EXACT SCIENCES CORP
Form 10-K
February 21, 2017
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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, 2016
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, $.01 Par Value (including attached Preferred Stock Purchase Rights)	The NASDAQ Stock Market LLC (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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting 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

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 $1,177,885,275 (based on the closing price of the Registrant's Common Stock on June 30, 2016 of $12.25 per share).

The number of shares outstanding of the Registrant's $.01 par value Common Stock as of February 20, 2017 was 110,603,808.

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, 2016. 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, 2016

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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," "could," "seek," "intend," "plan," "estimate," "an 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 payor 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 payors to cover Cologuard and reimburse us for our performance of the Cologuard test; the amount and nature of competition from other cancer screening 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 healthcare pricing, coverage and reimbursement; 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 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 currently 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 diagnostics.

Our Cologuard Test

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

- 135,000 new cases of colorectal cancer
- 50,000 deaths from colorectal cancer

Colorectal cancer treatment represents a significant, growing healthcare cost. As of 2010, $14 billion was spent annually in the U.S. on colorectal cancer treatment, and the projected annual treatment costs are expected to be $20 billion in 2020. The incidence of colorectal cancer in Medicare patients is expected to rise from 106,000 cases in 2010 to more than 180,000 cases in 2030.

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. Accordingly, the American Cancer Society ("ACS") recommends that all people age 50 and older undergo regular colorectal cancer screening. Of the more than 80 million people in the U.S. for whom routine colorectal cancer screening is recommended, 42 percent have not been screened according to current guidelines. 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 67 percent and 12 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 which utilizes a multi-target approach to detect DNA and hemoglobin biomarkers associated with colorectal cancer and pre-cancer. Ten 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.

On August 11, 2014 the U.S. Food and Drug Administration ("FDA") approved Cologuard for use as the first and only sDNA non-invasive colorectal cancer screening test. Our 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%

The competitive advantages of sDNA screening may provide a significant market opportunity. If the test were used by 30-percent of the eligible screening population at a three-year screening interval rate, we estimate the potential U.S. market for sDNA screening would be more than $4 billion, annually.

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Our Cologuard Commercialization Strategy

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

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 enroll them in our physician ordering system to enable them to prescribe the test. We focus on specific physicians based on Cologuard order history and on physician groups and larger regional and national health systems.

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 US 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 (which is Cologuard).

Professional colorectal cancer screening guidelines in the U.S., including those of the ACS, the American College of Gastroenterology (“ACG”), the American Gastroenterological Association (“AGA”) and the National Comprehensive Cancer Network (“NCCN”), recommend regular screening by a variety of methods. Since 2008, joint colorectal cancer screening guidelines endorsed by the ACS and the U.S. Multi-Society Task Force on Colorectal Cancer (“CRC Task Force”) have included sDNA screening technology as a screening option for the detection of colorectal cancer in average risk, asymptomatic individuals age 50 and older. The CRC Task Force is a consortium of several organizations that includes representatives of the ACG, AGA, the American Society for Gastrointestinal Endoscopy, and the American College of Physicians/Society of Internal Medicine. In October 2014, the ACS updated its colorectal cancer screening guidelines to specifically include Cologuard as a recommended sDNA screening test. 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 October 2016, the National Committee for Quality Assurance (“NCQA”) included Cologuard testing on a three-year interval in the final 2017 Healthcare Effectiveness Data and Information set (“HEDIS”) measures. More than 90 percent of America’s health plans measure quality based on HEDIS. In February 2017, the Centers for Medicare & Medicaid Services (“CMS”) proposed including Cologuard in the 2018 Star Ratings program, which uses HEDIS as a primary data source. The Star Ratings program is designed to measure quality in Medicare Advantage plans, help beneficiaries find a plan, and determine potential quality bonus payments. The proposal to include Cologuard in the Star Ratings program, as set forth in the Medicare Advantage Advance Notice and Draft Call letter dated February 1, 2017, is subject to a public comment period.

A critical part of the value proposition of Cologuard is our compliance program, which involves active engagement with patients and physicians. This activity is focused on enabling patients to complete Cologuard tests that have been ordered for them by their physicians and supporting physicians in their efforts to have their patients screened.

After the launch of Cologuard, we initiated a significant public relations effort to engage patients in the United States. We have conducted targeted direct-to-patient advertising campaigns through social media, print and other channels. In 2016 we began a national television advertising campaign. To date, we have focused our efforts on cable television most commonly viewed by our target patient demographic, and we have begun testing advertising campaigns on network television. In 2017, we plan to continue our targeted direct-to-patient advertising initiatives and launch new content for our television advertising campaign.

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Payors

The cornerstone of our payor-engagement strategy was securing Medicare coverage from CMS. Medicare covers 47% of patients in the screening population for Cologuard. On October 9, 2014, CMS issued a final National Coverage Determination ("NCD") for Cologuard following a parallel review process with FDA. Cologuard was the first screening test approved by FDA and covered by CMS through that 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).

In the 2017 Clinical Laboratory Fee Schedule, CMS set reimbursement for Cologuard at $512.43. Payments from CMS are subject to sequestration. Under the Protecting Access to Medicare Act of 2014 ("PAMA"), effective January 1, 2018, the CMS reimbursement rate for Cologuard will be calculated based on the volume-weighted median of private payor rates for Cologuard. The initial data collection period for that purpose was the period between January 1, 2016 and June 30, 2016. The CMS reimbursement rate will subsequently be reset every three years, or every year if the Company applies for, and is granted, Advanced Diagnostic Laboratory Test status for Cologuard, based on the volume-weighted median of private payor rates experienced in the applicable six-month data collection period. The data for the initial collection period must be submitted to CMS by March 31, 2017 and will be subject to review by CMS prior to the finalization of the new reimbursement rate.

In addition to Medicare reimbursement, we believe it is necessary to secure favorable coverage and reimbursement from commercial payors for Cologuard to achieve its full commercial potential. Some commercial payors have issued positive coverage decisions for Cologuard and others have agreed to cover Cologuard as an in-network service. We believe that commercial payors' reimbursement of Cologuard will depend on a number of factors, including payors' determination that it is: sensitive and specific for colorectal cancer; not experimental or investigational; approved or recommended by major organizations' guidelines; subject to applicable federal and state coverage mandates; reliable, safe and effective; medically necessary; appropriate for the specific patient; and cost-effective. Also, some payors may require that they give prior authorization for a Cologuard test before they are willing to pay for it. Prior authorization requirements may include requirements that we, patients, or physicians provide the payor with extensive medical records and other information.

Coverage of Cologuard may also depend, in whole or in part, on whether payors determine, or courts and/or governmental agencies 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" graded preventive services without patient cost-sharing. Following the updated USPSTF recommendation statement, the 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 certain health insurers to cover Cologuard without patient cost-sharing (following an initial phase-in period between one and two years from when the USPSTF recommendation statement was issued), it is possible that certain health insurers will disagree, in which case courts and/or governmental agencies may need to resolve this matter. It is also possible that the ACA Mandate will be repealed or significantly modified in the future.

Similarly, we believe the laws of several states currently mandate coverage of Cologuard by certain health insurance companies. While some of those insurance companies have agreed with our interpretation, in certain states, others 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.

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We are pursuing a variety of strategies to increase commercial payor coverage for Cologuard, including providing cost effectiveness data to payors to make the case for Cologuard reimbursement. We are focusing our efforts on large national and regional insurers, insurers in states with coverage mandates for colorectal cancer screening, and health plans that have affiliated health systems.

We believe quality metrics will help shape payors' coverage decisions, as well as physicians' cancer screening procedures. Some government and private payors 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. Payors may look to quality measures such as the HEDIS and CMS Star Ratings measures to assess quality of care. We believe inclusion in the HEDIS measures and the Star Ratings measures (if the Star Ratings are revised to include Cologuard, as proposed by CMS in February 2017) will have a positive impact on payors' willingness to reimburse Cologuard, as well as on physicians' willingness to prescribe the test.

Our Clinical Lab Facility

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 50,000 square foot facility in Madison, Wisconsin. At our lab, we currently have the capacity to process approximately one million tests per year, and we have capacity to expand, if needed.

Product Pipeline

We also are developing a pipeline of potential future products and services. We are continuing to collaborate with MAYO Foundation for Medical Education and Research ("MAYO") on developing new tests, with the goal of becoming a leader in cancer diagnostics. We believe Cologuard's technological platform provides a strong foundation for the development of additional cancer diagnostic tests. Through our collaboration with MAYO, we have identified proprietary methylation markers for several major cancers. We have successfully performed validation studies on tissue samples for seven major cancers, including lung cancer, and on blood samples for four major cancers.

The ACS estimates that lung cancer will be diagnosed in 223,000 Americans and cause 156,000 deaths in the United States in 2017. 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. If lung cancer is detected at an early stage, its five-year survival rate can be as high as 80%. We are currently developing 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") or other scan. Such a test may help reduce the number of unnecessary biopsies and other follow-up procedures, and thereby reduce costs and improve health outcomes. We recently completed a 400 patient lung cancer study which has been submitted for publication in the spring of 2017.

We also plan to continue to explore opportunities for improving Cologuard, including improvements that could lower our cost of sales.

Competition

The market for colorectal cancer and pre-cancer screening is large, consisting of more than 80 million Americans age 50 and above, and has attracted 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 flexible sigmoidoscopy, colonoscopy, and "virtual" colonoscopy, a radiological imaging approach that visualizes the inside of the bowel by CT scan (spiral computerized axial tomography), as well as traditional screening tests, such as the fecal occult blood test ("FOBT") and FIT, and newer screening technologies such as the PillCam® COLON cleared by FDA in February 2014. Our competitors may also be developing additional methods of detecting colorectal cancer and pre-cancer that have not yet been announced.

In addition, a number of companies and institutions are working to develop new blood and serum based tests for the detection of colorectal cancer or pre-cancer, including tests based on the detection of proteins, nucleic acids, or the presence of fragments of mutated genes in the blood that are produced by colorectal cancer or pre-cancer. We are aware

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of at least six other companies—Epigenomics AG, Applied Proteomics, Inc., Gene News, EDP Biotech Corporation, Illumina, Inc., and Quest Diagnostics—that are developing blood-based tests for the detection of colorectal cancer. Epigenomics AG completed a large, multi-center study designed to demonstrate the performance of its blood-based screening test for colorectal cancer and received FDA approval for its product, Epi proColon, in April 2016. On January 10, 2016, Illumina, Inc. announced the formation of GRAIL, a new company aiming to develop a blood-based, pan-cancer screening test that would seek to measure circulating nucleic acids in blood using next-generation sequencing ("NGS") technology. We believe other companies are also working on so-called "liquid biopsy" tests using NGS technology, 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 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. The leading method, colonoscopy, involves 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. Blood based DNA tests currently available are also disadvantaged by low sensitivity. Data from a validation study of one blood based test was released in late 2011 and published in the journal Gut in February 2013, demonstrating 48 percent sensitivity across all stages of cancer, with little sensitivity for pre cancer above the background false positive rate. Additionally, FIT testing suffers from low adherence over time. One study published in the American Journal of Managed Care demonstrated that only two out of every 1,000 patients studied adhered to FIT screening guidelines.

Beyond our Cologuard test, as we seek to develop other tools 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 diagnostic tools. 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 than us.

How We Recognize Revenue

For tests performed where we have an agreed-upon reimbursement rate or where we can estimate the amount that we will ultimately collect at the time delivery is complete, such as in the case of Medicare and certain other payors, we recognize the related revenue on an accrual basis upon delivery of a test result to an ordering physician. Accrual rates are based on the established billing rates less contractual and other adjustments, which arrive at the amount that we expect to ultimately collect. We determine the amount we expect to ultimately collect on a per-payor or per-agreement basis. 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 payors, and claim denials. Upon ultimate collection, the amount received from Medicare and other payors where reimbursement was estimated is compared to previous collection estimates and, if necessary, the contractual allowance is adjusted. Finally, should we recognize revenue from payors on an accrual basis and later determine the judgments underlying estimated collections change, our financial results could be negatively impacted in future periods. A portion of our revenue is recognized upon cash receipt, as we are currently unable to reasonably estimate the amount that will ultimately be collected from many payors.

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Our average reimbursement per test, as further defined below, was approximately $405 through December 31, 2016. This cumulative average Cologuard reimbursement rate will change over time due to a number of factors, including medical coverage decisions by payors, changes in the payor mix, the effects of contracts signed with payors, changes in allowed amounts by payors, our ability to successfully win appeals for payment, settlements reached with payors regarding previously denied claims, and our ability to collect cash payments from payors and individual patients. Historical average reimbursement is not necessarily indicative of future average reimbursement.

We calculate the average Cologuard reimbursement per test from all payors on a trailing twelve-month basis, whether they are on a cash or an accrual basis, for tests that are at least six months old, since it can often take that long, or in some cases longer, to collect from some payors. Thus, the average reimbursement per test represents the total cash collected through December 31, 2016 for tests performed during the relevant period divided by the number of tests performed during that same period.

We incur expense for tests in the period in which the testing activities occur and recognize revenue for tests in the period in which our revenue recognition criteria are met. Accordingly, any revenue that we recognize as a result of cash collection related to previously performed but unpaid tests will favorably impact our liquidity and results of operations in future periods.

The components of our revenue, as recognized upon accrual or cash receipt, were as follows:

	Year Ended December 31,		
(In thousands)	2016	2015	2014
Revenue recognized on an accrual basis	$ 87,037	$ 36,364	$ 1,388
Revenue recognized when cash is received	12,339	3,073	116
Total	$ 99,376	$ 39,437	$ 1,504

Of the revenue recognized in the year ended December 31, 2016, approximately $3.0 million relates to tests processed in the prior year for which our accrual revenue recognition criteria were not met until 2016 and for which we waited to recognize revenue until cash was received.

Research and Development

Research and development costs account for a substantial portion of our operating expenses. Our research and development expenses were $33.5 million, $33.9 million and $28.7 million for the years ended December 31, 2016, 2015, and 2014, respectively. Research and development expenses are expected to increase in the future as we work on developing additional products related to cancer diagnostic testing and improving Cologuard.

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 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 and regulations thereunder, including regulations governing the development, marketing, labeling, promotion, manufacturing, and export of diagnostic products. Our clinical laboratory is subject to oversight by CMS pursuant to CLIA, as well as agencies in various states, including New York. 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, civil money penalties, injunctions, and criminal prosecution.

U.S. Food and Drug Administration

FDA granted premarket approval ("PMA") for Cologuard in August 2014. That PMA approval places substantial restrictions on how Cologuard is marketed and sold, specifically, by prescription only. Additionally, the regulations governing our approval require controls on Cologuard, including, but not limited to, manufacturing facility registration,

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product listing with the FDA, complying with labeling requirements, maintenance of a satisfactory quality management system, and meeting post-market surveillance requirements. In addition, as a condition of our FDA approval, we are required to conduct a post-approval study. 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.

We may develop new diagnostic products and services that are regulated by the FDA as medical devices. 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 has recently retracted a proposal for increased LDT oversight.

FDA-Regulated Medical Devices

Unless otherwise exempted, medical devices must receive from the FDA either "510(k) clearance" or PMA before marketing them in the United States. Both the 510(k) clearance and PMA processes may be costly and time consuming, but the PMA approval process is typically more costly, lengthy, and uncertain.

The FDA determines whether a medical device will require either 510(k) clearance or the PMA process based on statutory criteria that utilize a risk-based classification system. If the FDA decides one of our future products may undergo the 510(k) clearance process (class II), we would typically be required to submit a premarket notification. In the premarket notification, we would need to demonstrate that our proposed device is "substantially equivalent" in intended use, safety, and effectiveness to certain existing, legally marketed devices. This is a traditional 510k clearance. In some instances, the risk criteria of a device may be deemed low enough for premarket clearance, but the FDA may reject the substantial equivalence argument that is presented. In these instances, a de novo 510k pathway ("de novo") may be available. The regulatory requirements of the de novo are similar to a PMA except that clinical evidence requirements may be less, and premarket inspections are not required. If we were to obtain 510(k) clearance for a product and then make changes to that product, we would need to seek a new 510(k) clearance.

The PMA process, which would be necessary if the product classification is high risk (class III), involves submitting extensive data to the FDA. These data allow the FDA to determine if the device is safe and effective for its intended use. The PMA process may include the convening of expert panels, inspection of our manufacturing facilities, and providing additional data and updates to the FDA, or new or supplemented PMA submissions, if the product is modified during the process or after approval.

Even if granted, a 510(k) clearance or PMA may place substantial restrictions on how a device is marketed or sold, and regulations governing any medical device products require controls, including but not limited to registering manufacturing facilities, listing the products with the FDA, complying with labeling requirements, maintaining an adequate quality management system, and meeting post-market surveillance requirements. The studies required in connection with our seeking either a 510(k) clearance or PMA for any of our new diagnostics products would be costly and time intensive. There can be no assurance that the FDA would ultimately clear any 510(k) premarket notification or approve any PMA request submitted by us in a timely manner or at all.

