EXACT SCIENCES CORP
Form 10-K
February 27, 2015
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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, 2014
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 $1,398,396,140 (based on the closing price of the Registrant's Common Stock on June 30, 2014 of $17.03 per share).

The number of shares outstanding of the Registrant's $.01 par value Common Stock as of February 26, 2015 was 88,671,335.

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, 2014. 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, 2014

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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 and 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,” “estimate,” “anticipate” or other comparable terms. All statements other than statements of historical facts included in this Annual Report on Form 10 K regarding our strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Examples of forward-looking statements include, among others, statements we make regarding expected future operating results, anticipated results of our sales and marketing efforts, expectations concerning 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; the acceptance of our products by patients and health care providers; the amount and nature of competition from other cancer screening products and procedures; our ability to maintain regulatory approvals and comply with applicable regulations; our success establishing and maintaining collaborative and licensing arrangements; our ability to successfully develop new products; 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 ("we," "us," "our" or the "Company") is a molecular diagnostics company currently focused on the early detection and prevention of colorectal cancer. We have developed a non invasive, patient friendly screening test called Cologuard® to meet our primary goal of becoming the market leader in non-invasive colorectal cancer screening products.

Our strategic roadmap to achieve this goal includes the following key components:

· commercialize an FDA-approved product that detects colorectal pre-cancer and cancer; and
· successfully operate a CLIA certified laboratory facility to process Cologuard tests and provide patient results
· secure favorable reimbursement for our laboratory services from payors.

Our Cologuard test is a non invasive stool based DNA (sDNA) screening test designed to detect DNA markers, which in published studies have been shown to be associated with colorectal cancer. In addition to DNA markers, our test includes a protein marker to detect blood in the stool, utilizing an antibody based fecal immunochemical test (FIT).

On August 11, 2014 the U.S. Food and Drug Administration (FDA) approved Cologuard for use as the first and only sDNA noninvasive colorectal cancer screening test. In addition on October 9, 2014 the Centers for Medicare and Medicaid Services (CMS) issued a final National Coverage Determination (NCD) extending coverage for Cologuard as a colorectal cancer screening test for asymptomatic, average risk Medicare beneficiaries, aged 50 to 85 years. CMS has established reimbursement for Cologuard (CPT Code G0464) at $492.72 in the CMS 2015 Clinical Lab Fee Schedule.

Background

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

· 137,000 new cases in the U.S.
· 50,000 deaths in the U.S.
· 1,200,000 new cases worldwide
· 600,000 deaths worldwide

Colorectal cancer treatment represents a significant and growing healthcare cost. Annually $14 billion is spent 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 rapidly 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, nearly 47 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

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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.

Professional colorectal cancer screening guidelines in the U.S., including those of the ACS, the American College of Gastroenterology, and the American Gastroenterological Association, recommend regular screening by a variety of methods. Historically, these recommendations consisted of colonoscopy, flexible sigmoidoscopy and fecal occult blood testing (FOBT) as well as combinations of some of these methods. On March 5, 2008, the ACS and the U.S. Multi Society Task Force on Colorectal Cancer included sDNA screening technology in the updated national colorectal cancer screening guidelines as a screening option for the detection of colorectal cancer in average risk, asymptomatic individuals age 50 and older. The U.S. Multi Society Task Force on Colorectal Cancer is a consortium of several organizations that includes representatives of the American College of Gastroenterology, American Gastroenterological Association, American Society for Gastrointestinal Endoscopy and the American College of Physicians/Society of Internal Medicine. In November 2014 the ACS updated the colorectal cancer screening guidelines to specifically include Cologuard as a recommended sDNA screening test.

Our Solution

Cologuard is designed to detect pre cancerous lesions or polyps, and each of the four stages of colorectal cancer and is a powerful, preventive tool. By detecting pre cancers and cancers early with our test, affected patients can be referred to colonoscopy, during which the polyps or lesions can be removed. The earlier pre cancer or cancer is detected, the greater the reduction in mortality.

Cologuard includes proprietary and patented methods that isolate and analyze the human DNA that are shed into stool every day from the exfoliation of cells that line the colon. When colorectal cancer or pre cancer is present, a minute portion of the total isolated human DNA represents DNA shed from cancerous or pre cancerous lesions. Once the human DNA in the sample is isolated, Cologuard looks for specific mutations and other abnormalities in that DNA known to be associated with colorectal cancer. Our test also detects blood in stool, utilizing an antibody based FIT test. A positive result does not necessarily mean that a patient has colorectal cancer. A positive result means that one or more of the genetic markers associated with colorectal cancer has been identified or that hemoglobin has been detected. Under these circumstances, the clinical protocol is for the patient to obtain a colonoscopy for confirmation and potentially have any polyps or lesions removed if confirmed.

We believe that screening with Cologuard in the general population offers an opportunity to increase screening rates for colorectal cancer. According to a 2012 study, when patients were given the option to be screened by either colonoscopy or with a non invasive FOBT rather than only being advised to get a colonoscopy, the percentage of patients screened within one year increased from 38% to 69%.

We believe that Cologuard has the following advantages over other screening options.

· It detects both pre cancers and cancers.
· It is non invasive and requires no bowel preparation or dietary restrictions like some other methods.
· The sample can be collected easily at home and shipped to the laboratory, where the testing is conducted.
· Our test is affordable, particularly relative to colonoscopy.
· Part of the service offering for Cologuard includes active engagement by our team to increase patient compliance

With repeat screening at regular intervals we believe Cologuard has the ability to achieve high cumulative sensitivity for cancer and pre cancer detection. Given the importance of early detection of pre cancer in the fight against colorectal cancer, we believe it is important that patients have alternatives that promote regular screening. Cologuard provides an affordable, sensitive, non invasive screening alterative.

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The competitive advantages of sDNA screening provide a significant market opportunity. Assuming a 30 percent test adoption rate and a three year screening interval, we estimate the potential U.S. market for sDNA screening to be more than $2 billion and we estimate the potential global market opportunity to be greater than $3 billion.

Commercialization

On August 11, 2014 the U.S. Food and Drug Administration (FDA) approved Cologuard for use as the first and only sDNA noninvasive colorectal cancer screening test. Our submission to the FDA for Cologuard with the results of our pivotal DeeP-C clinical trial that had over 10,000 patients enrolled at 90 enrollment 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%
· High-Grade Dysplasia Sensitivity: 69%
· Specificity: 87%

We believe having FDA approval for Cologuard is a prerequisite for building broad consumer and physician demand and successfully commercializing our sDNA colorectal cancer screening technology.

