development entity is also the owner of the land subject to the land purchase option. The Company has recorded the obligation and the land purchase option asset for $1.2 million to reflect the Company's assessment that it is probable that at least $1.2 million will be paid in the future based on resolution of the land purchase option. The asset is included in other long-term assets and the liability is included in other long-term liabilities on the consolidated balance sheet.

(13) 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 if the Company expends $26.3

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Notes to Consolidated Financial Statements (Continued)

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, 2018, the Company has earned $9.0 million of tax credits and has received payment of $4.3 million from the WEDC. The unpaid portion is $4.7 million, of which $1.6 million is reported in prepaid expenses and other current assets and $3.1 million is reported in other long-term assets, reflecting when collection of the refundable tax credits is expected to occur. As of December 31, 2018, the Company also has recorded a $2.4 million liability in other short-term liabilities and a $2.2 million liability in other long-term liabilities, reflecting when the expected benefit of the tax credit amortization will reduce future operating expenses.

During the year ended December 31, 2018, the Company amortized $2.2 million of the tax credits earned as a reduction of operating expenses.

(14) ACQUISITIONS

In August 2017, the Company acquired all of the outstanding equity of Sampleminded, the primary operations of which were customized software development for laboratory information systems and clinical information systems, for cash consideration of $3.2 million and 86,357 of the Company’s restricted stock units. Prior to the acquisition, Sampleminded provided certain consulting and software support services to the Company, and it licensed certain software to the Company. The restricted stock units were recorded by the Company as employee stock-based compensation because their vesting is contingent upon continued employment with the Company of certain former stockholders of Sampleminded. The $3.2 million of cash consideration was allocated to the estimated fair market value of the net (current or tangible) assets acquired of $0.2 million, $1.0 million in identifiable intangible assets

(comprised of developed technology, customer relationships and non-compete agreements) and a residual amount of goodwill of $2.0 million. The purposes of acquisition were to invest in a technology complementary to the Company's core business, to reduce costs by bringing certain technology and expertise in-house and to prepare for anticipated future growth.

In November 2017, the Company made a $3.0 million cash investment (the "2017 Biomatrica Investment") in Biomatrica, Inc. ("Biomatrica"), then a privately held company specializing in the collection and preservation of biological materials. The Company made the 2017 Biomatrica Investment in connection with entering into an agreement for Biomatrica to supply certain products to the Company. Through the 2017 Biomatrica Investment, the Company acquired shares of Biomatrica's Series E Preferred Stock representing 10 percent, of Biomatrica's then-outstanding shares of capital stock on an as-converted basis.

The 2017 Biomatrica Investment did not constitute a variable interest entity, as the Company did not have control over the supplier's business. Additionally, as the ownership percentage was below 20 percent, the equity method was not used to account for the investment. There were no quoted prices or observable pricing inputs available for Biomatrica's stock. Therefore, the Company accounted for the 2017 Biomatrica Investment at cost, less any impairments, plus or minus changes resulting from observable price changes in orderly transactions for an identical or similar investment. The carrying value of the 2017 Biomatrica Investment was $3.0 million as of December 31, 2017 and was reported in other

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Notes to Consolidated Financial Statements (Continued)

long-term assets in the Company's consolidated balance sheets.

In October 2018, the Company completed a full acquisition of Biomatrica. In the acquisition, the Company acquired all of the outstanding equity interests for an aggregate purchase price of $20.0 million net of cash received, debt repaid and certain other adjustments. Contingent consideration for an additional $20.0 million could be earned based upon certain revenue milestones being met. The purpose of the acquisition was to secure a key supplier for the Company's pipeline products and expand the Company's commercial offerings.

During 2018, the Company incurred approximately $0.6 million of acquisition-related costs associated with this transaction. These costs and expenses include fees associated with financial, legal, and accounting advisors.

The total purchase consideration for the 2018 Biomatrica Acquisition was $24.5 million consisting of a cash payment at closing of $17.9 million including $0.1 million for a post-closing working capital adjustment, contingent consideration payable in cash and having a fair value of $3.4 million, exchange of Series E Preferred stock with an acquisition date fair value of $2.2 million and the reduction of a $1 million Senior Secured Promissory Note and Security Agreement previously provided to Biomatrica and considered part of the consideration transferred. The Company's previously held Series E Preferred stock ownership and the contingent consideration fair value were determined through a valuation using the income approach and involved significant unobservable inputs including revenue and operating margin forecasts, an applicable tax rate, a terminal growth rate and discount rate (Level 3). The valuation of the previously held investment indicated a loss on the investment of $0.8 million. The contingent consideration has been recognized in other long-term liabilities in the consolidated financial statements. The total purchase consideration was allocated to the underlying assets acquired and liabilities assumed based upon their estimated fair values at the date of acquisition as follows:

(In thousands)	
Net operating assets	2,168
Goodwill	15,300
Trade name	700
Customer relationships and contracts	2,700
Developed technology	5,400
Net operating liabilities	(1,754)
Total purchase price	24,514

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. The customer relationships are valued using the multi-period excess earnings method.