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 FDA 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. The

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FDA's guidance documents, if and when finalized, or action by 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 impose certification requirements for clinical laboratories, and establish standards for quality assurance and quality control, among other things. 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 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, or HIPAA, established for the first time comprehensive protection for the privacy and security of health information. The HIPAA standards apply to three types of organizations, or "Covered Entities": health plans, healthcare clearinghouses, and healthcare providers that conduct certain healthcare transactions electronically. Covered Entities and their business associates must have in place administrative, physical, and technical standards to guard against the misuse of individually identifiable health information. We perform activities that may implicate HIPAA, such as providing clinical laboratory testing services and entering into specific kinds of relationships with Covered Entities and business associates of Covered Entities.

Our activities must also comply with other applicable privacy laws. For example, there are also state and international privacy laws that impose restrictions on the access, use, and disclosure of health information. All of these laws may impact our business. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain stool 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 payors;
- deceptive or fraudulent conduct;
- excessive or unnecessary services or services at excessive prices; and
- defrauding private sector health insurers.

We are subject to substantial penalties for violations of anti-fraud and abuse laws, including denial of payment and refunds, 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 payors. Within 60 days of identifying 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. On February 11, 2016, CMS published a final rule clarifying the obligation to report and return federal healthcare program overpayments. 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

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governmental payors. 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 payors.

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

Federal and State "Self Referral" and "Anti-Kickback" Restrictions

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

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

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 payors 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. Our failure to comply with the reporting requirements of this law 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

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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, 2016, and there are no material expenditures planned for such purposes for the year ended December 31, 2017.

Intellectual Property

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

Our success depends to a significant degree upon our ability to protect our technologies through patent coverage. As of December 31, 2016, we owned 26 issued patents and 36 pending patent applications in the United States, and 34 issued patents and 47 pending patent applications in foreign jurisdictions. In addition, as part of our 2009 strategic transaction with Genzyme Corporation, we exclusively license back from Genzyme, in the fields of colorectal cancer screening and stool based detection of any disease or condition, the 24 patents issued and 2 pending patent applications in the United States, and 36 patents issued in foreign jurisdictions sold to Genzyme.

Each of our patents generally has a term of 20 years from its respective priority filing date. The earliest of our issued patents to expire will expire in 2017, and the last of these to expire will expire in 2033.

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

On June 11, 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. 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 of matter claims that relate to 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., Canada, the European Union, and Japan. In addition to granting us a license to the covered MAYO intellectual property, MAYO agreed to make available personnel to provide us product development and research and development assistance. 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 through 2033, the year the last patent expires. The January 2016 amendment to the MAYO license agreement established

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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 our net sales of Cologuard increased and, if in the future, improvements are made to the Cologuard product, the royalty rate may further increase. However, the amendment provides that the Cologuard royalty will remain a low single-digit percentage of net sales.

In addition to the royalty rates described above, we are also required to issue MAYO shares of our common stock with a value of $0.2 million upon commercial launch of our second and third products that use the licensed MAYO intellectual property, as well as to pay MAYO, for each of our products that use licensed MAYO intellectual property, $0.2 million cash upon such product reaching $5.0 million in cumulative net sales, $0.8 million cash upon such product reaching $20 million in cumulative net sales, and $2 million cash upon such product reaching $50 million in cumulative net sales.

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., Canada, the European Union, Australia and Japan. The license agreement also provided us 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 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 agreement with MDx Health S.A. (formerly Oncomethylome Sciences, S.A.) (“MDx Health”). Under the license agreement, MDx Health granted us an exclusive, worldwide license to sell products, and a license to sell services in the United States, in the field of in vitro diagnostic testing of fecal

samples for detection of colorectal cancer and colorectal pre cancer to certain patents and patent applications related to DNA methylation biomarkers. 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., Canada, the European Union, China and Japan. Under the agreement, we are obligated to make commercially reasonable efforts to bring to market products using the licensed MDx Health patents. We are required to pay MDx Health a minimum royalty fee of $0.1 million on each anniversary of the agreement for the life of the contract. In 2015, we paid

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MDx Health $0.2 million after we reached net sales of $10 million of a licensed product after receipt of FDA approval. In 2016, we paid MDx Health $0.8 million after we reached cumulative net sales of $50 million. Additionally, we will pay them $1 million after we reach net sales of $50 million in a single calendar year. We are also required to pay MDx Health a low single-digit royalty on our net sales of licensed products and services. Unless earlier terminated by the parties in accordance with the agreement, the license agreement will remain in effect until the last of the licensed patents expires in 2028. The agreement contains customary termination provisions which, among other things, permit termination in the event of material uncured breaches.

Employees

As of December 31, 2016, we had 736 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, 2016, we have accumulated a total deficit of approximately $745.8 million. We expect that our losses will continue for at least the next several years and that we will be required to invest significant additional funds 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 Cologuard, the development and commercial success of future products or services, regulatory

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developments, the status and scope of our intellectual property, any ongoing litigation, our compliance with applicable laws and regulations and other factors. If we raise additional funds through the sale of equity, convertible debt or other equity-linked securities, our stockholders' ownership will be diluted. 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 the foreseeable future, our ability to generate revenues will depend almost entirely on the commercial success of our Cologuard test. 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, such as those developed by ACS and USPSTF;
- inclusion of Cologuard in quality measures including the HEDIS measures and the CMS 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;
- successful sales, marketing, and educational programs, including successful direct-to-patient marketing such as television advertising;
- the number of patients tested for colorectal cancer, as well as the number of patients who use Cologuard for that purpose;
- sufficient coverage and reimbursement by third-party payors, which may depend in whole or in part on multiple factors, including federal or state laws that mandate coverage for colorectal cancer screening and the extent to which those laws mandate coverage of Cologuard;
- 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:

- 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;
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our success in collecting payments from third-party payors, 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;
- 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 our ability to develop new and improved products and the timing of expensive clinical trials.

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Other companies or institutions may develop and market novel or improved methods for detecting colorectal cancer or pre-cancer, which may make our technologies less competitive or obsolete.

The market for colorectal cancer and pre-cancer screening is large, consisting of more than 80 million Americans age 50 and above for whom routine colorectal cancer screening is recommended. As a result, this market has attracted competitors, some of which possess significantly greater financial and other resources and development capabilities than we do. Some companies and institutions are developing serum-based tests and screening tests based on the detection of proteins, nucleic acids or the presence of fragments of mutated genes in the blood that are produced by colorectal cancer or pre-cancer. We are aware of at least six companies — Epigenomics AG, Applied Proteomics, Inc., Gene News, EDP Biotech Corporation, Illumina, Inc. and Quest Diagnostics — that have developed, or are developing blood-based tests for the detection of colorectal cancer. Epigenomics AG completed a large multi-center study designed to demonstrate the performance of its blood-based screening test for colorectal cancer and received FDA approval for its product, Epi proColon, in April 2016. On January 10, 2016, Illumina, Inc. announced the formation of GRAIL, a new company aiming to develop a blood-based, pan-cancer screening test that would seek to measure circulating nucleic acids in blood using next-generation sequencing ("NGS") technology. We believe other companies are also working on so-called "liquid biopsy" tests using NGS technology, and these tests could represent significant competition for Cologuard and other tests we may develop. Our Cologuard test also faces competition from procedure-based detection technologies such as flexible sigmoidoscopy, colonoscopy and "virtual" colonoscopy (a radiological imaging approach that visualizes the inside of the bowel by use of spiral computerized axial tomography known as a CT scan) as well as traditional screening tests such as FOBT and FIT and newer screening technologies such as the PillCam COLON cleared by FDA in February 2014. Our competitors may also be working on additional methods of detecting colorectal cancer and pre-cancer that have not yet been announced.

Beyond our Cologuard test, as we seek to develop other tools 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 diagnostic tools. 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. Our competitors may have broader product lines and greater name recognition than we do. We have limited experience developing tests for the detection of non-colorectal cancers and we cannot guarantee that our research and development activities will be successful in developing any marketable testing products or services. Further, 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, sooner than we are able to.

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

Recent 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 of the ACA following the 2016 elections, 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. Any change in reimbursement policy could result in a change in patient co-payments, which could adversely

affect patient 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 payors 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.

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The ACA requires that non-grandfathered health plans cover, without patient cost-sharing, preventive services that have in effect a grade of "A" or "B" in the current recommendations of USPSTF. The requirement to cover, without cost-sharing, a newly recommended preventive service applies to each non-grandfathered health plan starting with the first plan year that begins at least one year after the date of the recommendation. In June 2016, USPSTF issued an updated colorectal screening recommendation, assigning an A grade to "screening for colorectal cancer starting at age 50 years and continuing until age 75 years." We believe the "A" grade should be interpreted to apply to the seven types of colorectal cancer tests specifically identified by USPSTF in its recommendation – including Cologuard – for adults ages 50 to 75 and that Cologuard should therefore be included within the ACA Mandate for colorectal cancer screening tests. However, health plans may assert that they are not required to cover Cologuard under the ACA Mandate. Enforcement of the ACA Mandate may depend, in whole or in part, on state, federal or other third party enforcement actions that we would not control. Further, a court or regulatory agency may agree with arguments made by insurers and determine that the ACA Mandate does not require that they cover Cologuard. Also, following the 2016 elections, Congress may repeal all or part of the ACA, and any such repeal may include repeal of the ACA Mandate for preventive services. If the ACA Mandate for preventive services is repealed or modified, including through any potential ACA replacement legislation, if the ACA Mandate is determined not to require coverage of Cologuard, or if the company is unable to secure effective enforcement of the ACA Mandate, even if it is held to require coverage of Cologuard, our business prospects, financial condition and results of operation may be adversely affected.

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 or replaced, 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.

Under PAMA, effective January 1, 2018, the CMS reimbursement rate for Cologuard will be calculated based on the volume-weighted median of private payor rates for Cologuard. The initial data collection period for that purpose was the period between January 1, 2016 and June 30, 2016. The CMS reimbursement rate will subsequently be reset every three years, or every year if the Company applies for, and is granted, Advanced Diagnostic Laboratory Test status for Cologuard, based on the volume-weighted median of private payor rates experienced in the applicable six-month data collection period. If the CMS reimbursement rate for Cologuard is reduced pursuant to PAMA or otherwise, our revenues would likely be adversely affected. PAMA presents significant uncertainty for future CMS reimbursement rates for Cologuard. Because Medicare currently covers 47% of patients in the screening population for Cologuard, any reduction in the CMS reimbursement rates for Cologuard would negatively affect our revenues and our business prospects.

If third-party payors, 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 payors approve and maintain reimbursement for our Cologuard test at adequate reimbursement rates. Third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new healthcare products approved for marketing by the FDA. As a result, there is significant uncertainty surrounding whether the use of tests that incorporate new

technology, such as our Cologuard test, will be eligible for coverage by third-party payors or, if eligible for coverage, what the reimbursement rates will be. Reimbursement of sDNA colorectal cancer screening by a third-party payor may depend on a number of factors, including a payor'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 payors, 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. 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

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and commercial payors who initially decide to cover Cologuard will continue to do so. We are pursuing a variety of strategies to increase commercial payor coverage and reimbursement of Cologuard. In certain situations, where we believe payors are obligated to cover Cologuard under Medicare laws and state laws that mandate coverage for certain colorectal cancer screening tests, we have sued to enforce coverage obligations. We may pursue similar litigation in the future. Such litigation may be costly, may divert management attention from other responsibilities, may cause payors, including those not directly involved in the 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 difficult to enforce and are subject to repeal or modification. In particular, following the 2016 elections, the ACA may be repealed or materially modified, in whole or in part, or replaced with an alternative legal framework governing healthcare matters. 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. A reduction in our Medicare reimbursement rate could significantly and adversely affect our business products, financial condition and results of operation.

Even where a third-party payor agrees to cover Cologuard, other factors may have a significant impact on the actual reimbursement we receive for a Cologuard test from that payor. For example, if we do not have a contract with a given payor, we may be deemed an “out-of-network” provider by that payor, which could result in a greater portion of the cost of the Cologuard test being borne by the patient. To the extent Cologuard is out of network for a given payor, physicians may be less likely to prescribe Cologuard for their patients and their patients may be less likely to comply with any such orders. Also, some payors 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 requirements may require that we, patients or physicians provide the payor with extensive medical records and other information. Prior authorization and other medical management requirements impose a significant additional cost on us, may be difficult to comply with given our position as a laboratory, 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, payors, patients and others as to the reliability, effectiveness and superiority of our Cologuard test, we may experience reluctance or refusal on the part of physicians to order, and third-party payors to pay for, our 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 payors 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 payors to pay for, our Cologuard test, 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.

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

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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. Furthermore, if we do enter into these arrangements, these third parties may not perform as expected.

If we are unable to deploy and maintain effective sales and marketing 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 and marketing organization and our sales organization must effectively explain to healthcare providers the reliability, effectiveness and benefits of Cologuard as compared to alternative screening methods. 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, either as our employees or independent contractors or through independent sales organizations. Further, we may not be able to enter into agreements with sales representatives on commercially reasonable terms, if at all.

Establishing and maintaining sales and marketing 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.

The success of our Cologuard test depends on the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community.

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

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

Despite the availability of current colorectal cancer screening methods as well as the recommendations of the ACS and others that all Americans be screened for colorectal cancer beginning at age 50, 42 percent of these individuals are not screened according to current guidelines. 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, a 30-percent test adoption rate in the screening population and a three-year screening interval. Although ACS guidelines and others recommend a three-year screening interval and CMS has determined that Medicare will cover the test at this interval, physicians, healthcare payors, the FDA and other regulators and opinion leaders could recommend a different testing schedule. Further, patients may not adhere to the recommended testing interval.

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 payors' 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 payor engagement strategies. These guidelines, recommendations and quality metrics may shape payors' coverage decisions and physicians' cancer screening procedures.

The U.S. Preventive Services Task Force ("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 without. In June 2016, the USPSTF

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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). The updated 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 will require certain health insurers to cover Cologuard without patient cost-sharing (following an initial phase in period between one and two years), it is possible that certain health insurers will disagree, in which case courts and/or government agencies may need to resolve the issue. Enforcement of the ACA Mandate may be difficult and may depend, in whole or in part, on state, federal or other third party enforcement actions that we would not control. Further, a court or regulatory agency may agree with arguments proposed by insurers and determine that the ACA Mandate does not require that they cover Cologuard. Also, following the 2016 elections, efforts are underway to repeal all or part of the ACA, and any such repeal may include repeal of the ACA Mandate for preventive services. If the ACA Mandate for preventive services is repealed or modified, including through any potential ACA replacement legislation, if the ACA Mandate is determined not to require coverage of Cologuard, or if the company is unable to 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 payors 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. Payors may look to quality measures such as the National Committee for Quality Assurance (“NCQA”), Healthcare Effectiveness Data and Information Set (“HEDIS”) and the CMS 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 Ferbuary 2017, CMS proposed to include Cologuard in the 2018 CMS Star Ratings program, which uses the HEDIS as a primary data source. If for some reason Cologuard was removed from, or not included in, HEDIS, the Star Ratings or other quality metrics, payors may be less inclined to 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.

We expect to make significant investments to research and develop new cancer diagnostic tools, which may not be successful.

In addition to commercializing our Cologuard test, we are developing a pipeline for future products and services, including screening and diagnostic tests for lung and other types of cancers. We expect to incur significant expenses on these development efforts but they may not be successful.

Developing new cancer 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. We may need to explore a number of different marker combinations, alter our candidate products and repeat clinical studies before we identify a potentially successful candidate. 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 we may develop. Even if the FDA clears or approves a new product we develop, we would need to commit substantial resources to commercialize, sell and market the product before it could be profitable, and the product may never be commercially viable. Additionally, development of any product may be disrupted or made less viable by the department of competing products.

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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. Given our current levels of cash and resources, and our planned expenditures to support Cologuard commercialization, we expect that we may need to raise significant additional capital to bring any new products to market, which may not be available on acceptable terms, if at all.

We may not be able to successfully establish and maintain strategic collaborative and licensing arrangements with third parties, which could adversely affect our ability to commercialize our Cologuard test and to develop and commercialize other products and services.

The commercialization of our Cologuard test and the development and commercialization of other products and services rely, directly or indirectly, upon strategic collaborations and licensing agreements with third parties. We currently have a collaborative and licensing arrangements with MAYO Foundation for Medical Education and Research. In addition, we have licensing agreements with Hologic and MDx Health. 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.

As we seek to commercialize and market our Cologuard test and develop new products and services, we expect to continue and expand our reliance on collaborative and licensing arrangements. Establishing new strategic collaborations and licensing arrangements is difficult and time-consuming. Discussions with potential collaborators or licensors may not lead to the establishment of collaborations on favorable terms, if at all. To the extent we agree to work exclusively with one collaborator in a given area, our opportunities to collaborate with other entities could be limited. Potential collaborators or licensors may reject collaborations with us based upon their assessment of our financial, regulatory or intellectual property position. Even if we successfully establish new collaborations, these relationships may never result in the successful commercialization of any product or service.

If we fail to meet any applicable requirements of CLIA or similar state laws, that failure could adversely affect any future payor 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.

We are subject to federal and state laws and regulations regarding the operation of clinical laboratories. Federal Clinical Laboratory Improvement Amendments (“CLIA”) requirements and laws of certain states impose certification requirements for clinical laboratories, and establish standards for quality assurance and quality control, among other things. 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 future payor 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.

We must maintain FDA approval for Cologuard and of our Madison, Wisconsin facilities; failure to maintain compliance with FDA requirements may prevent or delay the marketing or manufacture 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 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 expect to 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 initiation and completion of the post-approval study may be prevented, delayed or halted for reasons outside our control.