On October 9, 2014 the Centers for Medicare & Medicaid Services (CMS) issued a final National Coverage Determination (NCD) for Cologuard. As outlined in the NCD, Medicare Part B will cover 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 of developing colorectal cancer (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 nonpolyposis colorectal cancer).

In the 2015 Clinical Laboratory Fee Schedule, CMS has established reimbursement for Cologuard (CPT code G0464) at $492.72. We believe that obtaining a favorable national coverage decision and a commercially viable reimbursement rate from CMS for Cologuard are necessary to achieve material commercial success. Medicare covers 43% of patients in the screening population for Cologuard. We believe the favorable CMS coverage decision may also aid in securing positive coverage decisions from major national and regional managed care organizations, insurance carriers, and self insured employer groups.

We also believe that it will be necessary to secure favorable coverage and reimbursement from commercial payors to achieve commercial success. We believe that third party payors’ reimbursement of Cologuard will depend on a number of factors, including payors’ determination that it is: sensitive for colorectal cancer; not experimental or investigational; approved by major guidelines organizations; reliable, safe and effective; medically necessary; appropriate for the specific patient; and cost effective.

Cologuard is currently recommended for colorectal cancer screening in ACS guidelines, which is a significant preliminary step to securing coverage with commercial payors.

A critical part of the value proposition of Cologuard is our physician and patient engagement team which helps to drive compliance for Cologuard as the team actively engages with patients to help them get screened. This activity is focused on having patients complete Cologuard tests that have been ordered for them by their physicians and supports

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physicians in their efforts to have their patients screened. In addition, monthly compliance reports are provided to physicians relevant to their patient population.

Our sales and marketing strategy includes three main elements with a focus on physicians, patients, and payors.

We are engaging physicians with several strategies. We have a 140 person sales team, including approximately 100 in a direct field sales force, actively engaging 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 are focused on specific physicians based on specialty and propensity to prescribe colorectal cancer screening tests. We are also focused on physician groups and larger regional and national health systems. Further, to build awareness, we have launched a medical education program that includes on-line training and peer-to-peer presentations.

After the launch of Cologuard we initiated a significant public relations effort to engage patients and we have also targeted direct to patient advertising through social media and targeted print and media advertising.

One of the key components to engaging with payors was securing coverage from CMS which we did in October of 2014. Additionally, we are providing cost effectiveness data to payors to make the case for Cologuard reimbursement. We are focusing our efforts on large national and regional insurers, states that require health insurers to cover colorectal cancer screening consistent with the ACS guidelines and health plans that have affiliated health systems.

As part of our commercialization strategy, we also established a state of the art, highly automated lab facility that is certified pursuant to applicable Federal Clinical Laboratory Improvement Amendments (CLIA) regulations to process Cologuard tests and provide patient results. Our commercial lab operation is housed in a 32,000 square foot facility in Madison, Wisconsin. We have the capacity at our lab to process one million tests per year.

Competition

The competitive landscape is favorable for Cologuard. All of the colorectal cancer detection methods in use today are constrained by some combination of poor sensitivity, poor compliance and cost. The leading method, colonoscopy involves advance dietary restrictions and bowel cleansing and can be uncomfortable, time consuming and expensive. 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 suffers from poor sensitivity, including for FIT testing, 73.8 percent detection rates for cancer and 23.8 percent detection rates for pre cancers. Blood based DNA testing also is disadvantaged by its 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 2012. It demonstrated 48 percent sensitivity across all stages of cancer, with little sensitivity for pre cancer above the background false positive rate.

A number of companies are working to develop new blood and serum based tests for the detection of colorectal cancer including tests based on the detection of proteins or nucleic acids produced by colorectal cancer in the blood. We are aware of several companies, including—Epigenomics AG, Gene News, EDP Biotech Corporation and Quest Diagnostics—that are developing blood-based tests for the detection of colorectal cancer. Epigenomics AG completed two multi-center studies designed to demonstrate the performance of its blood-based screening test for colorectal cancer. These data were submitted to the FDA and reviewed by an FDA Advisory Panel in March of 2014. In June 2014, Epigenomics AG announced that the FDA had issued a Not Approvable letter requesting additional clinical data. It is our understanding that Epigenomics AG is in the process of conducting a study to satisfy the FDA's requirements.

In addition, sDNA testing 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 FOBT and FIT and newer screening technologies such as the PillCam COLON approved by FDA in February 2014.

Research and Development

Research and development costs account for a substantial portion of our operating expenses. Our research and development expenses were $28.7 million, $27.7 million and $42.1 million for the years ended December 31, 2014,

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2013 and 2012, respectively. Research and development expenses are expected to increase in the future as we work on developing additional products related to cancer screening and expanding the indication for Cologuard.

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. 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, Cologuard 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.

Like we did for Cologuard, as we seek to develop additional products we may determine to seek a premarket approval (PMA) for such products. The PMA process 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 process will include the convening of expert panels and inspection of our manufacturing facilities, and also include providing additional data and updates to the FDA, and new or supplemented PMA submissions if the product is modified during the process. Even if granted, a PMA approval may place substantial restrictions on how a device is marketed or sold, and regulations governing any approved 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 FDA approval of our technologies have been and will be costly and time intensive. There can be no assurance that the FDA will ultimately approve any PMA submitted by us in a timely manner or at all.

Laboratory Certification, Accreditation and Licensing

We are also subject to U.S. and state laws and regulations regarding the operation of clinical laboratories. Federal Clinical Laboratory Improvement Amendments (CLIA) requirements and laws of certain other 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 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 associate of Covered Entities.

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Our activities must also comply with other applicable privacy laws. For example, there are also 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 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. 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;
· deceptive or fraudulent conduct;
· excessive or unnecessary services or services at excessive prices; and
· prohibitions in defrauding private sector health insurers.

We are subject to substantial penalties for violations of these 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.

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 health care 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. 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

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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. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

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, with limited exceptions. Manufacturers must also disclose to CMS any physician ownership or investment interests. On February 8, 2013, CMS issued a final rule implementing the Sunshine Act. Entities covered by the Sunshine Act must begin reporting by March 31, 2014, and failure to comply with the reporting requirement may subject us to substantial penalties.

Other Laws

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

Specimen Transportation. Our commercialization activities for Cologuard subject us to regulations of the Department of Transportation, the United States Postal Service and the CDC that apply to the surface and air transportation of clinical laboratory specimens.