Trade names represent the value identified associated with the Biomatrica trade name in the market. The trade name intangible is amortized on a straight-line basis over its estimated useful life of 15 years.

Developed technology represents purchased technology that had reached technological feasibility and for which Biomatrica had substantially completed development as of the date of acquisition. 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.

Customer relationships and contracts represent agreements with existing Biomatrica customers. Customer relationships and contracts are amortized on a straight-line basis over their estimated useful life of 15 years.

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Notes to Consolidated Financial Statements (Continued)

The goodwill generated from the acquisition of Biomatrica is primarily related to expected synergies. The total goodwill related to this acquisition is not deductible for tax purposes.

The initial accounting for the business combination was not complete at the time the financial statements were issued. Limitations on the use and carryforward of the net operating losses acquired from Biomatrica are being analyzed under IRS section 382.

The partial year results for Biomatrica's operations 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.

(15) 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, 2018, the Company had federal net operating loss, state net operating loss, and foreign net operating loss carryforwards of approximately $937.4 million, $403.5 million, and $7.8 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 $17.4 million and $7.5 million, respectively which may be used to offset future income tax liability. The federal credit carryforwards expire at various dates through 2038 and are subject to review and possible adjustment by the Internal Revenue Service. A portion of the state credit carryforwards expired in 2018 and the remainder begin to expire in 2019 through 2033 and are subject to review and possible adjustment by state 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.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act makes broad and complex changes to the U.S. tax code, including, but not limited to, the following that impacts the Company: (1) reducing the U.S. federal corporate income tax rate from 35 percent to 21 percent; (2) eliminating the corporate alternative minimum tax; (3) creating a new limitation on deductible interest expense; (4) limiting the deductibility of certain executive compensation; and (5) limiting certain other deductions.

The expense (benefit) for income taxes consists of:

	December 31,		
(In thousands)	2018	2017	2016
Current	$ 92	$ 106	$ —
Deferred	—	(293)	—
Total Tax Expense (Benefit)	$ 92	$ (187)	$ —

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

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)	2018	2017
Deferred tax assets:		
Operating loss carryforwards	$ 226,276	$ 186,963
Tax credit carryforwards	21,417	13,818
Other temporary differences	24,368	13,799
Tax assets before valuation allowance	272,061	214,580
Less - Valuation allowance	(209,868)	(214,250)
Total deferred tax assets	$ 62,193	$ 330
Deferred tax liabilities		
Convertible notes	$ (55,698)	$ —
Amortization	(2,182)	(126)
Fixed assets	(3,966)	—
Other temporary differences	(347)	(204)
Total deferred tax liabilities	(62,193)	(330)
Net deferred taxes	$ —	$ —

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, management has determined that a valuation allowance of $209.9 million and $214.3 million at December 31, 2018 and 2017, respectively, is necessary to reduce the tax assets to the amount that is more likely than not to be realized. The change in valuation allowance for December 31, 2018 and 2017 was a decrease of $4.4 million and $45.8 million, respectively, as revised for the correction of the immaterial items described below. Due to the existence of the valuation allowance, future changes in the Company’s unrecognized tax benefits will not impact the Company’s effective tax rate.

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

	December 31,		
	2018	2017	2016
U.S. Federal statutory rate	21.0 %	35.0 %	35.0
State taxes	3.4	2.4	2.4
Federal and state tax rate changes	—	(99.2)	0.5
Foreign tax rate differential	—	0.1	(0.4)
Research and development tax credits	1.9	(1.9)	0.9

Stock-based compensation expense	9.1	16.7	(0.6)
Non-deductible executive compensation	(4.9)	(10.7)	(5.1)
Other adjustments	1.1	(2.6)	(0.6)
Valuation allowance	(31.7)	60.4	(32.1)
Effective tax rate	(0.1) %	0.2 %	0.0