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Additionally, our Madison, Wisconsin facilities are periodically subject to inspection by the FDA and other governmental agencies to ensure they meet production and quality standards. Operations at these facilities could be interrupted or halted if the FDA deems the findings of such inspections unsatisfactory. Failure to comply with FDA or other regulatory requirements could result in fines, unanticipated compliance expenditures, recall or seizures of our products, total or partial suspension of production or distribution, termination of ongoing research, disqualification of data for submission to regulatory authorities, enforcement actions, injunctions and criminal prosecution.

Our inability to obtain without delay any necessary regulatory clearances or approvals for new diagnostic products or services, or improvements to our current offerings, could materially encumber 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 from the FDA either "510(k) clearance" or premarket approval ("PMA") before marketing them in the United States. The FDA determines whether a medical device will require either 510(k) clearance or the PMA process 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 510(k) clearance or PMA will likely be costly, time-consuming and uncertain. However, we believe the PMA process is generally more challenging. Even if we design a product that we expect to be eligible for the 510(k) clearance process, the FDA may require that the product undergo the PMA 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 is granted, such approval may include significant limitations on indicated uses, which could materially and adversely affect the prospects of any new product or service.

FDA regulatory approval or clearance is not just required for new products and services 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 or service, the FDA may withdraw or materially modify its clearance or approval.

In the future, we plan to develop tests that could be regulated as laboratory developed tests ("LDTs"). If the FDA proceeds with its plans to actively regulate LDTs or continues to regulate LDTs with enforcement discretion, we may need to obtain additional FDA or other regulatory approvals, which may delay, encumber or block us from commercializing these diagnostic tests.

We may also 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.

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. In November 2016, FDA 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.

The FDA's guidance documents, if and when finalized, or if FDA exercises enforcement discretion may materially impact our development of LDTs and may require us to change our business model in order to maintain compliance with these regulations. New laws and regulations may significantly slow the time it takes 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

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commercializing certain products or services. We cannot provide any assurance that FDA regulation will not be required in the future for any of our tests, whether through 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 which 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 our diagnostic tests 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. As 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. Our headquarters and manufacturing facilities 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 may need to expand or modify our existing laboratory facility or acquire new laboratory facilities to increase our processing capacity. Any failure to do so on terms acceptable to us, if at all, may significantly delay our processing times and capabilities, which may adversely affect our business, financial condition and results of operation.

If these, 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 acts, power outages, or otherwise, our business could be severely disrupted. If our Madison, Wisconsin, laboratory is disrupted, we may not be able to 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 and research and development restoration expenses, 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 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.

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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, or 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.

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, 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 payors including doctors, patients, hundreds of insurance companies, Medicare, Medicaid, and employer groups, all of which have different billing requirements. We are continuing to work with third-party payors 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 payors, including those not directly involved in the litigation, to resist contracting with us, and may ultimately prove unsuccessful. We may face write-offs of doubtful accounts, disputes with payors and long collection cycles. We may face patient dissatisfaction, complaints or lawsuits 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 payors 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 payors as to which payor is responsible for payment;

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- disparity in coverage among various payors or among various healthcare plans offered by a single payor;
- differing information and billing requirements among payors; and
- failure by patients or physicians to provide complete and correct billing information.

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

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, 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 begin to expire in 2017. This loss of patent 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

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

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. Violation of any FDA requirement could result in enforcement actions, such as seizures, injunctions, civil penalties and criminal prosecutions, and violation of any FTC 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 and FTC 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. Following the 2016 elections, such change may be swift and significant. 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 independent sales representatives, fail to comply with these laws and regulations, we could incur significant fines and penalties and our reputation and prospects could suffer. Additionally, our 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 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 to acquire or arrange for or recommend the acquisition of healthcare products or services. While the federal law applies only to

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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 payors 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. 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-party contractors who are contractually obligated to safeguard and maintain the confidentiality of PHI. Unauthorized persons may be able to gain access to PHI stored in such third-party contractors' computer networks. Any wrongful use or disclosure of PHI by us or our third-party contractors, including disclosure due to data theft or unauthorized access to our or our third-party contractors' computer networks, could subject us to fines or penalties that could adversely affect our business and results of operations. Although the HIPAA statute and regulations do not expressly provide for a private right of damages, we could also incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information.

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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, Maneesh Arora, our Senior Vice President and Chief Operating Officer, Dr. Graham Lidgard, our Senior Vice President and Chief Science Officer, 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 significant experience in 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 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, 2016, we had $311.1 million in combined cash and marketable securities. Our management currently expects to deploy these resources primarily to expand our Cologuard 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.

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 our Cologuard test.

Inherent risks are involved in providing and marketing cancer 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 payors' 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 based on, among other things, allegations that it contained a design or manufacturing defect or our laboratory was negligent in processing test results, which resulted in the failure to detect the condition for which it was designed or an unnecessary procedure which caused harm. 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

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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 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-party contractors 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 236, as of December 31, 2014, to 736, as of December 31, 2016. 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 forecast expenses accurately, and to properly forecast and expand operational and testing facilities, if necessary, 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 manufacturing, laboratory operations and sales and marketing needs. 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 the 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 and Asian countries, but 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.

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.

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Delaware law, our charter documents and rights agreement 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% 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.

In addition, we have adopted a rights agreement that provides that in the event of (i) an acquisition of 15% or more of our outstanding common stock or (ii) an announcement of an intention to make a tender offer or exchange offer for 15% or more of our outstanding common stock, our stockholders, other than the potential acquiror, shall be granted rights enabling them to purchase additional shares of our common stock at a substantial discount to the then prevailing market price. The rights agreement could significantly dilute such acquiror’s ownership position in our shares, thereby making a takeover prohibitively expensive and encouraging such acquiror to negotiate with our board of directors. Therefore, the rights agreement could make it more difficult for a third party to acquire control of us without the approval of our board of directors.

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

In the future, we may enter into transactions to acquire other businesses, products, services or technologies. Because we have not made any 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, 2016, we had federal and state net operating loss carryforwards ("NOLs") of approximately $725.1 million and $291.9 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% 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. For these reasons, even if we attain profitability our ability to utilize our NOLs may be limited, potentially

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significantly so.

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

The market price for our common stock varied between a high of $22.80 and a low of $4.67 in the twelve-month period ended December 31, 2016. 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 issuance of common stock or other securities;
- our inability to accurately forecast future performance;
- our inability to meet analysts' expectations;
- 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 in 2015 and at other 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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

As of December 31, 2016, we occupied approximately 195,000 square feet of space at our significant facilities in Madison, Wisconsin. See Note 8 in the notes to our consolidated financial statements for further discussion surrounding our leased facilities.

As of December 31, 2016, our significant facilities are as follows:

Location	Primary Function	Total Square Feet (approx.)	Leased or Owned
Madison, Wisconsin	Research and development	55,000	Owned

Madison, Wisconsin	Executive offices	34,000	Leased
Madison, Wisconsin	Operations	56,000	Leased
Madison, Wisconsin	Clinical laboratory	50,000	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." The following table provides, for the periods indicated, the high and low sales prices per share as reported on the NASDAQ Capital Market.

	High	Low
2016		
First quarter	$ 9.22	$ 4.67
Second quarter	13.20	5.36
Third quarter	22.80	11.48
Fourth quarter	20.40	13.22
2015		
First quarter	$ 29.60	$ 20.35
Second quarter	32.85	20.12
Third quarter	30.00	17.58
Fourth quarter	18.74	6.79

As of February 20, 2017, there were 110,603,808 shares of our common stock outstanding held by approximately 87 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.

On February 26, 2016, we issued Restricted Stock Unit awards to seventy new non-executive employees as inducement grants to enter into employment with the Company. These awards cover a total of 151,350 shares of the Company's common stock. These awards vest in four equal annual installments beginning on the first anniversary of the date of grant. These new hire inducement awards were granted pursuant to NASDAQ Listing Rule 5635(c)(4) and Section 4(a)(2) of the Securities Act of 1933. On May 3, 2016, the Company filed a registration statement on Form S-8 (File No. 333-211099) under which the shares of common stock underlying these awards were registered, prior to the time at which they vest.

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Item 6. Selected Financial Data

The selected historical financial data for the five years ended December 31, 2016 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,				
	2016	2015	2014	2013	2012
	(Amounts in thousands, except per share data)				
Statements of Operations Data:					
Revenue:					
Laboratory service revenue	$ 99,376	$ 39,437	$ 1,504	$ —	$ —
License fees	—	—	294	4,144	4,144
	99,376	39,437	1,798	4,144	4,144
Cost of sales(1)	45,195	24,501	4,325	—	—
Gross profit	54,181	14,936	(2,527)	4,144	4,144
Operating expenses:					
Research and development(1)	33,473	33,914	28,669	27,678	42,131
General and administrative(1)	76,898	57,950	30,435	13,649	9,900
Sales and marketing(1)	112,826	82,140	38,908	9,578	4,755
	223,197	174,004	98,012	50,905	56,786
Loss from operations	(169,016)	(159,068)	(100,539)	(46,761)	(52,642)
Investment income	2,018	1,271	542	316	262
Interest expense	(213)	(6)	(51)	(69)	(41)
Net loss	$ (167,211)	$ (157,803)	$ (100,048)	$ (46,514)	$ (52,421)
Net loss per share:					
Basic and diluted	$ (1.63)	$ (1.71)	$ (1.25)	$ (0.69)	$ (0.88)
Weighted average common shares outstanding:					
Basic and diluted	102,335	92,135	80,232	67,493	59,481
Balance Sheet Data:					
Cash and cash equivalents	$ 48,921	$ 41,135	$ 58,131	$ 12,851	$ 13,345
Marketable securities	262,179	265,744	224,625	120,408	94,776
Total assets	377,040	364,030	312,824	146,627	112,119
Long term debt	4,633	4,789	1,000	1,000	1,000
Other long term liabilities	5,734	4,601	3,599	—	—
Total liabilities	41,745	37,174	23,840	11,311	13,524
Stockholders' equity	335,295	326,856	288,984	135,316	98,595

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

2016	2015	2014	2013	2012

Cost of sales	$ 1,064	$ 876	$ 279	$ —	$ —
Research and development	4,014	3,744	4,149	2,817	2,396
General and administrative	14,597	9,358	5,575	3,054	2,579
Sales and marketing	4,057	4,072	1,517	1,873	518

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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 currently 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 diagnostics.

Our Cologuard Test

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

- 135,000 new cases of colorectal cancer
- 50,000 deaths from colorectal cancer

Colorectal cancer treatment represents a significant, growing healthcare cost. As of 2010, $14 billion was spent annually in the U.S. on colorectal cancer treatment, and the projected annual treatment costs are expected to be $20 billion in 2020. The incidence of colorectal cancer in Medicare patients is expected to rise from 106,000 cases in 2010 to more than 180,000 cases in 2030.

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. Accordingly, the American Cancer Society ("ACS") recommends that all people age 50 and older undergo regular colorectal cancer screening. Of the more than 80 million people in the U.S. for whom routine colorectal cancer screening is recommended, 42 percent have not been screened according to current guidelines. 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 67 percent and 12 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 which utilizes a multi-target approach to detect DNA and hemoglobin biomarkers associated with colorectal cancer and pre-cancer. Ten 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.

On August 11, 2014 the U.S. Food and Drug Administration (“FDA”) approved Cologuard for use as the first and only sDNA non-invasive colorectal cancer screening test. Our 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%

The competitive advantages of sDNA screening may provide a significant market opportunity. If the test were used by 30-percent of the eligible screening population at a three-year screening interval rate, we estimate the potential

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U.S. market for sDNA screening would be more than $4 billion, annually.

Our Cologuard Commercialization Strategy

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

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 enroll them in our physician ordering system to enable them to prescribe the test. We focus on specific physicians based on Cologuard order history and on physician groups and larger regional and national health systems.

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 US 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 (which is Cologuard).

Professional colorectal cancer screening guidelines in the U.S., including those of the ACS, the American College of Gastroenterology (“ACG”), the American Gastroenterological Association (“AGA”) and the National Comprehensive Cancer Network (“NCCN”), recommend regular screening by a variety of methods. Since 2008, joint colorectal cancer screening guidelines endorsed by the ACS and the U.S. Multi-Society Task Force on Colorectal Cancer (“CRC Task Force”) have included sDNA screening technology as a screening option for the detection of colorectal cancer in average risk, asymptomatic individuals age 50 and older. The CRC Task Force is a consortium of several organizations that includes representatives of the ACG, AGA, the American Society for Gastrointestinal Endoscopy, and the American College of Physicians/Society of Internal Medicine. In October 2014, the ACS updated its colorectal cancer screening guidelines to specifically include Cologuard as a recommended sDNA screening test. 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 October 2016, the National Committee for Quality Assurance (“NCQA”) included Cologuard testing on a three-year interval in the final 2017 Healthcare Effectiveness Data and Information set (“HEDIS”) measures. More than 90 percent of America’s health plans measure quality based on HEDIS. In February 2017, the Centers for Medicare & Medicaid Services (“CMS”) proposed including Cologuard in the 2018 Star Ratings program, which uses HEDIS as a primary data source. The Star Ratings program is designed to measure quality in Medicare Advantage plans, help beneficiaries find a plan, and determine potential quality bonus payments. The proposal to include Cologuard in the Star Ratings

program, as set forth in the Medicare Advantage Advance Notice and Draft Call letter dated February 1, 2017, is subject to a public comment period.

A critical part of the value proposition of Cologuard is our compliance program, which involves active engagement with patients and physicians. This activity is focused on enabling patients to complete Cologuard tests that have been ordered for them by their physicians and supporting physicians in their efforts to have their patients screened.

After the launch of Cologuard, we initiated a significant public relations effort to engage patients in the United States. We have conducted targeted direct-to-patient advertising campaigns through social media, print and other channels. In 2016 we began a national television advertising campaign. To date, we have focused our efforts on cable television most commonly viewed by our target patient demographic, and we have begun testing advertising campaigns on network television. In 2017, we plan to continue our targeted direct-to-patient advertising initiatives and launch new content for our television advertising campaign.

Payors

The cornerstone of our payor-engagement strategy was securing Medicare coverage from CMS. Medicare covers 47% of patients in the screening population for Cologuard. On October 9, 2014, CMS issued a final National Coverage Determination (“NCD”) for Cologuard following a parallel review process with FDA. Cologuard was the first screening

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test approved by FDA and covered by CMS through that 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).

In the 2017 Clinical Laboratory Fee Schedule, CMS set reimbursement for Cologuard at $512.43. Payments from CMS are subject to sequestration. Under the Protecting Access to Medicare Act of 2014 ("PAMA"), effective January 1, 2018, the CMS reimbursement rate for Cologuard will be calculated based on the volume-weighted median of private payor rates for Cologuard. The initial data collection period for that purpose was the period between January 1, 2016 and June 30, 2016. The CMS reimbursement rate will subsequently be reset every three years, or every year if the Company applies for, and is granted, Advanced Diagnostic Laboratory Test status for Cologuard, based on the volume-weighted median of private payor rates experienced in the applicable six-month data collection period. The data for the initial collection period must be submitted to CMS by March 31, 2017 and will be subject to review by CMS prior to the finalization of the new reimbursement rate.

In addition to Medicare reimbursement, we believe it is necessary to secure favorable coverage and reimbursement from commercial payors for Cologuard to achieve its full commercial potential. Some commercial payors have issued positive coverage decisions for Cologuard and others have agreed to cover Cologuard as an in-network service. We believe that commercial payors' reimbursement of Cologuard will depend on a number of factors, including payors' determination that it is: sensitive and specific for colorectal cancer; not experimental or investigational; approved or recommended by major organizations' guidelines; subject to applicable federal and state coverage mandates; reliable, safe and effective; medically necessary; appropriate for the specific patient; and cost-effective. Also, some payors may require that they give prior authorization for a Cologuard test before they are willing to pay for it. Prior authorization requirements may include requirements that we, patients, or physicians provide the payor with extensive medical records and other information.

Coverage of Cologuard may also depend, in whole or in part, on whether payors determine, or courts and/or governmental agencies 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" graded preventive services without patient cost-sharing. Following the updated USPSTF recommendation statement, the 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 certain health insurers to cover Cologuard without patient cost-sharing (following an initial phase-in period between one and two years from when the USPSTF recommendation statement was issued), it is possible that certain health insurers

will disagree, in which case courts and/or governmental agencies may need to resolve this matter. It is also possible that the ACA Mandate will be repealed or significantly modified in the future.

Similarly, we believe the laws of several states currently mandate coverage of Cologuard by certain health insurance companies. While some of those insurance companies have agreed with our interpretation, in certain states, others 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 increase commercial payor coverage for Cologuard, including providing cost effectiveness data to payors to make the case for Cologuard reimbursement. We are focusing our efforts on large national and regional insurers, insurers in states with coverage mandates for colorectal cancer screening, and health plans that have affiliated health systems.

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We believe quality metrics will help shape payors' coverage decisions, as well as physicians' cancer screening procedures. Some government and private payors 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. Payors may look to quality measures such as the HEDIS and CMS Star Ratings measures to assess quality of care. We believe inclusion in the HEDIS measures and the Star Ratings measures (if the Star Ratings are revised to include Cologuard, as proposed by CMS in February 2017) will have a positive impact on payors' willingness to reimburse Cologuard, as well as on physicians' willingness to prescribe the test.