Intellectual Property

Our intellectual property portfolio positions us to be a leader in the development and marketing of tests for the detection of colorectal cancer from stool samples. 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, 2014, we owned 12 issued patents and 30 pending patent applications in the United States, and 50 issued patents and 32 pending patent applications in foreign jurisdictions. In addition, as part of our 2009 strategic transaction with Genzyme Corporation, we received an exclusive license back from Genzyme Corporation in the fields of colorectal cancer screening and stool based detection of any disease or condition to the 29 patents issued and 2 pending patent applications in the U.S., and 35 patents issued and 1 pending patent applications in foreign jurisdictions sold to Genzyme.

Each of our patents generally has a term of 20 years from its respective priority filing date. Consequently, our earliest patents are set to expire in 2016.

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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.

Genzyme

On January 27, 2009, we entered into a Collaboration, License and Purchase Agreement (the "CLP Agreement") with Genzyme Corporation ("Genzyme"). Pursuant to the CLP Agreement, we (i) assigned to Genzyme all of our 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 our 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, we retained rights in our intellectual property to pursue only the fields of colorectal cancer detection and stool based detection of any disease or condition. Although the licenses granted under the CLP Agreement are perpetual and irrevocable, the Retained Intellectual Property includes patents, the last of which expires in 2028. The CLP Agreement contains customary termination provisions which permit termination in the event of material uncured breaches.

In connection with the CLP Agreement and certain related transactions, Genzyme agreed to pay us an aggregate of $18.5 million, 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 of our potential indemnification obligations. Genzyme also agreed to pay us double digit royalties on income received by Genzyme as a result of any licenses or sublicenses to 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. Under the CLP Agreement, we are required to deliver to Genzyme certain intellectual property improvements, if improvements are made during the initial five years following the date of the CLP Agreement.

In addition, we 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 of our 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 our shares represented a premium of $0.51 per share above the closing price of our common stock on that date of $1.49 per share, or an aggregate premium of $1.53 million.

MAYO

On June 11, 2009, we entered into a patent licensing agreement with MAYO Foundation for Medical Education and Research ("MAYO"). Under the license agreement, MAYO granted us an exclusive, worldwide license within the field of stool or blood based cancer diagnostics and screening (excluding a specified proteomic target) with regard to certain MAYO patents and patent applications, as well as a non exclusive, worldwide license within such field with regard to certain MAYO know how. 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. Pursuant to the license agreement, we 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. We agreed to pay MAYO a low single digit royalty on our net sales of products using the licensed MAYO intellectual property. We were also required to pay minimum annual royalty fees of $10,000 on June 12, 2012 and $25,000 on June 12, 2013 and June 12, 2014. We are required to continue to pay minimum annual royalty fees of $25,000 each year thereafter through

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2033. The MAYO license agreement required various other payments, including an upfront payment of $80,000, which we paid in the third quarter of 2009, a milestone payment of $250,000 on the commencement of patient enrollment in FDA trials for our Cologuard pre cancer and cancer screening test, which we paid in June 2011, and a milestone payment of $500,000 upon FDA approval of Cologuard, which we paid in August 2014.

In May 2012 we expanded our relationship with MAYO through an amendment to the license agreement. As part of the amendment, MAYO expanded the license to include all gastrointestinal cancers and diseases, and new cancer screening applications of stool and blood based testing. As consideration for the expanded license, we granted MAYO 97,466 shares of our common stock, one quarter of which vested immediately, with the remainder to vest in three equal annual installments. We sought rights to the MAYO intellectual property for the specific purpose of developing future non invasive, stool based DNA screening tests for gastrointestinal diseases other than colorectal cancer. In addition, we agreed to issue MAYO shares of our common stock with a value of $200,000 upon commercial launch of our second and third products that use the licensed MAYO intellectual property. Additionally, we agreed in the amendment to pay MAYO, for each of our products that use licensed MAYO intellectual property, $200,000 cash upon such product reaching $5 million in cumulative net sales, $750,000 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.

In February 2015 we amended and restated our license agreement with MAYO to extend our arrangement with MAYO for an additional five years and broaden our collaboration efforts to develop screening, surveillance and diagnostic tests and tools for use in connection with gastrointestinal cancers, precancers, diseases and conditions. MAYO agreed to continue to make available personnel during the additional five year period to provide us product development and research and development assistance. The amended and restated license agreement defines “gastrointestinal” to include certain airway organs (including the pharynx, larynx, trachea, bronchi and lungs) and certain head and neck organs (including nasal passages, mouth and throat). The amended and restated license agreement also reflects an expanded list of patent rights that MAYO licenses to us.

Pursuant to the amended and restated license agreement, we agreed to pay MAYO an additional $5,000,000, payable in five annual installments, the first of which was due February 10, 2015.

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 patents 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.

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 paid Hologic $50,000 upon executing the license agreement in 2009, $100,000 when we began enrollment in our FDA trial in June 2011, and $100,000 upon FDA approval of Cologuard. We are required to pay Hologic a low single digit royalty on our net sales of products using the Covered Hologic IP.

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Unless earlier terminated in accordance with the agreement, the license agreement will remain in effect until the last of the licensed patents expires in 2016 (or later, if certain licensed patent applications are issued). The agreement contains customary termination provisions which, among other things, permits termination in the event of material uncured breaches.

MDx Health

In July 2010, we entered into a technology license and royalty 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 U.S. license to sell services, 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 paid MDx Health $100,000 upon executing the agreement in July 2010, $100,000 in December 2014 which was due upon the first commercial sale of a licensed product after the receipt of FDA approval and we are required to pay MDx Health a minimum royalty fee of $100,000 on each anniversary of the agreement for the life of the contract. We are also required to pay MDx Health $150,000 after we have reached net sales of $10 million of a licensed product after receipt of FDA approval, $750,000 after we have reached net sales of $50 million, and $1 million after we have reached 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 products and services using the licensed patents. 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.

Pipeline Products

We plan on continuing to collaborate with MAYO on future products related to early detection of gastrointestinal (GI) cancers specifically in the areas of esophageal and pancreatic cancers. GI cancers account for 145,000 or 25% of all U.S cancer deaths annually and represent a significant market opportunity for future products. The incidence rate of esophageal cancer is one of the fastest growing in the U.S. where there are over 18,000 new cases every year and over 15,000 deaths from this disease. We are working with MAYO to develop products related to early detection of this deadly disease. For pancreatic cancer we are working on developing a test that can diagnose the disease earlier and with greater accuracy than currently developed methods. In the U.S. there are over 46,000 new cases of pancreatic cancer every year and over 39,000 estimated deaths.