During preparation of the 2018 financial statements, the Company corrected the prior year balance of deferred tax assets relating to net operating loss carryovers and other temporary differences, as well as the valuation allowance related to those assets by an equal and offsetting amount. The correction related to the application of §162(m) on the deductibility of executive compensation. At December 31, 2017, the deferred tax assets and related valuation allowance were adjusted by $19.6 million in the table above, as a result of these corrections. Additionally, non-deductible executive compensation has been added as a separate line item in the rate reconciliation, the federal and state tax rate changes were

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Notes to Consolidated Financial Statements (Continued)

decreased by 9.8% for 2017 and the valuation allowance was decreased by 5.5% for 2016. The Company carries a full valuation allowance against net deferred tax assets, therefore these immaterial adjustments to the disclosures had no effect on the consolidated balance sheets, statements of operations and cash flows for the year ended December 31, 2018, 2017, and 2016.

During 2018, the Company engaged in a research and development tax credit study for its historical tax credit carryovers. As a result of this study, the Company claimed an additional $5.0 million of federal and $2.2 million of state research and development credits. The credits are available to be carried forward. The study identified uncertain tax benefits of $1.9 million related to federal and state research and development tax credits. These amounts have been recorded as a reduction to our deferred tax assets. A valuation allowance was recorded against these attributes at December 31, 2017, therefore there was no impact to income tax expense as a result of recording the unrecognized tax benefits during the year ended December 31, 2018. Included in the balance of unrecognized tax benefits as of December 31, 2018 are $1.9 million of tax benefits that, if recognized, would affect the effective tax rate.

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

	December 31,	
(In thousands)	2018	2017
January 1,	$ —	$ —
Increase due to current year tax positions	392	—
Increase due to prior year tax positions	1,534	—
Decrease due to prior year tax positions	—	—
Settlements	—	—
December 31,	$ 1,926	$ —

As of December 31, 2018, 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 1999 through 2018, and to state income tax examinations for the tax years 2003 through 2018. 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, 2018, 2017 and 2016.

(16) RELATED PARTY TRANSACTIONS

In May 2017, the Company entered into a professional services agreement for recruiting and related services with a firm whose principal is a non-employee director. The Company incurred charges of $0.3 million and made payments of $0.3 million for the year ended December 31, 2018. The Company incurred charges of $0.2 million and made payments of $0.2 million for the year ended December 31, 2017.

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Notes to Consolidated Financial Statements (Continued)

(17) 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, 2018 and 2017. In the opinion of management, this information has been prepared on the same basis as the audited consolidated financial statements appearing elsewhere in this Form 10 K, and all necessary adjustments, consisting only of normal recurring adjustments, have been included in the amounts stated below to present fairly the unaudited quarterly results of operations. The quarterly data should be read in conjunction with the Company's audited consolidated financial statements and the notes to the consolidated financial statements appearing elsewhere in this Form 10 K.

	Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
	(Amounts in thousands, except per share data)			
2018				
Revenue	$ 90,296	102,894	118,291	142,981
Cost of revenue	22,914	26,888	30,020	38,160
Gross margin	67,382	76,006	88,271	104,821
Research and development	14,935	14,712	17,631	20,932
General and administrative	35,567	39,565	46,729	56,432
Sales and marketing	53,408	54,431	64,836	76,773
Loss from operations	(36,528)	(32,702)	(40,925)	(49,316)
Investment income	3,673	4,917	6,292	6,321
Interest expense	(6,510)	(8,603)	(10,704)	(10,972)
Net loss before tax	(39,365)	(36,388)	(45,337)	(53,967)
Income tax benefit (expense)	(59)	1	(27)	(7)
Net loss	$ (39,424)	$ (36,387)	$ (45,364)	$ (53,974)
Net loss per share—basic and diluted	$ (0.33)	$ (0.30)	$ (0.37)	$ (0.44)
Weighted average common shares outstanding—basic and diluted	121,016	122,129	122,671	122,981
2017				
Revenue	$ 48,363	57,646	72,574	87,406
Cost of revenue	16,981	17,991	20,729	23,495
Gross margin	31,382	39,655	51,845	63,911
Research and development	8,002	9,737	11,725	12,675
General and administrative	20,070	24,609	30,763	33,598
Sales and marketing	38,801	36,728	37,768	40,627
Loss from operations	(35,491)	(31,419)	(28,411)	(22,989)
Investment income	595	683	1,334	1,320
Interest expense	(50)	(54)	(51)	(51)
Net loss before tax	(34,946)	(30,790)	(27,128)	(21,720)
Income tax benefit (expense)	—	—	231	(44)
Net loss	$ (34,946)	(30,790)	(26,897)	(21,764)

Net loss per share—basic and diluted	$ (0.32)	$ (0.27)	$ (0.23)	$ (0.18)
Weighted average common shares outstanding—basic and diluted	110,582	112,847	119,215	119,950

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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 these disclosure controls and procedures were effective as of December 31, 2018 to provide reasonable assurance that information required to be disclosed by us in reports that we file 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, 2018, 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 effective 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 designed to provide reasonable assurance to the Company's management and board of directors regarding the preparation and fair presentation of published financial statements in accordance with generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2018. 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, we concluded that, as of December 31, 2018, our internal control over financial reporting was effective based on those criteria.