Our Clinical Lab Facility

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 50,000 square foot facility in Madison, Wisconsin. At our lab, we currently have the capacity to process approximately one million tests per year, and we have capacity to expand, if needed.

Product Pipeline

We also are developing a pipeline of potential future products and services. We are continuing to collaborate with MAYO Foundation for Medical Education and Research ("MAYO") on developing new tests, with the goal of becoming a leader in cancer diagnostics. We believe Cologuard's technological platform provides a strong foundation for the development of additional cancer diagnostic tests. Through our collaboration with MAYO, we have identified proprietary methylation markers for several major cancers. We have successfully performed validation studies on tissue samples for seven major cancers, including lung cancer, and on blood samples for four major cancers.

The ACS estimates that lung cancer will be diagnosed in 223,000 Americans and cause 156,000 deaths in the United States in 2017. 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. If lung cancer is detected at an early stage, its five-year survival rate can be as high as 80%. We are currently developing 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") or other scan. Such a test may help reduce the number of unnecessary biopsies and other follow-up procedures, and thereby reduce costs and improve health outcomes. We recently completed a 400 patient lung cancer study which has been submitted for publication in the spring of 2017.

We also plan to continue to explore opportunities for improving Cologuard, including improvements that could lower our cost of sales.

2017 Priorities

Our top priorities for 2017 are to (1) grow revenue for Cologuard, which includes leveraging Cologuard's growth towards becoming a standard of care, (2) improve the customer experience and continue to deliver world class service to patients and providers, and (3) expand our product portfolio by developing additional cancer diagnostic tests as further outlined in the pipeline section above.

Results of Operations

Our top priorities for 2016 included (1) growing revenue for Cologuard, (2) enhancing our infrastructure to support the growth of Cologuard and future products and (3) improving Cologuard, including reducing its cost.

During 2016, we completed approximately 244,000 Cologuard tests, which generated $99.4 million of revenue compared to 2015 when we completed 104,000 tests and generated $39.4 million of revenue. 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, 2016, more than 163 million people are in health plans that cover Cologuard.

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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 38% for 2015 to 55% for 2016.

In 2016 we continued to invest in research and development and focused on the development of additional cancer diagnostic tests as outlined in the “Product Pipeline” section above.

In order to support the commercialization of Cologuard and to achieve our goals for 2016, our selling, general, and administrative costs increased by $49.6 million during the year. In addition, our efforts in 2016 to develop our pipeline products and improvements to Cologuard remained consistent with the prior year which led to a slight decrease in research and development costs of $0.4 million. We ensured that we were well capitalized to meet our future goals by raising $144.2 million, net of issuance costs, through an underwritten public offering of common stock completed in August 2016 and finished the year with $311.1 million in cash, cash equivalents, and marketable securities.

Comparison of the years ended December 31, 2016 and 2015

Laboratory service revenue. Our laboratory service revenue is generated by performing diagnostic services using our Cologuard test. For the years ended December 31, 2016 and 2015, the Company completed approximately 244,000 and 104,000 Cologuard tests, respectively, and generated laboratory service revenue of $99.4 million and $39.4 million, respectively. The increase in revenue was primarily due to an increase in completed Cologuard tests during the period.

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

Cost of sales includes costs related to inventory production and usage, shipment of test collection kits, royalties and the cost of laboratory services to process tests and provide results to physicians. Gross margin as a percentage of laboratory service revenue is also affected by our current revenue recognition policy, which may result in costs being incurred in one period that relate to revenues recognized in a later period.

We expect that gross margin for our laboratory services will continue to fluctuate and be affected by Cologuard test volume, our revenue recognition policy, patient compliance rates, payor mix, the levels of reimbursement, and payment patterns of payors and patients.

Cost of sales. Cost of sales increased to $45.2 million for the year ended December 31, 2016 from $24.5 million for the year ended December 31, 2015. The increase in cost of sales is primarily due to the increases in completed Cologuard tests. The Company completed approximately 244,000 and 104,000 Cologuard tests for the years ended December 31, 2016 and 2015, respectively.

Amounts in millions	2016	2015	Change
Production costs	$ 29.7	$ 13.7	$ 16.0
Facility and support services	7.0	4.2	2.8

Personnel expenses	7.3	5.6	1.7
Stock-based compensation	1.1	0.9	0.2
Other cost of sales expenses	0.1	0.1	—
Total cost of sales expense	$ 45.2	$ 24.5	$ 20.7

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Research and development expenses. Research and development expenses decreased to $33.5 million for the year ended December 31, 2016 compared to $33.9 million for the year ended December 31, 2015. During 2016 we continued to work on Cologuard improvements and the development of pipeline products at similar levels to the prior year, which led to a comparable level of spending in research and development in 2016.

Amounts in millions	2016	2015	Change
Personnel expenses	$ 11.6	$ 9.6	$ 2.0
Direct research and development expenses	13.9	13.3	0.5
Legal and professional fees	1.9	4.4	(2.5)
Stock-based compensation	4.0	3.7	0.3
Other research and development expenses	2.1	2.9	(0.8)
Total research and development expenses	$ 33.5	$ 33.9	$ (0.5)

General and administrative expenses. General and administrative expenses increased to $76.9 million for the year ended December 31, 2016 compared to $58.0 million for the year ended December 31, 2015. The increase in general and administrative expenses was primarily a result of increased personnel costs and stock-based compensation expense due to increased headcount to support the overall growth of the Company.

Amounts in millions	2016	2015	Change
Personnel expenses	$ 30.4	$ 18.9	$ 11.5
Professional and legal fees	11.8	10.8	1.0
Stock-based compensation	14.6	9.4	5.2
Other general and administrative	4.2	4.3	(0.1)
Facility and support services	15.9	14.6	1.3
Total general and administrative expenses	$ 76.9	$ 58.0	$ 18.9

Sales and marketing expenses. Sales and marketing expenses increased to $112.8 million for the year ended December 31, 2016 compared to $82.1 million for the year ended December 31, 2015. The increase in sales and marketing expenses 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 our Cologuard test.

Amounts in millions	2016	2015	Change
Personnel expenses	$ 57.4	$ 48.1	$ 9.3
Direct marketing costs and professional fees	50.6	28.7	21.9
Stock-based compensation	4.1	4.1	—
Other sales and marketing expenses	0.7	1.2	(0.5)

Total sales and marketing expenses	$ 112.8	$ 82.1	$ 30.7

Investment income. Investment income increased to $2.0 million for the year ended December 31, 2016 compared to $1.3 million for the year ended December 31, 2015. This increase in investment income was due to a higher return on investments for the year ended December 31, 2016 when compared to the same period in 2015.

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Interest income and expense. Net interest expense increased to $0.2 million for the year ended December 31, 2016 compared to net interest expense of $6,000 for the year ended December 31, 2015. During the year ended December 31, 2015 the Company offset $0.1 million of interest expense due to the forgiveness of accrued interest expense previously recorded on the Wisconsin Department of Commerce loan, which was forgiven during 2015 due to the Company's meeting certain job creation targets. The increase in interest expense in 2016 was due to no similar offset during 2016.

Comparison of the years ended December 31, 2015 and 2014

Laboratory service revenue. Our laboratory service revenue is generated by performing diagnostic services using our Cologuard test. Our Cologuard test became available to be marketed and sold upon FDA approval on August 11, 2014. Total laboratory service revenue was $39.4 million for the year ended December 31, 2015 and $1.5 million for the year ended December 31, 2014.

License fee revenue. We generated no license fee revenue for the year ended December 31, 2015. Total license fee revenue was $0.3 million for the year ended December 31, 2014. License fee revenue consists of the amortization of up front technology license fee payments associated with our collaboration, license and purchase agreement with Genzyme. The previously unamortized Genzyme up front payment and holdback amounts were amortized on a straight line basis over the initial Genzyme collaboration period, which ended in January 2014.

Cost of sales. Cost of sales increased to $24.5 million for the year ended December 31, 2015 from $4.3 million for the year ended December 31, 2014. The increase in cost of sales is related to the production and testing services of our Cologuard test, which obtained FDA approval during the third quarter of 2014.

Amounts in millions	2015	2014	Change
Production costs	$ 13.7	$ 1.4	$ 12.3
Personnel expenses	5.6	1.7	3.9
Facility and support services	4.2	0.8	3.4
Stock-based compensation	0.9	0.3	0.6
Other cost of sales expenses	0.1	0.1	—
Total cost of sales expenses	$ 24.5	$ 4.3	$ 20.2

Research and development expenses. Research and development expenses increased to $33.9 million for the year ended December 31, 2015 from $28.7 million for the year ended December 31, 2014. This increase in overall research and development expenditures was related to additional focus on pipeline product development and improvements to Cologuard.

Amounts in millions	2015	2014	Change
Personnel expenses	$ 9.6	$ 8.7	$ 0.9
Stock-based compensation	3.7	4.2	(0.5)
Direct research and development expenses	13.3	10.4	2.9
Legal and professional fees	4.4	2.3	2.1
Other research and development expenses	2.9	3.1	(0.2)
Total research and development expenses	$ 33.9	$ 28.7	$ 5.2

General and administrative expenses. General and administrative expenses increased to $58.0 million for the year ended December 31, 2015 from $30.4 million for the year ended December 31, 2014. The increase in general and administrative expenses was primarily related to increased expenditures required to support our overall growth and the first full year of Cologuard commercialization.

Amounts in millions	2015	2014	Change
Personnel expenses	$ 18.9	$ 7.8	$ 11.1
Professional and legal fees	10.8	5.9	4.9
Stock-based compensation	9.4	5.6	3.8
Other general and administrative expenses	4.3	3.2	1.1
Facility and support services	14.6	7.9	6.7
Total general and administrative expenses	$ 58.0	$ 30.4	$ 27.6

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Sales and marketing expenses. Sales and marketing expenses increased to $82.1 million for the year ended December 31, 2015 from $38.9 million for the year ended December 31, 2014. 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 commercialization of Cologuard.

Amounts in millions	2015	2014	Change
Direct marketing costs and professional fees	$ 28.7	$ 22.4	$ 6.3
Personnel expenses	48.1	14.7	33.4
Stock-based compensation	4.1	1.5	2.6
Other sales and marketing expenses	1.2	0.3	0.9
Total sales and marketing expenses	$ 82.1	$ 38.9	$ 43.2

Investment income. Investment income increased to $1.3 million for the year ended December 31, 2015 from $0.5 million for the year ended December 31, 2014. This increase was primarily due to an overall higher cash and marketable securities balance, due to our increased issuance of common stock, during the year ended December 31, 2015 as compared to the same period of 2014.

Interest expense. Interest expense decreased to $6,000 for the year ended December 31, 2015 from $0.1 million for the year ended December 31, 2014. This decrease is primarily due to the reversal of the accrued interest expense previously recorded on the Wisconsin Department of Commerce loan which was forgiven during 2015 due to the Company meeting certain job creation targets. Additionally, there was less interest expense recognized for our capital lease during the year ended December 31, 2015 when compared to the same period in 2014. These decreases were offset with an increase in interest expense due to the new credit agreement entered into during 2015 to finance the purchase of a facility located in Madison, Wisconsin.

Liquidity and Capital Resources

We have financed our operations since inception primarily through private and public offerings of our common stock and through revenue generated by the sale of Cologuard. As of December 31, 2016, we had approximately $48.9 million in unrestricted cash and cash equivalents and approximately $262.2 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, consistent with these two objectives. Our investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer.

Net cash used in operating activities was $130.1 million, $134.0 million, and $81.5 million for the years ended December 31, 2016, 2015 and 2014, respectively. The principal use of cash in operating activities for each of the years ended December 31, 2016, 2015 and 2014 was to fund our net loss. The increase in net cash used in operating activities for the years ended December 31, 2016 and December 31, 2015, as compared to the year ended December 31, 2014 was primarily due to increased sales and marketing activities and general and administrative activities, including increases in stock-based compensation, personnel expenses, and direct marketing costs, to support the launch of the Cologuard test. Cash flows from operations can vary significantly due to various factors, including changes in our operations, prepaid expenses, accounts payable, and accrued expenses.

Net cash used in investing activities was $11.5 million, $64.8 million, and $117.3 million for the years ended December 31, 2016, 2015, and 2014, respectively. The decrease in cash used in investing activities for the year ended December 31, 2016 when compared to the same period in 2015 was primarily the result of increased maturities of marketable securities. Excluding the impact of purchases and maturities of marketable securities, net cash used in investing activities was $14.9 million for the year ended December 31, 2016, compared to $22.0 million for the year ended December 31, 2015. The decrease was primarily the result of a decrease in purchases of property and equipment. Excluding the impact of purchases and maturities of marketable securities, net cash used in investing activities for the year ended December 31, 2014 was primarily the result of purchases of property and equipment of $12.0 million. Purchases of property and equipment during 2016 and 2015 included facility improvements, investments in our IT infrastructure, and equipment related to laboratory processing.

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Net cash provided by financing activities was $149.6 million, $181.8 million, and $244.0 million for the years ended December 31, 2016, 2015, and 2014, respectively. The decrease in cash provided by financing activities for the year ended December 31, 2016 when compared to the same period in 2015 was primarily the result of a decrease in proceeds from the sale of common stock from $174.1 million in 2015 to $144.2 million in 2016. The decrease in cash provided by financing activities for the year ended December 31, 2015 when compared to the same period in 2014 was primarily the result of a decrease in proceeds from the sale of common stock from $238.6 million in 2014 to $174.1 million in 2015.

We expect that cash and cash equivalents and marketable securities on hand at December 31, 2016, 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. 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 reflects our estimated fixed obligations and commitments as of December 31, 2016. This table only includes potential milestone payments due upon FDA approval of future products or future sales based royalty obligations and milestones when we determine the likelihood of payment is probable:

		Payments Due by Period			
Description	Total	Less Than One Year	1 - 3 Years	3 - 5 Years	More Than 5 Years
	(in thousands)				
Long-term debt obligations(1)	$ 4,852	$ 174	$ 4,678	$ —	$ —
Other long-term liabilities(1)	1,200	—	1,200	—	—
Obligations under license and collaborative agreements(2)	3,542	1,256	512	512	1,262
Operating lease obligations	6,882	2,226	2,896	1,479	281
Total	$ 16,476	$ 3,656	$ 9,286	$ 1,991	$ 1,543

(1) Excludes expected interest payments related to long term debt obligations.
(2) We have entered into license and collaborative agreements with the Mayo Foundation, MDx Health, and Hologic, Inc. See Note 7 in the notes to our consolidated financial statements for further information. Commitments under license agreements generally expire concurrent with the expiration of the intellectual property licensed from the third party. Operating leases reflect remaining obligations associated with the leased facilities at our headquarters and lab facility in Madison, WI.

Net Operating Loss Carryforwards

As of December 31, 2016, we had federal, state, and foreign net operating loss carryforwards of approximately $725.1 million, $291.9 million, $1.4 million, respectively. We also had federal and state research tax credit carryforwards of approximately $8.5 million and $16.4 million, respectively. The net operating loss and tax credit carryforwards will expire at various dates through 2037, 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.

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.

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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 to our financial statements included in this report, 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.

Laboratory service revenue. Our laboratory service revenues are generated by performing diagnostic services using our Cologuard test, and the service is completed upon delivery of a test result to an ordering physician. We recognize revenue in accordance with the provision of ASC 954-605, Health Care Entities - Revenue Recognition. We recognize revenue related to billings for Medicare and other payors on an accrual basis, net of contractual and other adjustments, when amounts that will ultimately be collected can be reasonably estimated. Contractual and other adjustments represent the difference between the list price (the billing rate) and the estimated reimbursement rate for each payor. Upon ultimate collection, the amount received from Medicare and other payors where reimbursement was estimated is compared to previous collection estimates and, if necessary, the contractual allowance is adjusted.

The estimates of amounts that will ultimately be collected requires significant judgment by management. Some patients have out-of-pocket costs for amounts not covered by their insurance carrier, and we bill the patient for these amounts in the form of co-payments, deductibles and co-insurance in accordance with their insurance carrier and health plans. In the absence of the ability to reasonably estimate the amount that will ultimately be collected for our services, revenue is recognized upon cash receipt.

We use judgment in determining if we are able to make an estimate of what will ultimately be collected. We also use judgment in estimating the amounts we expect to collect by payor. Our judgments will continue to evolve in the future as we continue to gain payment experience with payors and patients.

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, stock-based payments, including grants of employee stock options, restricted stock and restricted stock units 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:

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· 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 estimated fair value of employee stock options is recognized to expense using the straight line method over the vesting period.

· 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 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 valuation method on the implied yield currently available on U.S. Treasury zero coupon issues with an equivalent remaining expected term.

· Forfeitures—We record stock based compensation expense only for those awards that are expected to vest. A forfeiture rate is estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from initial estimates. Our forfeiture rate used in the twelve months ended December 31, 2016, 2015, and 2014 was 3.48%, 4.99%, and 4.99%, respectively.