For colorectal cancer, we will focus on expanding the indications of Cologuard for screening outside of the standard indication for Cologuard. There may be a significant opportunity for Cologuard in patients between the ages of 40-50. In addition, there may be an opportunity for Cologuard to be used with high risk patients such as those with inflammatory bowel disease who may refuse colonoscopy. Additional research and development efforts will be necessary to evaluate and pursue these opportunities.

Additional research and development efforts will be necessary to evaluate and pursue these opportunities.

International Expansion

Our initial efforts for international expansion are focusing on the European launch of Cologuard. There is a significant unmet need in the European market as it relates to colorectal cancer screening. There are 152,000 deaths annually in

Europe and the screening rates for colorectal cancer are only ~20%. There are 136 million people aged 50-75 years old which we believe is a large, addressable market. We received a CE mark for Cologuard in December 2014, which is a mandatory conformity marking for certain products sold within the European Economic Area. Our initial launch into Europe in 2015 will be limited and focused.

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Employees

As of December 31, 2014, we had two hundred and thirty six full time employees. None of our employees are represented by a labor union. We consider our relationship with our employees to be good.

Financial Information

See the Company's consolidated financial statements included elsewhere in this Form 10 K and accompanying notes to the consolidated financial statements for information concerning revenues, profits and losses and total assets.

Available Information

We were incorporated in the State of Delaware on February 10, 1995. Our executive offices 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 have had only modest revenues to date. From our date of inception on February 10, 1995 through December 31, 2014, we have accumulated a total deficit of approximately $420.8 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 commercialization of Cologuard and the development and commercialization of new 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 the commercialization of Cologuard and other business expansion activities, including the development of new products and services. 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 or licensing arrangements, we may relinquish rights to certain of our technologies or products or grant

licenses to third parties on terms that are unfavorable to us.

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Our success depends heavily on our Cologuard colorectal cancer screening test.

For the foreseeable future, our ability to generate revenues will depend entirely on the commercial success of Cologuard. The commercial success of Cologuard and our ability to generate revenues will depend on several factors, including the following:

- acceptance in the medical community;
- patient acceptance of and demand for the Cologuard test;
- successful sales, marketing and educational programs;
- 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;
- the amount and nature of competition from other colorectal cancer or pre-cancer screening products and procedures;
- maintaining FDA marketing approval of Cologuard in the United States and the receipt and maintenance of marketing approval from foreign regulatory authorities;
- maintaining and defending patent protection for the intellectual property relevant to Cologuard; and
- our ability to establish and maintain commercial manufacturing, distribution, sales force and CLIA laboratory testing capabilities.

If we are unable to develop substantial sales of Cologuard or if we are significantly delayed or limited in doing so, our business prospects would be adversely affected.

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. 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 or pre-cancer. We are aware of at least four companies—Epigenomics AG, Gene News, EDP Biotech Corporation 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 submitted the results to the FDA in June 2014. It is our understanding that the FDA issued a response letter to Epigenomics AG requiring additional clinical studies to demonstrate the performance of its test and Epigenomics AG is in the process of conducting a study to satisfy the FDA’s requirements. We also face competition from procedure-based detection technologies such as flexible sigmoidoscopy, colonoscopy and “virtual” colonoscopy (a radiological imaging approach which 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 approved by FDA in February 2014. Our competitors may also be working on additional methods of detecting colorectal and pre-cancer that have not yet been announced. We may be unable to compete effectively against these competitors either because their tests are superior or because they may have more expertise, experience, financial resources or stronger business relationships.

If third-party payors, including managed care organizations, do not approve reimbursement for Cologuard at adequate reimbursement rates, we may be unable to successfully commercialize Cologuard which would likely have a material adverse effect on our business.

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Successful commercialization of Cologuard 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 national coverage decision and what we believe is a commercially viable initial reimbursement rate from the Centers for Medicare and Medicaid (CMS) for Cologuard, it is also critical that other third party payors approve reimbursement for Cologuard at adequate reimbursement rates. Third-party payors may attempt 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 Cologuard, will be eligible for coverage by third-party payors or, if eligible for coverage, what the reimbursement rates will be. Reimbursement of Cologuard by a third-party payor may depend on a number of factors, including a payor's determination that it is: adequately sensitive for colorectal cancer and pre-cancer; not experimental or investigational; approved by the major guidelines organizations; reliable, safe and effective; medically necessary; appropriate for the specific patient; and cost-effective.

Under the Affordable Care Act (ACA), private payors are required to cover preventive services that receive a Grade A or Grade B from the United States Preventive Services Task Force (USPSTF). Obtaining a Grade of A or B from USPSTF for Cologuard will be critical to successfully commercializing Cologuard. There can be no assurance that Cologuard will receive a Grade A or Grade B from the USPSTF, and its failure to do so would negatively impact our ability to secure private payor reimbursement. There also can be no assurance regarding whether the ACA's mandated coverage for preventive services will remain in effect, or in effect in its current form, if and when Cologuard receives a Grade A or Grade B from the USPSTF, whether private payors will agree to pay our stated price for Cologuard, or whether private payers will impose material co-payments or deductibles on their insureds for Cologuard even if coverage of Cologuard is mandated under the ACA.

Inclusion of Cologuard as a qualified screening test in performance measurement tools such as the Healthcare Effectiveness Data and Information Set (HEDIS) will also be critical for commercial adoption by private payors. Even if Cologuard receives an A or B Grade from the USPSTF, there is no guarantee that it will be included in HEDIS measures or other similar performance measurement tools and failure to do so would negatively impact our ability to secure third party reimbursement.

If we are unable to obtain positive coverage decisions from third-party payors, including managed care organizations, approving reimbursement for Cologuard at adequate levels, its commercial success would be compromised and our revenues would be significantly limited. We may also experience material delays in obtaining such reimbursement decisions and payment for Cologuard which are beyond our control. 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 Cologuard in the future.

If our clinical studies do not satisfy providers, payors, patients and others as to the reliability, effectiveness and superiority of Cologuard, we may experience reluctance or refusal on the part of physicians to order, and third-party payors to pay for, this product.