Our independent registered public accounting firm, BDO USA, LLP, has issued an audit report on the effectiveness of our internal control over financial reporting as of December 31, 2018, which is included herein.

Item 9B. Other Information

None.

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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 2019 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 2019 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 2019 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 2019 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 2019 Annual Meeting of Stockholders: “Independent Registered Public Accounting Firm” and “Pre Approval Policies and Procedures.”

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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
3.1	Sixth Amended and Restated Certificate of Incorporation of the Registrant		S-1 (Exhibit 3.3)	12/4/00	333-48812
3.2	First Amendment to Sixth Amended and Restated Certificate of Incorporation of the Registrant		DEF 14A (Appendix B)	6/20/14	001-35092
3.3	Third Amended and Restated By-Laws of the Registrant		10-Q (Exhibit 3.3)	10/30/17	001-35092
4.1	Specimen certificate representing the Registrant’s Common Stock		S-1 (Exhibit 4.1)	12/26/00	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)	1/17/18	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)	1/17/18	001-35092

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Lease Agreements

10.1	Second Amended and Restated Lease Agreement, dated September 28, 2018, by and between University Research Park Incorporated and the Registrant	X			
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)	8/2/13	001-35092

Agreements with Executive Officers and Directors

10.3*	Employment Agreement dated March 18, 2009 by and between Kevin T. Conroy and the Registrant		8-K (Exhibit 10.1)	3/18/09	000-32179
10.4*	Employment Agreement dated October 30, 2015 by and between Scott Coward and the Registrant		10-K (Exhibit 10.7)	2/24/16	001-35092
10.5*	Employment Agreement dated August 1, 2009 by and between Graham Lidgard and the Registrant		10-Q (Exhibit 10)	11/12/09	000-32179
10.6*	Employment Agreement dated November 8, 2016 by and between Jeffrey T. Elliott and the Registrant		10-K (Exhibit 10.9)	2/21/17	001-35092
10.7*	Employment Agreement dated April 2, 2018 by and between Mark Stenhouse and the Registrant		10-Q (Exhibit 10.2)	10/30/18	001-35092
10.8*	Employment Agreement dated September 11, 2017 by and between Scott Johnson and the Registrant	X			
10.9*	Employee Transition Agreement dated April 25, 2018 by and between Maneesh Arora and the Registrant		10-Q (Exhibit 10.4)	4/26/18	001-35092

Equity Compensation Plans and Policies

10.10*	2000 Stock Option and Incentive Plan	10-K (Exhibit 10.2)	3/31/09	000-32179
10.11*	The Registrant's 2010 Employee Stock Purchase Plan	DEF 14A (Appendix B)	4/30/10	000-32179

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10.12*	First Amendment to the Registrant's 2010 Employee Stock Purchase Plan	DEF 14A (Appendix A)	6/20/14	001-35092
10.13*	Second Amendment to the Registrant's 2010 Employee Stock Purchase Plan	DEF 14A (Appendix A)	4/29/16	001-35092
10.14*	The Registrant's 2016 Inducement Award Plan	10-Q (Exhibit 10.3)	5/3/16	001-35092
10.15*	The Registrant's 2016 Inducement Award Plan Form Restricted Stock Unit Award Agreement	S-8 (Exhibit 4.7)	5/3/16	333-211099
10.16*	The Registrant's 2010 Omnibus Long Term Incentive Plan (As Amended and Restated Effective July 27, 2017)	10-Q (Exhibit 10.1)	10/30/17	001-35092
10.17*	The Registrant's 2010 Omnibus Long Term Incentive Plan (As Amended and Restated Effective July 27, 2017) Form Incentive Stock Option Award Agreement	10-K (Exhibit 10.31)	2/22/18	001-35092
10.18*	The Registrant's 2010 Omnibus Long Term Incentive Plan (As Amended and Restated Effective July 27, 2017) Form Restricted Stock Award Agreement	10-K (Exhibit 10.32)	2/22/18	001-35092
10.19*	The Registrant's 2010 Omnibus Long Term Incentive Plan (As Amended and Restated Effective July 27, 2017) Form Restricted Stock Unit Award Agreement	10-K (Exhibit 10.33)	2/22/18	001-35092
10.20*	The Registrant's Non-Employee Director Compensation Policy dated January 29, 2019	X		
10.21*	The Registrant's Non-Employee Director Compensation Policy dated October 25, 2018	X		
10.22*	The Registrant's Executive Deferred Compensation Plan dated January 1, 2019	X		