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 to our 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 $277.9 million and $215.1 million valuation allowance at December 31, 2016 and 2015 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, 2016 and 2015 was $62.8 million and $53.2 million, respectively. Due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact our effective tax rate.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board issued ASU No. 2014-9, Revenue from Contracts with Customers (Topic 606), (the “New Revenue Standard”) requiring an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. Additional disclosures will also be required to enable users to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. The New Revenue Standard will replace most existing revenue recognition guidance in GAAP when it becomes effective and permits the use of either the retrospective or modified retrospective method upon adoption. Adoption of the New Revenue Standard is permitted as early as the first quarter of 2017 and is required by the first quarter of 2018. We do not plan to early adopt this standard and we have not yet selected a transition method. We have completed our preliminary evaluation of the potential financial statement impact of the

New Revenue Standard on prior and future reporting periods. We do not expect material changes to the timing of when we recognize revenue or the method by which we measure our single revenue stream, lab service revenue. Further, regarding the contract acquisition cost component of the New Revenue Standard, our preliminary analysis supports the use of the practical expedient when recognizing expense related to incremental costs incurred to acquire a contract, as the recovery of such costs is completed in less than one year's time. Additionally, incremental costs to obtain contracts have been immaterial to date. Accordingly, we do not expect any material changes to the timing of when we recognize expenses related to contract acquisition costs. We will continue our evaluation of the New Revenue Standard through the date of adoption.

In February 2016, the Financial Accounting Standards Board issued Accounting Standards Update No. 2016-02, "Leases (Topic 842)," ("Update 2016-02") which requires recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. The amendments in this update are effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. In transition, lessees and

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lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. Early adoption is permitted. We are currently evaluating the effects that the adoption of Update 2016-02 will have on our consolidated financial statements, and anticipate that the new guidance will impact our consolidated financial statements as we have several leases. As further described in Note 7. Commitments and Contingencies, as of December 31, 2016, we had future minimum operating lease payments of $6.9 million.

In March 2016, the Financial Accounting Standards Board issued Accounting Standards Update No. 2016-09, “Compensation —Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting” (“Update 2016-09”) as part of its Simplification Initiative. The areas for simplification in this update involve several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, accounting for forfeitures, and classification in the statements of cash flows. The amendments in this update are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. 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. We will adopt Update 2016-09 in the first quarter of 2017 and we plan to no longer use a forfeiture rate. The adoption of this aspect of the guidance is not expected to have a material impact on our financial statements.

Additionally, if in the future, we are able to utilize our deferred tax assets to offset taxes payable, excess tax benefit stock option deductions will be reflected in the consolidated statements of operations as a component of the provision for income taxes, whereas they previously would have been recognized in equity on the consolidated balance sheet. As of December 31, 2016, the Company had $62.7 million in excess tax benefit stock option deductions which would be subject to this reclassification if the deferred tax assets are realized in the future. Upon adoption, all such deductions will be fully offset by the valuation allowance.

In August 2016, the Financial Accounting Standards Board issued Accounting Standards Update 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 amendments in Update 2016-15 are effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. We have evaluated Update 2016-15 and we do not expect the adoption of this guidance to have a material impact on our statement of cash flows.

In October 2016, the Financial Accounting Standards Board issued Accounting Standards Update 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. Update 2016-16 is effective for fiscal years and interim periods within those years beginning after December 15, 2017. Early adoption is permitted. We do not anticipate that the adoption of Update 2016-16 will have a significant impact on our consolidated financial statements.

In October 2016, the Financial Accounting Standards Board issued Accounting Standards Update No. 2016-17, "Consolidation (Topic 810): Interests Held through Related Parties That Are Under Common Control," ("Update 2016-17"). The amendments in Update 2016-17 change how a reporting entity that is the single decision maker of a variable interest entity should treat indirect interests in the entity held through related parties that are under common control with the reporting entity when determining whether it is the primary beneficiary of that variable interest entity. The amendment is effective for fiscal years and interim periods within those years beginning after December 15, 2016. We do not expect the adoption of Update 2016-17 to have a material impact on our consolidated financial statements.

In November 2016, the Financial Accounting Standards Board issued Accounting Standards Update 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 amendments are effective for interim and annual periods beginning after December 15, 2017. Early adoption is permitted. The amendments in the Update 2016-18 should be adopted on a retrospective basis. We do not expect that adoption of this amendment to have a material effect on our consolidated financial statements as we do not have restricted cash.

In January 2017, the Financial Accounting Standards Board issued Accounting Standards Update No. 2017-01, "Business Combinations (Topic 805): Clarifying the Definition of a Business," ("Update 2017-01"). in an effort to

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clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The amendments of this update are effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The adoption of this guidance is not expected to have a material impact on our financial statements.

Off Balance Sheet Arrangements

As of December 31, 2016, we had no off balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk is principally confined to our cash, cash equivalents and marketable securities. We invest our cash, cash equivalents, and marketable securities in securities of the U.S. governments and its agencies and in investment grade, highly liquid investments consisting of commercial paper, bank certificates of deposit, and corporate bonds, which as of December 31, 2016 and December 31, 2015 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.

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Item 8. Consolidated Financial Statements and Supplementary Data

EXACT SCIENCES CORPORATION

Index to Financial Statements

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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

Exact Sciences Corporation

Madison, Wisconsin

We have audited the accompanying consolidated balance sheets of Exact Sciences Corporation (the “Company”) as of December 31, 2016 and 2015 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, 2016. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Exact Sciences Corporation at December 31, 2016 and 2015, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, 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), Exact Sciences Corporation’s internal control over financial reporting as of December 31, 2016, 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, 2017 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Milwaukee, Wisconsin

February 21, 2017

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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

Exact Sciences Corporation

Madison, Wisconsin

We have audited Exact Sciences Corporation's (the "Company") internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Exact Sciences Corporation'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 conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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.

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.

In our opinion, Exact Sciences Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Exact Sciences Corporation as of December 31, 2016 and 2015, 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, 2016 and our report dated February 21, 2017 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Milwaukee, Wisconsin

February 21, 2017

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EXACT SCIENCES CORPORATION

Consolidated Balance Sheets

(Amounts in thousands, except share data)

	December 31, 2016	December 31, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 48,921	$ 41,135
Marketable securities	262,179	265,744
Accounts receivable, net	8,526	4,933
Inventory, net	6,833	6,677
Prepaid expenses and other current assets	7,114	7,375
Total current assets	333,573	325,864
Property and Equipment, at cost:		
Computer equipment and computer software	20,767	14,025
Laboratory equipment	14,749	12,786
Leasehold improvements	13,549	7,118
Assets under construction	6,711	8,038
Buildings	4,792	4,777
Furniture and fixtures	2,515	1,265
	63,083	48,009
Less—Accumulated depreciation	(24,941)	(13,913)
Net property and equipment	38,142	34,096
Other long-term assets	5,325	4,070
Total assets	$ 377,040	$ 364,030
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 710	$ 3,308
Accrued liabilities	28,106	22,253
Debt and capital lease obligation, current portion	174	166
Other short-term liabilities	1,702	996
Total current liabilities	30,692	26,723
Long-term debt	4,633	4,789
Other long-term liabilities	5,734	4,601
Lease incentive obligation, less current portion	686	1,061
Total liabilities	41,745	37,174
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.01 par value Authorized—5,000,000 shares issued and outstanding—no shares at December 31, 2016 and December 31, 2015	—	—
	1,102	967

Common stock, $0.01 par value Authorized—200,000,000 shares issued and outstanding—110,236,127 and 96,674,786 shares at December 31, 2016 and December 31, 2015		
Additional paid-in capital	1,080,432	904,932
Accumulated other comprehensive loss	(418)	(433)
Accumulated deficit	(745,821)	(578,610)
Total stockholders' equity	335,295	326,856
Total liabilities and stockholders' equity	$ 377,040	$ 364,030

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,		
	2016	2015	2014
Laboratory service revenue	$ 99,376	$ 39,437	$ 1,504
License fees	—	—	294
Total revenue	99,376	39,437	1,798
Cost of sales	45,195	24,501	4,325
Gross margin	54,181	14,936	(2,527)
Operating expenses:			
Research and development	33,473	33,914	28,669
General and administrative	76,898	57,950	30,435
Sales and marketing	112,826	82,140	38,908
Total operating expenses	223,197	174,004	98,012
Loss from operations	(169,016)	(159,068)	(100,539)
Other income (expense)			
Investment income	2,018	1,271	542
Interest expense	(213)	(6)	(51)
Total other income	1,805	1,265	491
Net loss	$ (167,211)	$ (157,803)	$ (100,048)
Net loss per share—basic and diluted	$ (1.63)	$ (1.71)	$ (1.25)
Weighted average common shares outstanding—basic and diluted	102,335	92,135	80,232

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,		
	2016	2015	2014
Net loss	$ (167,211)	$ (157,803)	$ (100,048)
Other comprehensive loss, net of tax:			
Unrealized gain (loss) on available-for-sale investments	230	(329)	(240)
Foreign currency translation gain (loss)	(215)	11	—
Comprehensive loss	$ (167,196)	$ (158,121)	$ (100,288)

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 , 2014	71,071,838	$ 711	$ 455,239	$ 125	$ (320,759)	$ 135,316
Issuance of common stock, net of issuance costs of $11.0 million	15,500,000	155	238,425	—	—	238,580
Exercise of common stock options and warrants	1,522,753	15	2,625	—	—	2,640
Issuance of common stock to fund the Company's 2013 401(k) match	32,666	—	456	—	—	456
Compensation expense related to issuance of stock options and restricted stock awards	410,619	4	11,516	—	—	11,520
Purchase of employee stock purchase plan shares	88,166	1	759	—	—	760
Net loss	—	—	—	—	(100,048)	(100,048)
Accumulated other comprehensive income	—	—	—	(240)	—	(240)
Balance, December 31 , 2014	88,626,042	$ 886	$ 709,020	$ (115)	$ (420,807)	$ 288,984
Issuance of common stock, net of issuance costs of $4.4 million	7,000,000	70	174,070	—	—	174,140
Exercise of common stock options and warrants	281,315	3	1,245	—	—	1,248
Issuance of common stock to fund the Company's 2014 401(k) match	21,826	—	836	—	—	836
Compensation expense related to issuance of	568,818	6	18,044	—	—	18,050

stock options and restricted stock awards						
Purchase of employee stock purchase plan shares	176,785	2	1,717	—	—	1,719
Net loss	—	—	—	—	(157,803)	(157,803)
Accumulated other comprehensive income	—	—	—	(318)	—	(318)
Balance, December 31, 2015	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

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,		
	2016	2015	2014
Cash flows from operating activities:			
Net loss	$ (167,211)	$ (157,803)	$ (100,048)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of fixed assets	11,309	7,600	3,710
Loss on disposal of property and equipment	151	40	49
Stock-based compensation	23,732	18,050	11,520
Amortization of deferred license fees	—	—	(294)
Amortization of other liabilities	(1,013)	(573)	—
Amortization of deferred financing costs	52	44	—
Forgiveness of long-term debt	—	(1,000)	—
Amortization of premium on short-term investments	463	1,323	842
Amortization of intangible assets	200	150	—
Proceeds from refundable tax credits	800	—	—
Changes in assets and liabilities:			
Accounts receivable, net	(3,593)	(3,557)	(1,376)
Inventory, net	(156)	(2,660)	(4,017)
Prepaid expenses and other current assets	761	(3,057)	(1,329)
Accounts payable	(2,598)	661	1,886
Accrued liabilities	7,349	7,424	8,064
Lease incentive obligation	(312)	(553)	(487)
Accrued interest	—	(106)	22
Net cash used in operating activities	(130,066)	(134,017)	(81,458)
Cash flows from investing activities:			
Purchases of marketable securities	(189,989)	(205,054)	(209,471)
Maturities of marketable securities	193,321	162,283	104,172
Purchases of property and equipment	(14,851)	(20,084)	(11,991)
Purchases of intangible assets	—	(1,900)	—
Net cash used in investing activities	(11,519)	(64,755)	(117,290)
Cash flows from financing activities:			
Proceeds from exercise of common stock options	3,411	1,248	2,640
Proceeds from sale of common stock, net of issuance costs	144,242	174,140	238,580
Payments on capital lease obligations	—	(360)	(351)
Proceeds from mortgage payable	—	5,062	—
Payments on mortgage payable	(166)	(44)	—
Proceeds from New Market Tax Credit financing agreements	—	—	2,399
Proceeds in connection with the Company's employee stock purchase plan	2,099	1,719	760

Net cash provided by financing activities	149,586	181,765	244,028
Effects of exchange rate changes on cash and cash equivalents	(215)	11	—
Net increase (decrease) in cash and cash equivalents	7,786	(16,996)	45,280
Cash and cash equivalents, beginning of period	41,135	58,131	12,851
Cash and cash equivalents, end of period	$ 48,921	$ 41,135	$ 58,131
Supplemental disclosure of non-cash investing and financing activities:			
Property and equipment acquired but not paid	$ 655	$ 1,705	$ 546
Unrealized gain on available-for-sale investments	$ 230	$ (329)	$ (240)
Issuance of 341,507, 21,826 and 32,666 shares of common stock to fund the Company's 401(k) matching contribution for 2015, 2014 and 2013, respectively	$ 2,151	$ 836	$ 456
Interest paid	$ 209	$ 95	$ 29

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 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, Exact Sciences Laboratories, LLC, Exact Sciences Finance Corporation, Exact Sciences Europe LTD, Beijing Exact Sciences Medical Technology Company Limited, and variable interest entities. See Note 11 for the discussion of financing arrangements involving certain entities that are variable interest entities that are included in our 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, 2016 and 2015.

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, 2016 and December 31, 2015 the Company's investments 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.

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

The Company's investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer. Investments in which the Company has the ability and intent, if necessary, to liquidate in order to support its current operations (including those with a contractual term greater than one year from the date of purchase) are classified as current. All of the Company's investments are considered current. Realized gains were $24,132, $14,205, and $11,000, net of insignificant realized losses, for the years ended December 31, 2016, 2015, and 2014, 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, 2016, no investments were identified with other-than-temporary declines in value.

Available for sale securities at December 31, 2016 consist of the following:

	December 31, 2016			
(In thousands)	Amortized Cost	Gains in Accumulated Other Comprehensive Income	Losses in Accumulated Other Comprehensive Income	Estimated Fair Value
Corporate bonds	$ 137,013	$ 17	$ (93)	$ 136,937
Asset backed securities	55,667	3	(30)	55,640
U.S. government agency securities	49,591	3	(120)	49,474
Commercial paper	19,069	8	(1)	19,076
Certificates of deposit	1,053	—	(1)	1,052
Total available-for-sale securities	$ 262,393	$ 31	$ (245)	$ 262,179

Available for sale securities at December 31, 2015 consist of the following:

	December 31, 2015			
		Gains in Accumulated Other Comprehensive	Losses in Accumulated Other Comprehensive	Estimated Fair

(In thousands)	Amortized Cost	Income	Income	Value
Corporate bonds	$ 179,471	$ 2	$ (262)	$ 179,211
Asset backed securities	77,661	—	(166)	77,495
U.S. government agency securities	7,057	—	(18)	7,039
Certificates of deposit	1,999	—	—	1,999
Total available-for-sale securities	$ 266,188	$ 2	$ (446)	$ 265,744

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

Changes in Accumulated Other Comprehensive Income (Loss)

The amount recognized in accumulated other comprehensive income (loss) ("AOCI") for the years ended December 31, 2016, 2015 and 2014 were as follows:

(In thousands)	Cumulative Translation Adjustment	Unrealized Gain (Loss) on Securities	Accumulated Other Comprehensive Income (Loss)
Balance at January 1, 2014	$ —	$ 125	$ 125
Other comprehensive (loss) income before reclassifications	—	(200)	(200)
Amounts reclassified from accumulated other comprehensive loss	—	(40)	(40)
Net current period change in accumulated other comprehensive income (loss)	—	(240)	(240)
Balance at December 31, 2014	$ —	$ (115)	$ (115)
Other comprehensive (loss) income before reclassifications	11	(361)	(350)
Amounts reclassified from accumulated other comprehensive loss	—	32	32
Net current period change in accumulated other comprehensive income (loss)	11	(329)	(318)
Balance at December 31, 2015	$ 11	$ (444)	$ (433)
Other comprehensive (loss) income 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)

Amounts reclassified from accumulated other comprehensive income (loss) for the years ended December 31, 2016, 2015 and 2014 were as follows:

Details about AOCI Components (In thousands)	Affected Line Item in the Statement of Operations	Year Ended December 31, 2016	2015	2014

Change in value of available-for-sale investments

Sales and maturities of available-for-sale investments	Investment income	$ 113	$ 32	$ (40)
Total reclassifications		$ 113	$ 32	$ (40)

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. For the years ended December 31, 2016, 2015 and 2014, 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 certain batches or units of product no longer meet quality specifications or

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

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.

Inventory consists of the following:

	December 31,	
(In thousands)	2016	2015
Raw materials	$ 2,408	$ 1,772
Semi-finished and finished goods	4,425	4,905
Total inventory	$ 6,833	$ 6,677

Property and Equipment

Property and equipment are stated at cost and depreciated using the straight line method over the assets' estimated useful lives. Maintenance and repairs are expensed when incurred; additions and improvements are capitalized. The estimated useful lives of fixed assets are as follows:

	Estimated
Asset Classification	Useful Life
Laboratory equipment	3 - 5 years
Computer equipment and computer software	3 years
Leasehold improvements	Lesser of the remaining lease term or useful life
Building Improvements	Lesser of the remaining building life or useful life
Furniture and fixtures	3 years
Buildings	30 years

Depreciation expense for the years ended December 31, 2016, 2015, and 2014 was $11.3 million, $7.6 million, and $3.7 million, respectively.