Although we have received FDA approval for Cologuard, if the results of our research and clinical studies and our sales and marketing activities relating to communication of these results, do not convince thought-leading gastroenterologists, guidelines organizations, primary care physicians and other healthcare providers, third-party payors and patients that Cologuard is reliable, effective and superior to existing screening methods, including Hemoccult II, Hemoccult Sensa and immunochemical FOBT, we may experience reluctance or refusal on the part of physicians to order, and third-party payors to pay for, Cologuard, which could prevent us from successfully commercializing it.

We have limited selling and marketing resources and lack sales, marketing, customer support, manufacturing, distribution and commercial laboratory experience, which may restrict our success in commercializing products.

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 Cologuard. In addition, as part of our commercialization strategy, we have recently established 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

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retaining and managing the specialized workforce these activities require. We may seek to partner with others to assist us with any or all of these functions. However, we may be unable to find appropriate third parties with whom to enter into these arrangements. 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 Cologuard and our future products and services, we must continue to develop and grow our sales and marketing organization. We currently have a 140 person sales team, including approximately 100 in a direct field sales force. Our direct sales force calls directly on healthcare providers throughout the United States to initiate sales of Cologuard. Our sales organization must explain to healthcare providers the reliability, effectiveness and benefits of Cologuard as compared to existing screening methods such as FOBT and FIT. We may not be able to successfully manage our dispersed sales force. We have also entered into marketing arrangements with independent sales organizations, but we cannot be assured that they will 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 Cologuard depends on the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community.

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

· its demonstrated sensitivity and specificity for detecting colorectal pre-cancer and cancer;
· its price;
· the availability of alternative screening methods;
· the willingness of physicians to prescribe Cologuard; and
· sufficient third-party coverage or reimbursement.

Even if Cologuard is superior to other colorectal cancer screening options, adequate third-party reimbursement is obtained and medical practitioners choose to order Cologuard, only a small number of people may decide to be screened for colorectal cancer. Despite the availability of current colorectal cancer screening methods as well as the recommendations of the ACS that all Americans age 50 and above be screened for colorectal cancer, approximately 47 percent of these individuals are not screened according to current guidelines. Use of a stool-based DNA colorectal cancer screening test will require people to collect a stool sample, which some people may be reluctant to do. If Cologuard does not achieve an adequate level of acceptance, we may not generate material revenues and we may not become profitable.

We may not be able to successfully establish and maintain collaborative and licensing arrangements, which could adversely affect our ability to develop and commercialize products and services.

The development and commercialization of our products and services relies, directly or indirectly, upon strategic collaborations and licensing agreements with third parties. We currently have a collaborative and licensing arrangement with MAYO Foundation for Medical Education and Research. In addition, we have licensing

agreements with Hologic and MDx Health. Such arrangements provide us with intellectual property crucial to our product development, including

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technology that we have incorporated into Cologuard. 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, not breached or not terminated early or that we will be able to enter into the future relationships necessary to successfully commercialize Cologuard or any other product or service we may develop. Any failure to obtain or retain the rights to necessary technologies 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 Cologuard 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 Cologuard or any other product or service.

Even though Cologuard has received regulatory clearance in the United States, if we do not receive regulatory clearance for Cologuard in other jurisdictions, our prospects may be materially and negatively affected.

Governments in countries outside the United States also regulate diagnostic tests marketed in such countries, and obtaining their approvals can be lengthy, expensive and highly uncertain. The approval process varies from country to country and the requirements governing the conduct of clinical trials, pricing and reimbursement vary greatly from country to country. In certain jurisdictions, we are required to finalize operational, reimbursement, price approval and funding processes prior to marketing Cologuard. We may not receive regulatory approval for Cologuard in countries other than the United States on a timely basis, if ever. Even if approval is granted in any such country, the approval may require limitations on the uses or availability of Cologuard. Failure to obtain regulatory approval for Cologuard in territories outside the United States could have a material adverse effect on our business prospects.

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

Recent health care reform laws, including the Patient Protection and Affordable Care Act, are significantly affecting the U.S. healthcare and medical services industry. Existing legislation, and possible future legal and regulatory changes, 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 Cologuard and any other product or service we may develop. Healthcare reforms, which may intend to reduce health care 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 Cologuard.

Even without further legislative reform, there can be no assurance that CMS will maintain its current reimbursement rate for Cologuard. If the CMS reimbursement rate for Cologuard is reduced, our revenues could be adversely affected. There can be no assurance that CMS and third party payors who initially decide to cover Cologuard will continue to cover Cologuard.

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

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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 currently perform Cologuard predominantly in one laboratory facility. If this or any future facility 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 Cologuard predominantly in a single laboratory facility in Madison, Wisconsin. Our headquarters and manufacturing facilities are also located in Madison, Wisconsin. 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 Cologuard 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 Cologuard 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.

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 Cologuards. 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.

We rely on courier delivery services to transport Cologuard collection kits to patients and samples back to our laboratory facility for analysis. If these delivery services are disrupted, customer satisfaction and our business could be negatively impacted.

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.

We may be subject to substantial costs and liability, or be prevented from using technologies incorporated in Cologuard, 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 in the United States and, potentially, in certain foreign countries. We have filed patent applications that we believe cover the methods we have designed and use in Cologuard to detect colorectal cancer and

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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 commercialization of products. While none of these inquiries to date have had any material effect on us, and while we do not believe that any pending correspondence would have such an effect, 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 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. Additionally, the U.S. Congress recently passed the Leahy-Smith America Invents Act, or the America Invents Act, which was signed into law in September 2011. The America Invents Act reforms United States patent law in part by changing the standard for patent approval from a “first to invent” standard to a “first to file” standard and developing a post-grant review system. This new legislation changes United States patent law in a way that may weaken our ability to obtain or maintain patent protection for future inventions in the United States.

We cannot assure you that any of our currently pending or future patent applications will result in issued patents, and we cannot predict how long it will take for any such patents to be issued. Further, we cannot assure you that other parties will not challenge any patents issued to us or that courts or regulatory agencies will hold our patents to be valid or enforceable. We have been in the past, and may be in the future, the subject of opposition proceedings relating to our patents. We cannot guarantee you that we will be successful in defending challenges made against our patents and patent applications. Any successful third-party challenge to our patents could result in co-ownership of such patents with the third party or the unenforceability or invalidity of such patents. Furthermore, in the life sciences field, courts frequently render opinions that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of isolated DNA and/or methods for analyzing or comparing DNA. Such decisions

may adversely impact our ability to obtain new patents and facilitate third-party challenges to our existing patents.

If we or our partners fail to comply with regulatory requirements, we may be subject to stringent penalties and our business may be materially adversely affected.