Credit Agreements

10.23	Loan and Security Agreement, dated as of December 15, 2017, by and among MB Financial Bank, N.A., the Registrant and Exact Sciences Laboratories, LLC	8-K	12/18/17	001-35092

		(Exhibit 10.1)		
10.24	Loan Agreement, dated as of December 15, 2017, by and between MB Financial Bank, N.A. and CG Growth LLC	8-K (Exhibit 10.2)	12/18/17	001-35092

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Other

10.25**	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)	3/12/10	000-32179	
10.26**	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)	3/1/13	001-35092	
10.27**	Amended and Restated License Agreement dated effective January 31, 2015, by and between the Registrant and Mayo Foundation for Medical Education and Research	10-Q (Exhibit 10.1)	5/4/15	001-35092	
10.28**	First Amendment dated effective July 1, 2015 to Amended and Restated License Agreement dated effective January 31, 2015, by and between the Registrant and Mayo Foundation for Medical Education and Research	10-Q/A (Exhibit 10.2)	6/3/16	001-35092	
10.29**	Second Amendment dated effective October 1, 2017 to Amended and Restated License Agreement dated effective January 31, 2015, by and among the Registrant, Mayo Foundation for Medical Education and Research and Exact Sciences Development Company, LLC	10-K (Exhibit 10.21)	2/22/18	001-35092	
10.30**	Third Amendment dated effective October 1, 2017 to Amended and Restated License Agreement dated effective January 1, 2019, by and among the Registrant, Mayo Foundation for Medical Education and Research and Exact Sciences Development Company, LLC	X			
10.31**	License Agreement dated July 26, 2010 by and between MDx Health S.A. and the Registrant	10-K (Exhibit 10.25)	2/28/14	001-35092	
10.32**	Addendum dated May 6, 2011 to License Agreement dated July 26, 2010 by and between MDx Health S.A. and the Registrant	10-K (Exhibit 10.26)	2/28/14	001-35092	
10.33	Royalty Buy-Out Agreement by and between MDx Health S.A. and the Registrant, dated April 25, 2017	8-K (Exhibit 10.1)	4/27/17	001-35092	

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10.34	Promotion Agreement dated August 21, 2018 between the Registrant and Pfizer, Inc.	8-K (Exhibit 10.1)	8/22/18	001-35092
21	Subsidiaries of the Registrant	X		
23.1	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	Interactive Data Files	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.

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SIGNATURES

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

EXACT SCIENCES CORPORATION

Date: February 21, 2019 By: /s/ Kevin T. Conroy

Kevin T. Conroy
President & Chief Executive Officer

POWER OF ATTORNEY AND SIGNATURES

We, the undersigned officers and directors of Exact Sciences Corporation, hereby severally constitute and appoint Kevin T. Conroy our true and lawful attorney, with full power to him to sign for us and in our names in the capacities indicated below, any amendments to this Annual Report on Form 10 K, and generally to do all things in our names and on our behalf in such capacities to enable Exact Sciences Corporation to comply with the provisions of the Securities Exchange Act of 1934, as amended, and all the requirements of the Securities Exchange Commission.

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

Name	Title	Date
/s/ Kevin T. Conroy Kevin T. Conroy	President and Chief Executive Officer (Principal Executive Officer) and Chairman of the Board	February 21, 2019
/s/ Jeffrey T. Elliott Jeffrey T. Elliott	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 21, 2019

/s/ Thomas D. Carey Thomas D. Carey	Director	February 21, 2019
/s/ Eli Casdin Eli Casdin	Director	February 21, 2019
/s/ James E. Doyle James E. Doyle	Director	February 21, 2019
/s/ John A. Fallon M.D. John A. Fallon	Director	February 21, 2019
/s/ Daniel J. Levangie Daniel J. Levangie	Director	February 21, 2019
/s/ David Thompson David Thompson	Lead Independent Director	February 21, 2019
/s/ Michael S. Wyzga Michael S. Wyzga	Director	February 21, 2019
/s/ Katherine Zanotti Katherine Zanotti	Director	February 21, 2019

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