At December 31, 2016, the Company had $6.7 million of assets under construction which consisted of $0.1 million related to building and leasehold improvements, $1.7 million of capitalized costs related to software projects and $4.9 million of costs related to machinery and equipment. Depreciation will begin on these assets once they are placed into service. The Company expects to incur minimal costs to complete these projects and expects to be complete these projects in 2017. The Company assesses its long-lived assets, consisting primarily of 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, 2016, 2015 or 2014.

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 and Intangible Assets

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

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

expensed upon disapproval, upon a decision by the Company to no longer pursue the patent or when the related intellectual property is either sold or deemed to be no longer of value to the Company. The Company determined that all patent costs incurred during the year ended December 31, 2016, 2015 and 2014 should be expensed and not capitalized as the future economic benefit derived from the transactions cannot be determined.

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.

Under a technology license and royalty agreement entered into with MDx Health, the Company is required to pay MDx Health milestones on sales of products or services covered by the licensed intellectual property. Once the achievement of a milestone has occurred or is considered probable, an intangible asset and corresponding liability is reported in other long-term assets and accrued expenses, respectively. The intangible asset is amortized over the estimated ten-year useful life of the licensed intellectual property, and such amortization is reported in cost of sales. The liability is relieved once the milestone has been achieved and payment has been made. As of December 31, 2016, an intangible asset of $1.6 million and a liability of $1.3 million are reported in other long-term assets and accrued expenses, respectively. Amortization expense for the years ended December 31, 2016 and 2015 was $0.2 million.

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)	2016	2015	2014
Shares issuable upon exercise of stock options	3,505	4,937	4,934
Shares issuable upon the release of restricted stock awards	5,601	3,445	1,541
Shares issuable upon the vesting of restricted stock awards related to licensing agreement	—	—	24
	9,106	8,382	6,499

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 ESPP (if certain parameters are not met), to be recognized in the financial statements based on their fair values.

Revenue Recognition

Laboratory service revenue. The Company's laboratory service revenue is generated by performing diagnostic services using its Cologuard test, and the service is completed upon delivery of a test result to an ordering physician. The Company recognizes revenue in accordance with the provisions of ASC 954-605, Health Care Entities - Revenue Recognition. The Company recognizes revenue related to billings for Medicare and other payors on an accrual basis, net of contractual and other adjustments, when amounts that will ultimately be collected can be reasonably estimated. Contractual and other adjustments represent the difference between the list price (the billing rate) and the estimated reimbursement rate for each payor. Upon ultimate collection, the amount received from Medicare and other payors

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

where reimbursement was estimated is compared to previous estimates and, if necessary, the prior allowance is adjusted.

The estimates of amounts that will ultimately be collected require significant judgment by management. Some patients have out-of-pocket costs for amounts not covered by their insurance carrier, and the Company bills the patient directly for these amounts in the form of co-payments, deductibles and co-insurance in accordance with their insurance carrier and health plans. In the absence of the ability to estimate the amount that will ultimately be collected for the Company's services, revenue is recognized upon cash receipt.

The Company uses judgment in determining if it is able to make an estimate of what will ultimately be collected. The Company also uses judgment in estimating the amounts it expects to collect by payor. The Company's judgments will continue to evolve in the future as it continues to gain payment experience with payors and patients.

The components of our laboratory service revenue, as recognized upon accrual or cash receipt, for the years ended December 31, 2016 and 2015 were as follows:

	Year Ended December 31,		
(In thousands)	2016	2015	2014
Revenue recognized on an accrual basis	$ 87,037	$ 36,364	$ 1,388
Revenue recognized when cash is received	12,339	3,073	116
Total	$ 99,376	$ 39,437	$ 1,504

License fees. License fees for the licensing of product rights are recorded as deferred revenue upon receipt of cash and recognized as revenue on a straight line basis over the license period.

As more fully described in Note 3 below, in connection with the Company's transaction with Genzyme Corporation, Genzyme agreed to pay the Company a total of $18.5 million, of which $16.65 million was paid on January 27, 2009 and $1.85 million was subject to a holdback by Genzyme to satisfy certain potential indemnification obligations in exchange for the assignment and licensing of certain intellectual property to Genzyme. The Company's on going performance obligations to Genzyme under the Collaboration, License and Purchase Agreement (the "CLP Agreement"), as described below, including its obligation to deliver through licenses certain intellectual property improvements to Genzyme, if improvements are made during the initial five year collaboration period, were deemed to be undelivered elements of the CLP Agreement on the date of closing. Accordingly, the Company deferred the initial $16.65 million in cash received at closing and amortized that up front payment on a straight line basis into revenue over the initial five year collaboration period ending in January 2014. The Company received the first holdback amount of $962,000, which included accrued interest, due from Genzyme during the first quarter of 2010. The Company received the second holdback amount of $934,000 which included accrued interest due, from Genzyme

during the third quarter of 2010. The amounts were deferred and were amortized on a straight line basis into revenue over the remaining term of the collaboration at the time of receipt.

In addition, Genzyme purchased 3,000,000 shares of common stock purchased from the Company on January 27, 2009 for $2.00 per share, representing a premium of $0.51 per share above the closing price of the Company's common stock on that date of $1.49 per share. The aggregate premium paid by Genzyme over the closing price of the Company's common stock on the date of the transaction of $1.53 million is deemed to be a part of the total consideration for the CLP Agreement. Accordingly, the Company deferred the aggregate $1.53 million premium and amortized that amount on a straight line basis into revenue over the initial five year collaboration period ending in January 2014.

The Company did not recognize license fee revenue for the years ended December 31, 2016 and 2015. The Company recognized approximately $0.3 million in license fee revenue for the year ended December 31, 2014 in connection with the amortization of the up-front payments from Genzyme.

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Advertising Costs

The Company expenses the costs of media advertising at the time the advertising takes place. The Company expensed approximately $38.1 million, $10.8 million, and $5.3 million of media advertising during the years ended December 31, 2016, 2015, and 2014, 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 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 and mutual funds 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.

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The following table presents the Company's fair value measurements as of December 31, 2016 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, 2016 Using:		
(In thousands)	Fair Value at December 31, 2016	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	$ 48,921	48,921	—	—
Available-for-sale Marketable securities				
Corporate bonds	136,937	—	136,937	—
Asset backed securities	55,640	—	55,640	—
U.S. government agency securities	49,474	—	49,474	—
Commercial paper	19,076	—	19,076	—
Certificates of deposit	1,052	—	1,052	—
Total	$ 311,100	$ 48,921	$ 262,179	$ —

The following table presents the Company's fair value measurements as of December 31, 2015 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, 2015 Using:		
(In thousands)	Fair Value at December 31, 2015	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	$ 37,435	$ 37,435	$ —	$ —
Commercial paper	3,700	—	3,700	—

Available-for-sale				
Marketable securities				
Corporate bonds	179,211	—	179,211	—
Asset backed securities	77,495	—	77,495	—
U.S. government agency securities	7,039	—	7,039	—
Certificates of deposit	1,999	—	1,999	—
Total	$ 306,879	$ 37,435	$ 269,444	$ —

The Company monitors investments for other-than-temporary impairment. It was determined that unrealized gains and losses at December 31, 2016 and 2015 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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The following table summarizes the gross unrealized losses and fair values of investments in an unrealized loss position as of December 31, 2016, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position:

	December 31, 2016					
	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	$ 94,999	$ (93)	$ —	$ —	$ 94,999	$ (93)
Asset backed securities	41,656	(27)	3,506	(2)	45,162	(29)
U.S. government agency securities	44,911	(120)	—	—	44,911	(120)
Commercial paper	5,606	(2)	—	—	5,606	(2)
Certificates of deposit	1,052	(1)	—	—	1,052	(1)
Total	$ 188,224	$ (243)	$ 3,506	$ (2)	$ 191,730	$ (245)

The following table summarizes the gross unrealized losses and fair value of investments in an unrealized loss position as of December 31, 2015, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position:

	December 31, 2015					
	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	$ 166,238	$ (262)	$ —	$ —	$ 166,238	$ (262)
U.S. government agency securities	7,039	(18)	—	—	7,039	(18)
Asset backed securities	72,792	(164)	3,887	(2)	76,679	(166)
Total	$ 246,069	$ (444)	$ 3,887	$ (2)	$ 249,956	$ (446)

The following table summarizes contractual underlying maturities of the Company's available for sale investments at December 31, 2016:

	Due one year or less		Due after one year through four years	
(In thousands)	Cost	Fair Value	Cost	Fair Value
Marketable securities				
Corporate bonds	$ 128,443	$ 128,389	$ 8,570	$ 8,548
Certificates of deposit	—	—	1,053	1,052
Commercial paper	19,069	19,076	—	—
U.S. government agency securities	14,553	14,545	35,038	34,929
Asset backed securities	—	—	55,667	55,640
Total	$ 162,065	$ 162,010	$ 100,328	$ 100,169

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, 2016, 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 $47.9 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, 2016, all of the Company's laboratory service revenues have been derived from the sale of Cologuard, and one payor, Centers for Medicare and Medicaid Services, has provided greater than 10% of revenue during the years ended December 31, 2016 and 2015. Medicare revenue as a percentage of total laboratory service revenue was 60% and 71% for the years ended December 31, 2016 and 2015, respectively. Medicare accounts receivable as a percentage of total accounts receivable were 63% and 64% at December 31, 2016 and 2015, respectively. As the number of payors reimbursing for Cologuard increases, the percentage of laboratory service revenue derived from Medicare 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 $277.9 million and $215.1 million valuation allowance at December 31, 2016 and 2015 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, 2016 and 2015 was $62.8 million and $53.2 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. 2014-9, Revenue from Contracts with Customers (Topic 606), (the "New Revenue Standard") requiring an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. Additional disclosures will also be required to enable users to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. The New Revenue Standard will replace most existing revenue recognition guidance in GAAP when it becomes effective and permits the use of either the retrospective or modified retrospective method upon adoption. Adoption of the New Revenue Standard is permitted as early as the first quarter of 2017 and is required by the first quarter of 2018. The Company does not plan to early adopt this standard and has not yet selected a transition method. The Company has completed its preliminary evaluation of the potential financial statement impact of the New Revenue Standard on prior and future reporting periods. The Company does not expect material

changes to the timing of when the Company recognizes revenue or the method by which the Company measures its single revenue stream, lab service revenue. Further, regarding the contract acquisition cost component of the New Revenue Standard, the Company's analysis supports use of the practical expedient when recognizing expense related to incremental costs incurred to acquire a contract, as the recovery of such costs is completed in less than one year's time. Additionally, incremental costs to obtain contracts have been immaterial to date. Accordingly, the Company does not expect any material changes to the timing of when it recognizes expenses related to contract acquisition costs. The Company will continue its evaluation of the New Revenue Standard through the date of adoption.

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In February 2016, the Financial Accounting Standards Board issued Accounting Standards Update No. 2016-02, "Leases (Topic 842)," ("Update 2016-02") which requires recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. The amendments in this update are effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. Early adoption is permitted. The Company is currently evaluating the effects that the adoption of Update 2016-02 will have on the Company's consolidated financial statements, and anticipate that the new guidance will impact the Company's consolidated financial statements as it has several leases. As further described in Note 7. Commitments and Contingencies, as of December 31, 2016, we had future minimum operating lease payments of $6.9 million.

In March 2016, the Financial Accounting Standards Board issued Accounting Standards Update No. 2016-09, "Compensation —Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting" ("Update 2016-09") as part of its Simplification Initiative. The areas for simplification in this update involve several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, accounting for forfeitures, and classification in the statements of cash flows. The amendments in this update are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. 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 Company will adopt Update 2016-09 in the first quarter of 2017 and will no longer use a forfeiture rate. The adoption of this aspect of the guidance is not expected to have a material impact on the Company's financial statements.

Additionally, if in the future, the Company is able to utilize its deferred tax assets to offset taxes payable, excess tax benefit stock option deductions will be reflected in the consolidated statements of operations as a component of the provision for income taxes, whereas they previously would have been recognized in equity on the consolidated balance sheet. As of December 31, 2016, the Company had $62.7 million in excess tax benefit stock option deductions which would be subject to this reclassification if the deferred tax assets are realized in the future. Upon adoption, all such deductions will be fully offset by the valuation allowance.

In August 2016, the Financial Accounting Standards Board issued Accounting Standards Update 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 amendments in Update 2016-15 are effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The company has evaluated Update 2016-15 and we do not expect the adoption of this guidance to have a material impact on our statement of cash flows.

In October 2016, the Financial Accounting Standards Board issued Accounting Standards Update 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. Update 2016-16 is effective for fiscal years and interim periods within those years beginning after December 15, 2017. Early adoption is permitted. The Company does not anticipate that the adoption of Update 2016-16 to have a significant impact on its consolidated financial statements.

In October 2016, the Financial Accounting Standards Board issued Accounting Standards Update No. 2016-17, "Consolidation (Topic 810): Interests Held through Related Parties That Are Under Common Control," ("Update 2016-17"). The amendments in Update 2016-17 change how a reporting entity that is the single decision maker of a variable interest entity should treat indirect interests in the entity held through related parties that are under common control with the reporting entity when determining whether it is the primary beneficiary of that variable interest entity. The amendment is effective for fiscal years and interim periods within those years beginning after December 15, 2016. The Company does

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not expect the adoption of Update 2017-17 to have a material impact on its consolidated financial statements.

In November 2016, the Financial Accounting Standards Board issued Accounting Standards Update 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 amendments are effective for interim and annual periods beginning after December 15, 2017. Early adoption is permitted. The amendments in the Update 2016-18 should be adopted on a retrospective basis. The Company does not expect that adoption of this amendment to have a material effect on its consolidated financial statements as the Company does not have restricted cash.

In January 2017, the Financial Accounting Standards Board issued Accounting Standards Update No. 2017-01, "Business Combinations (Topic 805): Clarifying the Definition of a Business," ("Update 2017-01"). in an effort to clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The amendments of this ASU are effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The adoption of this guidance is not expected to have a material impact on the Company's financial statements.

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 statement 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) GENZYME STRATEGIC TRANSACTION

Transaction summary

On January 27, 2009, the Company entered into a Collaboration, License and Purchase Agreement (the "CLP Agreement") with Genzyme Corporation ("Genzyme"). Pursuant to the CLP Agreement, the Company (i) assigned to Genzyme all of its intellectual property applicable to the fields of prenatal and reproductive health (the "Transferred Intellectual Property"), (ii) granted Genzyme an irrevocable, perpetual, exclusive, worldwide, fully paid, royalty free license to use and sublicense all of the Company's remaining intellectual property (the "Retained Intellectual Property") in the fields of prenatal and reproductive health (the "Genzyme Core Field"), and (iii) granted Genzyme an irrevocable, perpetual, non exclusive, worldwide, fully paid, royalty free license to use and sublicense the Retained Intellectual Property in all fields other than the Genzyme Core Field and other than colorectal cancer detection and stool based disease detection (the "Company Field"). Following the transaction, the Company retained rights in its intellectual property to pursue only the fields of colorectal cancer detection and stool based detection of any disease or condition. The Company agreed to deliver to Genzyme certain intellectual property improvements, if improvements were made during the initial five year collaboration period.

Pursuant to the Genzyme Strategic Transaction, Genzyme agreed to pay an aggregate of $18.5 million to the Company, of which $16.65 million was paid at closing and $1.85 million (the "Holdback Amount") was subject to a holdback by Genzyme to satisfy certain potential indemnification obligations of the Company. Genzyme also agreed to pay a double digit royalty to the Company on income received by Genzyme as a result of any licenses or sublicenses to

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third parties of the Transferred Intellectual Property or the Retained Intellectual Property in any field other than the Genzyme Core Field or the Company Field.

The Company's on going performance obligations to Genzyme under the CLP were deemed to be undelivered elements of the CLP Agreement on the date of closing. Accordingly, the Company deferred the initial $16.65 million in cash received at closing and amortized that up front payment on a straight line basis into the License Fee Revenue line item in its statements of operations over the initial five year collaboration period. The Company received the first holdback amount of $962,000, which included accrued interest, due from Genzyme during the first quarter of 2010. The Company received the second holdback amount of $934,000 which included accrued interest due, from Genzyme during the third quarter of 2010. The amounts were deferred and were amortized on a straight line basis into revenue over the remaining term of the collaboration through January 2014.

In addition, the Company entered into a Common Stock Subscription Agreement with Genzyme on January 27, 2009, which provided for the private issuance and sale to Genzyme of 3,000,000 shares (the "Shares") of the Company's common stock, $0.01 par value per share, at a per share price of $2.00, for an aggregate purchase price of $6.0 million. The price paid by Genzyme for the Shares represented a premium of $0.51 per share above the closing price of the Company's common stock on that date of $1.49 per share. The aggregate premium paid by Genzyme over the closing price of the Company's common stock on the date of the transaction of $1.53 million is included as a part of the total consideration for the CLP. Accordingly, the Company deferred the aggregate $1.53 million premium and amortized that amount on a straight line basis into the License fees line item in the Company's statements of operations over the initial five year collaboration period.