The marketing and sale of Cologuard is subject to various state, federal and foreign regulations. We cannot assure you that we or our strategic partners will be able to comply with applicable regulations and regulatory guidelines. If we or our partners, including independent sales representatives, fail to comply with any such applicable regulations and

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guidelines, we could incur significant liability and/or our partners could be forced to cease offering our products and services in certain jurisdictions.

Healthcare policy has been a subject of extensive discussion in the executive and legislative branches of the federal and many state governments and healthcare laws and regulations are subject to change. Development of the existing commercialization strategy for Cologuard 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.

Our business is subject to various complex laws and regulations. We could be subject to significant fines and penalties if we fail to comply with these regulations.

As a provider of clinical diagnostic products and services, we 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 regulation, 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.

If we fail to comply with these laws and regulations, we could incur significant fines and penalties and our reputation and prospects could suffer.

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 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

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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. Anti-kickback and 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 is 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 which 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.

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 President and Chief Executive Officer, Maneesh Arora, our Senior Vice President and Chief Operating Officer, Scott Coward, our Senior Vice President, General Counsel and Secretary, William Megan, our Senior Vice President, Finance, and Dr. Graham Lidgard, our Senior Vice President and Chief Science 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 in the United States and abroad. While our management team has significant experience in securing FDA approvals for diagnostic products, we have considerably less experience in commercializing a product or service. The efforts of our management team will be critical to us as we develop our technologies and seek to commercialize Cologuard and other FDA approved 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 Cologuard could materially adversely affect our business, financial condition and results of operations.

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 Cologuard could lead to product or professional liability claims based on allegations that one of our products contained a design or manufacturing defect or our laboratory was negligent in processing test results, which resulted in the failure to detect the disease for which it was designed or an unnecessary procedure which caused harm. A product or professional liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm our business or financial condition. We cannot assure you that our liability insurance would protect our assets from the financial impact of defending a 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 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 approval for future products we may develop or the approval of foreign regulatory bodies that may be required for such future products as well as Cologuard. Accordingly, we expect to rely on third parties such as contract research organizations, medical institutions and clinical investigators to conduct any such studies. Our reliance on these third parties for clinical development activities will reduce our control over these activities. These third-party contractors may

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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.

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, in February 2011, we 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.

Our inability to manage growth could harm our business.

As we launch the commercialization of Cologuard, we expect to require additional personnel in the areas of sales and marketing, laboratory operations, billing and collections, quality assurance and compliance. As a result, our operating expenses and capital requirements may increase significantly. Our ability to manage our growth effectively requires us to forecast expenses accurately and to expend funds to improve our operational, financial and management controls, reporting systems and procedures. As we move forward in commercializing Cologuard, we will also need to effectively manage our manufacturing, laboratory operations and sales and marketing needs, which represent new areas of oversight for us. If we are unable to manage our anticipated growth effectively, our business could be harmed.

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Our growing international operations could subject us to risks and expenses that could adversely impact the business and results of operations.

We expect to increase the availability of Cologuard in non-U.S. markets and to expand our operations in foreign countries. Our international expansion exposes us to risks from 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 may be adversely affected by other risks associated with operating in foreign countries. Economic uncertainty in some of the geographic regions in which we operate, including developing regions, could result in the disruption of commerce and negatively impact cash flows from our operations in those areas.

Risks inherent in our international operations include:

· numerous and varied non-U.S. regulatory requirements, including with respect to health care, that are subject to change and that could limit our ability to offer or market Cologuard or other products and services we may develop on acceptable terms, if at all;
· numerous and varied U.S. regulatory requirements, including import- and export-related laws and regulations and the U.S. Foreign Corrupt Practices Act;
· changes by foreign governments and other foreign healthcare payors in reimbursement rates for Cologuard or other products and services we may develop;
· differing local preferences and expectations for healthcare services;
· differing private and public health insurance systems, including differing approaches to coverage determinations and reimbursement amounts;
· foreign currency exchange controls and tax rates;
· foreign currency exchange rate fluctuations, including devaluations;
· potential changes in regional and local economic conditions, including local inflationary pressures;
· political instability and actual or anticipated military or political conflicts;
· difficulty in establishing, staffing and managing non-U.S. operations
· differing labor regulations;
· potential changes in or interpretations of tax laws;
· minimal protection of intellectual and other property rights in certain jurisdictions;
· varying enforcement of contractual rights in certain jurisdictions; and
· restrictive governmental actions such as those on transfer or repatriation of funds and trade protection matters, as well as the potential nationalization or seizure of business enterprises or assets.

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

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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 stock price may be volatile.

The market price of our common stock has fluctuated widely. 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 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. Because we are a company with no significant operating revenue, any of the risk factors listed in this "Item 1A. Risk Factors" may be deemed material and may affect our stock price.

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, 2014, we occupied approximately 35,000 square feet of space in our headquarters located in Madison, Wisconsin under a lease which expires in October 2016, but can be extended to October 2019. In addition, we have leased a 32,000 square foot facility in Madison, Wisconsin to house our commercial lab operations. This lease expires in November 2019 but can be extended to November 2029.

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.

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Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Our common stock is currently listed on the NASDAQ Capital Market under the symbol "EXAS." 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
2014		
First quarter	$ 15.60	$ 11.63
Second quarter	17.74	10.69
Third quarter	23.20	15.01
Fourth quarter	29.97	17.34
2013		
First quarter	$ 11.98	$ 9.62
Second quarter	14.42	6.93
Third quarter	14.70	11.47
Fourth quarter	12.59	9.53

As of February 26, 2015, there were 88,671,335 shares of our common stock outstanding held by approximately 89 holders of record.