The Company did not recognize license fee revenue from the CLP Agreement during the years ended December 31, 2016 and 2015. The Company recognized approximately $0.3 million in license fee revenue in connection with the amortization of the up-front payments and holdback amounts from Genzyme during the year ended December 31, 2014.

(4) MAYO LICENSE AGREEMENT

On June 11, 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. 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 of matter claims that relate to 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., Canada, the European Union and Japan. 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

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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 amendment, would remain a low-single-digit percentage of net sales.

In addition to royalties, the Company is required to issue stock or cash to MAYO upon achievement of several milestones. The Company is required to issue MAYO shares of the Company's common stock with a value of $0.2 million upon commercial launch of its second and third products that use the licensed MAYO intellectual property. Additionally, for the second and third products that use licensed MAYO intellectual property, the Company is required to pay MAYO cash of $0.2 million upon commercialization and cash of $0.2 million, $0.8 million and $2.0 million upon such product 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 and 2016.

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 $3.6 million and has made payments of $3.9 million for the year ended December 31, 2016. The Company has recorded an estimated liability in the amount of $1.0 million for research and development efforts as of December 31, 2016. The Company incurred charges of $2.6 million and made payments of $2.6 million for the year ended December 31, 2015. The Company recorded an estimated liability in the amount of $1.3 million for research and development efforts at December 31, 2015. The Company incurred charges of $2.3 million and made payments of $0.7 million for the year ended December 31, 2014.

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 we are still using the licensed MAYO know how or certain MAYO provided biological specimens or their derivatives on such expiration date, the term shall continue until the earlier of the date we stop using such know how and materials and the date that is five years after the last licensed patent expires. The license agreement contains customary termination provisions and permits MAYO to terminate the license agreement if the Company sues MAYO or its affiliates, other than any such suit claiming an uncured material breach by MAYO of the license agreement.

(5) ISSUANCES OF EQUITY

Underwritten Public Offerings

On April 2, 2014, the Company completed an underwritten public offering of 11.5 million shares of common stock at a price of $12.75 per share to the public. The Company received approximately $137.7 million of net proceeds from the offering, after deducting $8.9 million for the underwriting discount and commissions and other stock issuance costs paid by the Company.

On December 16, 2014, the Company completed an underwritten public offering of 4.0 million shares of common stock at a price of $25.75 per share to the public. The Company received approximately $100.9 million of net proceeds

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from the offering, after deducting $2.1 million for the underwriting discount and commissions and other stock issuance costs paid by the Company.

On July 24, 2015 the Company completed an underwritten public offering of 7.0 million shares of common stock at a price of $25.50 per share to the public. The Company received approximately $174.1 million of net proceeds from the offering, after deducting $4.4 million for the underwriting discount and commissions and other stock issuance costs paid by the Company.

On August 2, 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.

Rights Agreement

In February 2011, the Company adopted a rights agreement and subsequently distributed to the Company's stockholders preferred stock purchase rights. Under certain circumstances, each right can be exercised for one one thousandth of a share of Series A Junior Participating Preferred Stock. In general, the rights will become exercisable in the event of an announcement of an acquisition of 15% or more of the Company's outstanding common stock or the commencement or announcement of an intention to make a tender offer or exchange offer for 15% or more of the Company's outstanding common stock. If any person or group acquires 15% or more of the Company's common stock, the Company's stockholders, other than the acquiror, will have the right to purchase additional shares of the Company's common stock (in lieu of the Series A Junior Participating Preferred Stock) at a substantial discount to the then prevailing market price. The rights agreement could significantly dilute such acquiror's ownership position in the Company's shares, thereby making a takeover prohibitively expensive and encouraging such acquiror to negotiate with the Company's board of directors. The ability to exercise these rights is contingent on events that the Company has determined to be unlikely at this time, and therefore this provision has not been considered in the computation of equity or earnings per share.

(6) STOCK BASED COMPENSATION

Stock Based Compensation Plans

The Company maintains the 2010 Omnibus Long Term Incentive Plan, 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, 2016, options to purchase 1,063,476 shares were outstanding under the 2000 Option Plan. There were no shares of restricted stock outstanding under the 2000 Option Plan.

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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, 2016, options to purchase 2,442,005 shares were outstanding under the 2010 Stock Plan and 4,943,782 shares of restricted stock and restricted stock units were outstanding. On July 23, 2015 the Company's stockholders approved an amendment and restatement of the 2010 Stock Plan which, among other items, increased the number of shares available for issuance thereunder by 8,360,000 shares. At December 31, 2016, there were 1,426,375 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 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 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 will 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, 2016, there were 132,550 shares of restricted stock and restricted stock units outstanding under the 2015 Inducement Award Plan. At December 31, 2016, 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 will expire on the date of the Company's 2017 Annual Stockholder's Meeting and after such date no further awards may be granted under the plan. Under the terms of the 2016 Inducement 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 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 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 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, 2016, there were 524,984 shares of restricted stock and restricted stock units outstanding under the 2016

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Inducement Award Plan. At December 31, 2016, there were 845,604 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, 2016, there were 2,006,569 shares of common stock available for purchase by participating employees under the 2010 Purchase Plan.

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% and 15% of the employee's compensation, to be deducted from the employee's pay during the offering period. On the last day of the offering period, the employee is deemed to have exercised the employee's option to purchase shares of Company common stock, at the option exercise price, to the extent of accumulated payroll deductions. Under the terms of the 2010 Purchase Plan, the option exercise price is an amount equal to 85% of the fair market value, as defined under the 2010 Purchase Plan, and no employee can purchase more than $25,000 of Company common stock under the 2010 Purchase Plan in any calendar year. Rights granted under the 2010 Purchase Plan terminate upon an employee's voluntary withdrawal from the 2010 Purchase Plan at any time or upon termination of employment. At December 31, 2016, there were 793,431 cumulative shares issued under the 2010 Purchase Plan, and 356,823 shares were issued in the year ended December 31, 2016, as follows:

Offering period ended	Number of Shares	Weighted Average price per Share
April 30, 2016	177,331	$ 5.95
October 31, 2016	179,492	$ 5.95

Stock Based Compensation Expense

The Company recorded approximately $23.7 million, $18.1 million, and $11.5 million in stock based compensation expense during the years ended December 31, 2016, 2015, and 2014, 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, 2016, 2015, and 2014 are as follows:

	December 31,		
(In thousands)	2016	2015	2014
Cost of sales	$ 1,064	$ 876	$ 279
Research and development	4,014	3,744	4,149
General and administrative	14,597	9,358	5,575
Sales and marketing	4,057	4,072	1,517
Total stock-based compensation	$ 23,732	$ 18,050	$ 11,520

In connection with the November 8, 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.

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Notes to Consolidated Financial Statements (Continued)

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 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. 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 option, 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—The Company records stock based compensation expense only for those awards that are expected to vest. A forfeiture rate is estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from initial estimates. The Company's forfeiture used in the twelve months ended December 31, 2016, 2015 and 2014 was 3.48%, 4.99%, and 4.99%, respectively.

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

	Year Ended December 31,		
	2016	2015	2014
Option Plan Shares			
Risk-free interest rates	1.48% - 1.69%	1.5% - 1.92%	1.96% - 2.01%
Expected term (in years)	6.25 - 6.74	6.25 - 6.6	6.25
Expected volatility	58.9% - 59.4%	67.1% - 73.2%	77.6% - 80.8%
Dividend yield	0 %	0 %	0 %
Weighted average fair value per share of options granted during the period	$ 3.17	$ 15.81	$ 10.05
Market Measure-Based Shares			

Risk-free interest rates	0.76% - 0.91%	1.12 %	(1)
Expected term (in years)	2.43 - 2.84	3.16	(1)
Expected volatility	68.3 - 79.6%	64.3 %	(1)
Dividend yield	0 %	0 %	(1)
Weighted average fair value per share of stock purchase rights granted during the period	$ 3.77	$ 5.91	(1)
ESPP Shares			
Risk-free interest rates	0.41% - 0.83%	0.25% - 0.75%	0.1% - 0.5%
Expected term (in years)	0.5 - 2	0.5 - 2	0.5 - 2
Expected volatility	70.1% - 92.7%	51.2% - 110%	42.5% - 62.7%
Dividend yield	0 %	0 %	0 %
Weighted average fair value per share of stock purchase rights granted during the period	$ 3.30	$ 4.67	$ 6.30

(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 2016, 2015 and 2014 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, 2014	6,062,587	$ 2.78	6.6	
Granted	266,477	14.28		
Exercised	(1,378,372)	1.91		
Forfeited	(16,375)	6.37		
Outstanding, December 31, 2014	4,934,317	$ 3.63	5.2	
Granted	340,978	23.51		
Exercised	(281,315)	4.44		
Forfeited	(57,386)	16.99		
Outstanding, December 31, 2015	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	$ 25,700
Exercisable, December 31, 2016	2,265,691	$ 5.42	3.8	$ 18,943
Vested and expected to vest, December 31, 2016	3,429,333	$ 3.97	5.5	$ 25,201

(1) The aggregate intrinsic value of options outstanding at December 31, 2016 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 3,505,481 options that had exercise prices that were lower than the $13.36 market price of our common stock at December 31, 2016. The aggregate intrinsic value of options exercisable at December 31, 2016 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 2,265,691 options that had exercise prices that were lower than the $13.36 market price of our common stock at December 31, 2016. The total intrinsic value of options exercised during the years ended December 31, 2016, 2015 and 2014 was $30.5 million, $3.6 million, and $29.2 million, respectively, determined as of the date of exercise.

Warrants to purchase 75,000 shares of common stock were issued in connection with a consulting agreement in 2009 to provide specific assistance to the Company in attaining FDA approval of Cologuard. The 75,000 warrants vested in the third quarter of 2014 upon successful approval for Cologuard. The Company recorded $1.3 million, the fair value of the warrant on the vesting date, as stock-based compensation expense during the third quarter of 2014 in connection with the vesting of this warrant.

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A summary of restricted stock and restricted stock unit activity under the Stock Plans during the years ended December 31, 2016, 2015 and 2014 is as follows:

	Restricted Shares	Weighted Average Grant Date Fair Value
Outstanding, January 1, 2014	1,150,694	$ 11.23
Granted	926,171	15.61
Released	(491,370)	11.17
Forfeited	(44,381)	12.44
Outstanding, December 31, 2014	1,541,114	$ 13.86
Granted	2,895,818	15.23
Released	(578,033)	13.77
Forfeited	(414,205)	20.84
Outstanding, December 31, 2015	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

As of December 31, 2016, there was approximately $41.5 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 2.4 years.

The Company received approximately $3.4 million, $1.2 million, and $2.6 million from stock option exercises during the years ended December 31, 2016, 2015 and 2014, respectively. During the years ended December 31, 2016, 2015 and 2014, 356,823, 176,785, and 88,166 shares of common stock, respectively, were issued under the Company's 2010 Purchase Plan, resulting in proceeds to the Company of $2.1 million, $1.7 million, and $0.8 million, respectively.

The following table summarizes information relating to currently outstanding and exercisable stock options as of December 31, 2016:

	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 - $3.00	1,041,176	2.2	$ 0.86	1,041,176	$ 0.86

$3.01 - $6.00	1,121,647	7.2	5.08	361,447	4.40
$6.01 - $9.00	217,705	6.3	7.34	133,116	8.00
$9.01 - $12.00	571,202	5.5	9.71	524,840	9.61
$12.01 - $15.00	220,000	7.2	13.96	110,000	13.96
$15.01 - $18.00	18,477	7.6	16.52	12,318	16.52
$18.01 - $24.00	302,666	8.0	23.38	78,592	23.38
$24.01- $26.98	12,608	8.1	26.98	4,202	26.98
	3,505,481	5.5	$ 7.00	2,265,691	$ 5.42

During the first quarter of 2015, the Company granted a total of 203,100 restricted stock units to certain executives that would have vested based upon the satisfaction of certain service and performance conditions. The Company performed an evaluation of internal and external factors, and determined the number of shares that were most likely to

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Notes to Consolidated Financial Statements (Continued)

vest based on the probability of what performance conditions were met. The expense for the fair value of the awards that were expected to vest of $0.4 million was recognized during the year ended December 31, 2015. The service and performance conditions were not met and the expense of $0.4 million was reversed in the fourth quarter of the year ended December 31, 2015.

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, 2016, as follows:

Shares reserved for issuance	
2010 Option Plan	1,426,375
2010 Purchase Plan	2,006,569
2016 Inducement Plan	845,604
	4,278,548

(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 October 2016, 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 Company leases a 48,845 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 February 2016. 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. As of December 31, 2016 and 2015, the lease incentive obligation was $1.3 million and $1.6 million, respectively.

The Company leases a 33,803 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 November 2015. 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 lease for up to five years each.

During July 2015, the Company entered into a lease for a 21,000 square foot warehouse facility in Madison, Wisconsin. The lease commenced in October 2015 and is effective until May 2025 and includes an option for a five-year extension. The lease contains periodic rent escalation adjustments.

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Future minimum payments under operating leases as of December 31, 2016 are as follows. Amounts included in the table are in thousands.

Year Ending December 31,	
2017	$ 2,226
2018	1,724
2019	1,172
2020	892
2021	587
Thereafter	281
Total lease obligations	$ 6,882

Rent expense included in the accompanying consolidated statements of operations was approximately $2.1 million, $1.5 million, and $1.0 million for the years ended December 31, 2016, 2015 and 2014, 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 4 for information related to the MAYO license agreement.

Hologic

On October 14, 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., Canada, the European Union, Australia and Japan. 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 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

On July 26, 2010, the Company entered into a technology license and royalty agreement with MDx Health (formerly Oncomethylome Sciences, S.A.). Under the license agreement, MDx Health granted the Company a royalty bearing, exclusive, worldwide license to certain patents. Under the licensing agreement, the Company is obligated to make commercially reasonable efforts to bring products covered by the license agreement to market. The Company is required to pay MDx Health 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 $0.1 million upon the first commercial sale of a licensed product after the receipt of FDA approval and $0.2 million after the Company has reached net sales of $10 million of a licensed product

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Notes to Consolidated Financial Statements (Continued)

after receipt of FDA approval. In 2016, we paid $0.8 million after the Company reached cumulative net sales of $50 million. Additionally, we will pay them $1.0 million after the Company has reached net sales of $50 million in a single calendar year. The Company is also required to pay MDx Health a low single digit royalty fee based on a certain percentage of the Company's net sales of the licensed products.

Capital Lease

In 2012, the Company entered into a lease agreement which is accounted for as a capital lease and the final lease payment was made in September 2015. The leased equipment is recorded at $1.2 million and is included in the balance sheet as laboratory equipment. The cost of the leased equipment was depreciated over the three year lease term, and the expense was recorded as depreciation expense. The leased equipment was fully depreciated at December 31, 2015. The Company was required to make principal and interest payments of approximately $32,000 per month over the three year term of the lease agreement.

(8) ACCRUED LIABILITIES

Accrued liabilities at December 31, 2016 and 2015 consisted of the following:

	December 31,	
(In thousands)	2016	2015
Compensation	$ 16,555	$ 8,460
Licenses	5,359	3,761
Professional fees	3,375	5,834
Research and trial related expenses	1,035	1,528
Other	792	688
Assets under construction	655	1,646
Occupancy costs	208	47
Miscellaneous taxes	127	289
	$ 28,106	$ 22,253

(9) LONG TERM DEBT

Building Purchase Mortgage

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

Borrowings under the credit agreement bear interest at 4.15%. The Company made interest-only payments on the outstanding principal balance for the period between July 12, 2015 and September 12, 2015. Beginning on October 12, 2015 and continuing through May 12, 2019, the Company is required to make monthly principal and interest payments of $31,000. The final principal and interest payment due on the maturity date of June 12, 2019 is $4.4 million.

Additionally, the Company has recorded $73,000 in mortgage issuance costs, which are recorded as a direct deduction from the mortgage liability. The issuance costs are being amortized through June 12, 2019. For the year ended December 31, 2016, the Company has recorded $18,000 in amortization of mortgage issuance costs.

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Notes to Consolidated Financial Statements (Continued)

The table below represents the future principal obligations as of December 31, 2016. Amounts included in the table are in thousands:

Year ending December 31,	
2017	$ 174
2018	182
2019	4,496
2020	—
2021	—
Thereafter	—
	$ 4,852

Wisconsin Department of Commerce Loan

During November 2009, the Company entered into a loan agreement with the Wisconsin Department of Commerce pursuant to which the Wisconsin Department of Commerce agreed to lend up to $1.0 million to the Company subject to the Company's satisfaction of certain conditions. The Company received the $1.0 million in December 2009. The terms of the loan are such that portions of the loan become forgivable if the Company meets certain job creation requirements at a specified wage rate. The loan agreement provided that, after the Company created 100 full time positions, the principal will be reduced at the rate of $5,405 for each new position created thereafter during the measurement period. The loan bore an interest rate of 2%, which was subject to an increase to 4% if the Company did not meet certain job creation requirements. Both principal and interest payments under the loan agreement were deferred for five years. The loan's terms also contained a milestone that if the Company created 185 new full-time positions as of June 30, 2015, the full amount of principal would be forgiven. The Company met this job creation milestone and the $1.0 million benefit associated with the loan forgiveness was recorded as an offset to the operating expenses during the year ended December 31, 2015.