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

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Item 6. Selected Financial Data

The selected historical financial data for the five years ended December 31, 2014 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,				
	2014	2013	2012	2011	2010
	(Amounts in thousands, except per share data)				
Statements of Operations Data:					
Revenue:					
Laboratory service revenue	$ 1,504	$ —	$ —	$ —	$ —
Product royalty fees	—	—	—	20	26
License fees	294	4,144	4,144	4,143	5,318
	1,798	4,144	4,144	4,163	5,344
Cost of sales(1)	4,325	—	—	24	24
Gross profit	(2,527)	4,144	4,144	4,139	5,320
Operating expenses:					
Research and development(1)	28,669	27,678	42,131	21,968	9,023
General and administrative(1)	30,435	13,649	9,900	8,137	6,330
Sales and marketing(1)	38,908	9,578	4,755	2,857	1,793
	98,012	50,905	56,786	32,962	17,146
Loss from operations	(100,539)	(46,761)	(52,642)	(28,823)	(11,826)
Investment income	542	316	262	169	46
Interest expense	(51)	(69)	(41)	(21)	(20)
Other income	—	—	—	—	244
Net loss	$ (100,048)	$ (46,514)	$ (52,421)	$ (28,675)	$ (11,556)
Net loss per share:					
Basic and diluted	$ (1.25)	$ (0.69)	$ (0.88)	$ (0.54)	$ (0.29)
Weighted average common shares outstanding:					
Basic and diluted	80,232	67,493	59,481	52,512	40,455
Balance Sheet Data:					
Cash and cash equivalents	$ 58,131	$ 12,851	$ 13,345	$ 35,781	$ 78,752
Marketable securities	224,625	120,408	94,776	57,580	16,663
Total assets	311,624	146,627	112,119	96,953	96,515
Long term debt	1,000	1,000	1,000	1,000	1,000
Other long term liabilities	2,399	—	—	—	—
Total liabilities	22,640	11,311	13,524	13,458	16,761
Stockholders' equity	288,984	135,316	98,595	83,495	79,754

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

	2014	2013	2012	2011	2010
Cost of sales	$ 279	$ —	$ —	$ —	$ —
Research and development	4,135	2,817	2,396	1,685	1,087
General and administrative	5,589	3,054	2,579	1,622	993
Sales and marketing	1,517	1,873	518	657	41

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

The information contained in this section has been derived from our consolidated financial statements and should be read together with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10 K.

Exact Sciences Corporation ("we," "us," "our" or the "Company") is a molecular diagnostics company currently focused on the early detection and prevention of colorectal cancer. We have developed a non invasive, patient friendly screening test called Cologuard® to meet our primary goal of becoming the market leader in non-invasive colorectal cancer screening products.

Our strategic roadmap to achieve this goal includes the following key components:

· commercialize an FDA-approved product that detects colorectal pre-cancer and cancer; and
· successfully operate a CLIA certified laboratory facility to process Cologuard tests and provide patient results
· secure favorable reimbursement for our laboratory services from payors.

Our Cologuard test is a non invasive stool based DNA (sDNA) screening test designed to detect DNA markers, which in published studies have been shown to be associated with colorectal cancer. In addition to DNA markers, our test includes a protein marker to detect blood in the stool, utilizing an antibody based fecal immunochemical test (FIT).

On August 11, 2014 the U.S. Food and Drug Administration (FDA) approved Cologuard for use as the first and only sDNA noninvasive colorectal cancer screening test. In addition on October 9, 2014 the Centers for Medicare and Medicaid Services (CMS) issued a final National Coverage Determination (NCD) extending coverage for Cologuard as a colorectal cancer screening test for asymptomatic, average risk Medicare beneficiaries, aged 50 to 85 years. CMS has established reimbursement for Cologuard (CPT Code G0464) at $492.72 in the CMS 2015 Clinical Lab Fee Schedule.

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

· 137,000 new cases in the U.S.
· 50,000 deaths in the U.S.
· 1,200,000 new cases worldwide
· 600,000 deaths worldwide

Colorectal cancer treatment represents a significant and growing healthcare cost. Annually $14 billion is spent 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 rapidly 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, nearly 47 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

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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.

Professional colorectal cancer screening guidelines in the U.S., including those of the ACS, the American College of Gastroenterology, and the American Gastroenterological Association, recommend regular screening by a variety of methods. Historically, these recommendations consisted of colonoscopy, flexible sigmoidoscopy and fecal occult blood testing (FOBT) as well as combinations of some of these methods. On March 5, 2008, the ACS and the U.S. Multi Society Task Force on Colorectal Cancer included sDNA screening technology in the updated national colorectal cancer screening guidelines as a screening option for the detection of colorectal cancer in average risk, asymptomatic individuals age 50 and older. The U.S. Multi Society Task Force on Colorectal Cancer is a consortium of several organizations that includes representatives of the American College of Gastroenterology, American Gastroenterological Association, American Society for Gastrointestinal Endoscopy and the American College of Physicians/Society of Internal Medicine. In November 2014 the ACS updated the colorectal cancer screening guidelines to specifically include Cologuard as a recommended sDNA screening test.

The competitive advantages of sDNA based screening provide a significant market opportunity. Assuming a 30 percent test adoption rate and a three year screening interval, we estimate the potential U.S. market for sDNA screening to be more than $2 billion and we estimate the potential global market opportunity to be greater than $3 billion.

On August 11, 2014 the U.S. Food and Drug Administration (FDA) approved Cologuard for use as the first and only sDNA noninvasive colorectal cancer screening test. Our submission to the FDA for Cologuard with the results of our pivotal DeeP-C clinical trial that had over 10,000 patients enrolled at 90 enrollment 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%
· High-Grade Dysplasia Sensitivity: 69%
· Specificity: 87%

We believe having FDA approval for Cologuard is a prerequisite for building broad consumer and physician demand and successfully commercializing our sDNA colorectal cancer screening technology.

On October 9, 2014 the Centers for Medicare & Medicaid Services (CMS) issued a final National Coverage Determination (NCD) for Cologuard. As outlined in the NCD, Medicare Part B will cover 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 of developing colorectal cancer (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 nonpolyposis colorectal cancer).

In the 2015 Clinical Laboratory Fee Schedule, CMS has established reimbursement for Cologuard (CPT code G0464) at $492.72. We believe that obtaining a favorable national coverage decision and a commercially viable reimbursement rate from CMS for Cologuard are necessary to achieve material commercial success. Medicare covers 43% of patients in the screening population for Cologuard. We believe the favorable CMS coverage decision may also aid in securing positive coverage decisions from major national and regional managed care organizations, insurance carriers, and self insured employer groups.

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We also believe that it will be necessary to secure favorable coverage and reimbursement from commercial payors to achieve commercial success. We believe that third party payors' reimbursement of Cologuard will depend on a number of factors, including payors' determination that it is: sensitive for colorectal cancer; not experimental or investigational; approved by major guidelines organizations; reliable, safe and effective; medically necessary; appropriate for the specific patient; and cost effective.

Cologuard is currently recommended for colorectal cancer screening in ACS guidelines, which is a significant preliminary step to securing coverage with commercial payors.

A critical part of the value proposition of Cologuard is our physician and patient engagement team which helps to drive compliance for Cologuard as the team actively engages with patients to help them get screened. This activity is focused on having patients complete Cologuard tests that have been ordered for them by their physicians and supports physicians in their efforts to have their patients screened. In addition, monthly compliance reports are provided to physicians relevant to their patient population.