(10) 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, 2016, 2015 and 2014 in the form of Company common stock equal to 100% up to 6% of the participant's eligible compensation for that year. The Company recorded compensation expense of approximately $3.0 million, $2.1 million, and $0.8 million, respectively, in the statements of operations for the years ended December 31, 2016, 2015 and 2014 in connection with 401(k) Plan matching contributions.

(11) 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% 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

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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 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 year ended December 31, 2016. At December 31, 2016, the remaining balance of $1.7 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% 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.

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

(12) 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 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, 2016, the Company has earned $5.0 million of tax credits and has received payment of $0.8 million from the WEDC. The unpaid portion is $4.2 million, of which $1.6 million is reported in prepaid expenses and other current assets and $2.6 million is reported in other long-term assets, reflecting when collection of the refundable tax credits is expected to occur. As of December 31, 2016, the Company also has recorded a $1.1 million liability in other short-term liabilities and a $3.0 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, 2016, the Company amortized $0.7 million of the tax credits earned as a reduction of operating expenses.

(13) INCOME TAXES

The Company is subject to taxation in the U.S. and various state jurisdictions. All of the Company's tax years are subject to examination by the U.S. and state tax authorities due to the carryforward of unutilized net operating losses.

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, 2016, the Company had federal net operating loss, state net operating loss, and foreign net operating loss carryforwards of approximately $725.1 million, $291.9 million, and $1.4 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 $8.5 million and $16.4 million, respectively which may be used to offset future income tax liability. The federal and state carryforwards expire beginning 2017 through 2036 and are subject to review and possible adjustment by the Internal Revenue Service and 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.

As of December 31, 2016 and 2015, the Company had $62.7 million and $45.5 million, respectively, in excess tax benefit stock option deductions. Historically, the excess tax benefit arising from these deductions is credited to additional paid in capital as the benefit is realized. In March 2016, the Financial Accounting Standards Board issued Accounting Standards Update No. 2016-09, “Compensation —Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting” as part of its Simplification Initiative which among other things changed the accounting for excess tax benefit stock option deductions. If in the future, the Company is able to utilize its deferred

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

tax assets to offset taxes payable, excess tax benefit stock option deductions or deficiencies will now be reflected in the consolidated statements of operations as a component of the provision for income taxes. The Company will adopt Update 2016-09 in the first quarter of 2017.

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)	2016	2015
Deferred tax assets:		
Operating loss carryforwards	$ 244,465	$ 189,007
Tax credit carryforwards	19,271	17,947
Other temporary differences	14,176	8,146
Tax assets before valuation allowance	277,912	215,100
Less—Valuation allowance	(277,912)	(215,100)
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 $277.9 million and $215.1 million at December 31, 2016 and 2015, 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, 2016 and 2015 was $62.8 million and $53.2 million, respectively. Due to the existence of the valuation allowance, future changes in our 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,		
	2016	2015	2014
U.S. Federal statutory rate	35.0 %	35.0 %	34.0 %
State taxes	2.4	2.1	5.5
Federal and state tax rate changes	0.6	(1.7)	—
Foreign tax rate differential	(0.4)	—	—
Research and development tax credits	0.9	0.9	(1.1)
Stock-based compensation expense	(0.6)	(0.6)	(0.5)

Other adjustments	(0.3)	(0.9)	(0.8)
Valuation allowance	(37.6)	(34.8)	(37.1)
Effective tax rate	0.0 %	0.0 %	0.0 %

There are no unrecognized tax benefits as of December 2016, 2015 and 2014, nor are there any tax positions where it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within the 12 months following December 31, 2016.

As of December 31, 2016, due to the carryforward of unutilized net operating losses and research and development credits, the Company is subject to U.S. Federal and state income tax examinations for the tax years 1996 through 2016, and to state income tax examinations for the tax years 1996 through 2016. 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, 2016, 2015 and 2014.

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

(14) QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)

The following table sets forth unaudited quarterly statement of operations data for each of the eight quarters ended December 31, 2016 and 2015. 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 our 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)			
2016				
Laboratory service revenue	$ 14,835	$ 21,185	$ 28,115	$ 35,241
Cost of revenue	9,059	10,097	12,174	13,865
Gross profit	5,776	11,088	15,941	21,376
Research and development	10,126	8,640	7,625	7,082
General and administrative	17,824	17,284	20,292	21,498
Sales and marketing	25,711	30,301	26,308	30,506
Loss from operations	(47,885)	(45,137)	(38,284)	(37,710)
Investment income	466	425	535	592
Interest income (expense)	(54)	(53)	(54)	(52)
Net loss	$ (47,473)	$ (44,765)	$ (37,803)	$ (37,170)
Net loss per share—basic and diluted	$ (0.49)	$ (0.46)	$ (0.36)	$ (0.34)
Weighted average common shares outstanding—basic and diluted	97,246	97,902	104,807	109,274
2015				
Laboratory service revenue	$ 4,266	$ 8,119	$ 12,632	$ 14,420
Cost of revenue	4,212	5,094	7,528	7,667
Gross profit	54	3,025	5,104	6,753
Research and development	6,571	8,115	9,863	9,365
General and administrative	12,971	13,683	15,432	15,864
Sales and marketing	16,524	20,593	23,079	21,944
Loss from operations	(36,012)	(39,366)	(43,270)	(40,420)
Investment income	222	193	365	491
Interest expense	(11)	107	(40)	(62)
Net loss	$ (35,801)	$ (39,066)	$ (42,945)	$ (39,991)
Net loss per share—basic and diluted	$ (0.40)	$ (0.44)	$ (0.45)	$ (0.41)
	88,662	88,919	94,444	96,404

Weighted average common shares outstanding—basic and diluted	

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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, 2016 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, 2016, 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, 2016. 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, 2016, 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, 2016, 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 2017 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 2017 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 2017 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 2017 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 2017 Annual Meeting of Stockholders: “Independent Registered Public Accounting Firm” and “Pre Approval Policies and Procedures.”

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this Form 10 K:
(1) Financial Statements (see “Consolidated Financial Statements and Supplementary Data” at Item 8 and incorporated herein by reference).
(2) Financial Statement Schedules (Schedules to the Financial Statements have been omitted because the information required to be set forth therein is not applicable or is shown in the accompanying Financial Statements or notes thereto).
(3) Exhibits (The exhibits required to be filed as a part of this Report are listed in the Exhibit Index).

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, 2017 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, 2017
/s/ Maneesh K. Arora Maneesh K. Arora	Senior Vice President and Chief Operating Officer and Director	February 21, 2017
/s/ Jeffrey T. Elliott	Chief Financial Officer (Principal	February 21, 2017

Jeffrey T. Elliott	Financial Officer and Principal Accounting Officer)	
/s/ Thomas D. Carey Thomas D. Carey	Director	February 21, 2017
/s/ James E. Doyle James E. Doyle	Director	February 21, 2017
/s/ John A. Fallon M.D John A. Fallon	Director	February 21, 2017
./s/ Daniel J. Levangie Daniel J. Levangie	Director	February 21, 2017
/s/ Katherine Zanotti Katherine Zanotti	Director	February 21, 2017
/s/ Lionel Sterling Lionel Sterling	Director	February 21, 2017
/s/ David Thompson David Thompson	Lead Independent Director	February 21, 2017

/s/ Michael S. Wyzga Michael S. Wyzga	Director	February 21, 2017

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Exhibit Index to Annual Report on Form 10 K

Exhibit Number	Description
3.1	Sixth Amended and Restated Certificate of Incorporation of the Registrant (previously filed as Exhibit 3.3 to the Registrant's Registration Statement on Form S 1 (File No. 333 48812) and incorporated herein by reference)
3.2	First Amendment to Sixth Amended and Restated Certificate of Incorporation of the Registrant (previously filed as Appendix A to the Definitive Proxy Statement for the Registrant's 2014 Annual Meeting of Stockholders filed on June 20, 2014 and incorporated herein by reference)
3.3	Second Amended and Restated By-Laws of the Registrant (previously filed as Exhibit 3.3 to the Registrant's Report on Form 10-Q for the period ended September 30, 2015 and incorporated herein by reference)
3.4	Certificate of Designations of Series A Junior Participating Preferred Stock of the Registrant (previously filed as Exhibit 3.1 to the Registrant's Registration Statement on Form 8-A filed on February 23, 2011 and incorporated herein by reference)
4.1	Specimen certificate representing the Registrant's Common Stock (previously filed as Exhibit 4.1 to the Registrant's Registration Statement on Form S 1 (File No. 333 48812) and incorporated herein by reference)
4.4	Rights Agreement, dated February 22, 2011, by and between the Registrant and American Stock Transfer & Trust Company, LLC (previously filed as Exhibit 4.1 to the Registrant's Registration Statement on Form 8 A filed on February 23, 2011 and incorporated herein by reference)
10.1*	2000 Stock Option and Incentive Plan (previously filed as Exhibit 10.2 to the Registrant's Annual Report on Form 10 K filed for the period ended December 31, 2008 and incorporated herein by reference)
10.2*	2000 Stock Option and Incentive Plan Form of Restricted Stock Award Agreement (previously filed as Exhibit 10.29 to the Registrant's Annual Report on Form 10 K for the period ended December 31, 2007 and incorporated herein by reference)
10.3**	Collaboration, License and Purchase Agreement dated January 27, 2009 by and between the Registrant and Genzyme Corporation (previously filed as Exhibit 10.1 to the Registrant's Report on Form 8 K filed on January 28, 2009 and incorporated herein by reference)
10.4*	Employment Agreement dated March 18, 2009 by and between Kevin T. Conroy and the Registrant (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8 K filed on March 18, 2009 and incorporated herein by reference)
10.5*	Employment Agreement dated March 18, 2009 by and between Maneesh Arora and the Registrant (previously filed as Exhibit 10.2 to the Registrant's Current Report on Form 8 K filed on March 18, 2009 and incorporated herein by reference)
10.6*	Employment Agreement dated January 1, 2016 by and between John Bakewell and the Registrant (previously filed as Exhibit 10.6 to the Registrant's Annual Report on Form 10-K for the period ended December 31, 2015 and incorporated herein by reference)
10.7*	Employment Agreement dated October 30, 2015 by and between Scott Coward and the Registrant (previously filed as Exhibit 10.7 to the Registrant's Annual Report on Form 10-K for the period ended December 31, 2015 and incorporated herein by reference)
10.8*	Employment Agreement dated August 1, 2009 by and between Graham Lidgard and the Registrant (previously filed as Exhibit 10 to the Registrant's Current Report on Form 10 Q for the period ended September 30, 2009 and incorporated herein by reference)
10.9*+	Employment Agreement dated November 8, 2016 by and between Jeffrey T. Elliott and the Registrant

10.10**	Technology License Agreement by and among Hologic, Inc., Third Wave Technologies, Inc., and the Registrant, dated as of October 14, 2009 (previously filed as Exhibit 10.39 to the Registrant's Annual Report on Form 10 K filed for the period ended December 31, 2009 and incorporated herein by reference)
10.11	Loan Agreement, dated November 10, 2009, by and between the Wisconsin Department of Commerce and the Registrant (previously filed as Exhibit 10.40 to the Registrant's Annual Report on Form 10 K filed for the period ended December 31, 2009 and incorporated herein by reference)
10.12	Lease Agreement, dated November 1, 2009, by and between University Research Park Incorporated and the Registrant (previously filed as Exhibit 10.41 to the Registrant's Annual Report on Form 10 K filed for the period ended December 31, 2009 and incorporated herein by reference)
10.13*	The Registrant's 2010 Omnibus Long Term Incentive Plan, as amended and restated effective April 28, 2015 (previously filed as Appendix A to the Definitive Proxy Statement for the Registrant's 2015 Annual Meeting of Stockholders filed on April 30, 2015 and incorporated herein by reference)
10.14*	The Registrant's 2010 Employee Stock Purchase Plan (previously filed as Appendix B to the Definitive Proxy Statement for the Registrant's 2010 Annual Meeting of Stockholders filed on April 30, 2010 and incorporated herein by reference)
10.15*	First Amendment to the Registrant's 2010 Employee Stock Purchase Plan (previously filed as Appendix A to the Definitive Proxy Statement for the Registrant's 2014 Annual Meeting of Stockholders filed of June 20, 2014, and incorporated herein by reference)
10.16*	Second Amendment to the Registrant's 2010 Employee Stock Purchase Plan (previously filed as Appendix A to the Definitive Proxy Statement for the Registrant' 2016 Annual Meeting of Stockholders filed on April 29, 2016, and incorporated herein by reference)

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Exhibit Number	Description
10.17*	2010 Omnibus Long Term Incentive Plan Form Stock Option Award Agreement, as amended and restated effective April 28, 2015 (previously filed as Exhibit 4.7 to the Registrant's Registration Statement on Form S 8 (File No. 333 207703) filed on October 30, 2015 and incorporated herein by reference)
10.18*	2010 Omnibus Long Term Incentive Plan Form Restricted Stock Award Agreement, as amended and restated effective April 28, 2015 (previously filed as Exhibit 4.6 to the Registrant's Registration Statement on Form S 8 (File No. 333 207703) filed on October 30, 2015 and incorporated herein by reference)
10.19*	2010 Omnibus Long Term Incentive Plan Form Restricted Stock Unit Award Agreement, as amended and restated effective April 28, 2015 (previously filed as Exhibit 4.5 to the Registrant's Registration Statement on S 8 (File No. 333 207703) filed on October 30, 2015 and incorporated herein by reference)
10.20*	2015 Inducement Award Plan (previously filed as Exhibit 4.8 to the Registrant's Registration Statement on Form S 8 (File No. 333 207703) filed on October 30, 2015 and incorporated herein by reference)
10.21*	2015 Inducement Award Plan Form Restricted Stock Unit Award Agreement (previously filed as Exhibit 4.9 to the Registrant's Registration Statement on Form S 8 (File No. 333 207703) filed on October 30, 2015 and incorporated herein by reference)
10.22*	2016 Inducement Award Plan (previously filed as Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the period ended March 31, 2016 filed on May 3, 2016 and incorporated herein by reference)
10.23*	2016 Inducement Award Plan Form Restricted Stock Unit Award Agreement (previously filed as Exhibit 4.7 to the Registrant's Registration Statement on Form S-8 (File No. 333-211099) filed on May 3, 2016 and incorporated herein by reference)
10.24*	Amended and Restated License Agreement between the Registrant and MAYO Foundation for Medical Education and Research (previously filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the period ended March 31, 2015 and incorporated herein by reference)
10.25*	First Amendment to Amended and Restated License Agreement between the Registrant and MAYO Foundation for Medical Education and Research (previously filed as Exhibit 10.2 to Amendment No. 1 to the Registrant's Quarterly Report on Form 10-Q for the period ended March 31, 2016 filed on June 3, 2016 and incorporated herein by reference)
10.26**	Amendment dated December 7, 2012 to Technology License Agreement dated October 14, 2009 by and between Hologic, Inc., Third Wave Technologies, Inc., and the Registrant (previously filed as Exhibit 10.37 to the Registrant's Annual Report on Form 10 K for the period ended December 31, 2012 and incorporated herein by reference)
10.27*	Non Employee Director Compensation Policy dated April 28, 2015 (previously filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10 Q for the period ended June 30, 2015 and incorporated herein by reference)
10.28	Lease Agreement dated June 25, 2013 by and between Tech Building I, LLC and Exact Sciences Laboratories, Inc. (previously filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10 Q for the period ended June 30, 2013 and incorporated herein by reference)
10.29**	License Agreement dated July 26, 2010 by and between MDx Health S.A. and the Registrant (previously filed as Exhibit 10.25 to the Registrant's Annual Report on Form 10-K for the period ended December 31, 2013 and incorporated herein by reference)
10.30**	Addendum dated May 6, 2011 to License Agreement dated July 26, 2010 by and between MDx Health S.A. and the Registrant (previously filed as Exhibit 10.26 to the Registrant's Annual Report on Form 10-K for the period ended December 31, 2013 and incorporated herein by reference)
10.31	Amendment One to Lease dated November 1, 2010 by and between University Research Park Incorporated and the Registrant(previously filed as Exhibit 10.27 to the Registrant's Annual Report on Form 10-K for the period ended December 31, 2014 and incorporated herein by reference).

10.32	Lease Agreement dated April 16, 2014 by and between Ultratec, Inc. and the Registrant (previously filed as Exhibit 10.28 to the Registrant's Annual Report on Form 10-K for the period ended December 31, 2014 and incorporated herein by reference)
10.33	First Amendment to Lease dated September 26, 2014 by and between Ultratec, Inc. and the Registrant (previously filed as Exhibit 10.29 to the Registrant's Annual Report on Form 10-K for the period ended December 31, 2014 and incorporated herein by reference)
21+	Subsidiaries of the Registrant
23.1+	Consent of BDO USA, LLP
24.1	Power of Attorney (included on signature page)
31.1+	Certification Pursuant to Rule 13a 14(a) or Rule 15d 14(a) of the Securities Exchange Act of 1934
31.2+	Certification Pursuant to Rule 13a 14(a) or Rule 15d 14(a) of the Securities Exchange Act of 1934
32+	Certification Pursuant to 18 U.S.C Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes Oxley Act of 2002
101	Interactive Data Files

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

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

+Filed herewith.