Our sales and marketing strategy includes three main elements with a focus on physicians, patients, and payors.

We are engaging physicians with several strategies. We have a 140 person sales team, including approximately 100 in a direct field sales force, actively engaging 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 are focused on specific physicians based on specialty and propensity to prescribe colorectal cancer screening tests. We are also focused on physician groups and larger regional and national health systems. Further, to build awareness, we have launched a medical education program that includes on-line training and peer-to-peer presentations.

After the launch of Cologuard we initiated a significant public relations effort to engage patients and we have also targeted direct to patient advertising through social media and targeted print and media advertising.

One of the key components to engaging with payors was securing coverage from CMS which we did in October of 2014. Additionally, we are providing cost effectiveness data to payors to make the case for Cologuard reimbursement. We are focusing our efforts on large national and regional insurers, states that require health insurers to cover colorectal cancer screening consistent with the ACS guidelines and health plans that have affiliated health systems.

As part of our commercialization strategy, we also established a state of the art, highly automated lab facility that is certified pursuant to applicable Federal Clinical Laboratory Improvement Amendments (CLIA) regulations to process Cologuard tests and provide patient results. Our commercial lab operation is housed in a 32,000 square foot facility in Madison, Wisconsin. We have the capacity at our lab to process one million tests per year.

We have generated limited operating revenues since inception and, as of December 31, 2014, we had an accumulated deficit of approximately $420.8 million. We expect to continue to incur losses for the next several years, and it is possible we may never achieve profitability.

2015 Priorities

Our top priorities for 2015 include growing revenue for Cologuard, continuing to provide world class service as order volume grows, and developing our product pipeline for future products.

We plan to grow Cologuard revenue through the continued efforts of our sales force to work with physicians and systems to adopt Cologuard for colorectal cancer screening. In addition, we are working with payers to secure

favorable reimbursement for Cologuard which will be a key component to growing revenue for 2015.

One of the key priorities for 2015 is to continue to provide world class service to patients and achieve a greater than 70% compliance rate for patients who are prescribed Cologuard.

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We plan on continuing to collaborate with MAYO on future products related to early detection of gastrointestinal (GI) cancers specifically in the areas of esophageal and pancreatic cancers. GI cancers account for 145,000 or 25% of all U.S cancer deaths annually and represent a significant market opportunity for future products. Additionally we will continue to explore opportunities for expanding the indications of Cologuard such as for patients between the ages of 40-50 or for high risk patients like those with inflammatory bowel disease.

Results of Operations

Our key priorities during 2014 were securing FDA approval and a favorable national coverage decision from CMS for Cologuard and ultimately launching the product. This led to an increase in general and administrative costs during the year of $16.8 million, and an increase in sales and marketing costs during the year of $29.3 million. In addition, during 2014 we worked on developing pipeline products and improvements to Cologuard which led to a slight increase in research and development costs during the year of $1.0 million. We ensured that we were well capitalized to meet our 2014 goals by raising $238.6 million net of issuance costs through two public offerings of common stock in April 2014 and December 2014.

Comparison of the years ended December 31, 2014 and 2013

Laboratory service revenue.

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

License fee revenue.

Total license fee revenue was $0.3 million for the year ended December 31, 2014 and $4.1 million for the year ended December 31, 2013. License fee revenue is composed 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 therefore leading to a decline in revenue when compared to the prior year. Due to completion of the collaboration period in January 2014, we do not expect to recognize any further significant revenues under this agreement.

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 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 the adoption rates of the Cologuard test, our revenue recognition policy, the levels of reimbursement, and payment patterns or third-party payors and patients.

Cost of sales.

Cost of sales includes costs related to inventory production and usage and the cost of laboratory services to process the tests and provide results to physicians. Gross margin as a percentage of laboratory service revenue is affected by our current revenue recognition policy, which may result in costs being incurred in one period that relate to revenue recognized in a later period. Cost of sales was $4.3 million for the twelve months ended December 31, 2014 compared to

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none in the comparable prior year periods. The increase in cost of sales is related to the production of Cologuard which obtained FDA approval during the third quarter of 2014. Cost of sales includes $1.6 million related to excess capacity and $2.7 million related to inventory production and lab service costs, which includes materials, personnel expenses and stock-based compensation expense.

Research and development expenses.

Research and development expenses increased to $28.7 million for the year ended December 31, 2014 from $27.7 million for the year ended December 31, 2013. This increase was primarily due to an increase in stock-based compensation expense and lab expenses offset by a decrease in clinical trial costs. The increase in stock-based compensation expense from prior year is primarily related to warrants to purchase 75,000 shares of common stock that 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 FDA 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.

Amounts in millions	2014	2013	Change
Personnel expenses	$ 8.7	$ 9.1	$ (0.4)
Stock-based compensation	4.2	2.8	1.4
Other research and development	3.8	4.2	(0.4)
Lab expenses	3.8	2.8	1.0
Clinical trial expenses	2.9	5.3	(2.4)
Research collaborations	2.3	1.8	0.5
Professional fees	2.1	1.3	0.8
License and royalty fees	0.9	0.4	0.5
Total research and development expenses	$ 28.7	$ 27.7	$ 1.0

General and administrative expenses.

General and administrative expenses increased to $30.4 million for the year ended December 31, 2014 from $13.6 million for the year ended December 31, 2013. The increase in general and administrative expenses was primarily the result of increased legal and professional fees, increased personnel costs and stock-based compensation expense due to increased headcount, additional information technology costs, and other general and administrative expenses to support the overall growth of the Company and the launch of Cologuard in 2014.

Amounts in millions	2014	2013	Change
Personnel expenses	$ 7.6	$ 2.8	$ 4.8
Legal and professional fees	6.9	4.1	2.8
Stock-based compensation	5.4	3.1	2.3
Other general and administrative	4.0	2.3	1.7
Information technology costs	4.0	0.5	3.5
Depreciation expense	1.6	0.3	1.3

Facility costs	0.9	0.5	0.4
Total general and administrative expenses	$ 30.4	$ 13.6	$ 16.8

Sales and marketing expenses.

Sales and marketing expenses increased to $38.9 million for the year ended December 31, 2014 from $9.6 million for the year ended December 31, 2013. 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. The increase was partially offset by a decrease in stock-based compensation for the year ended December 31, 2014 as compared to the same period in 2013 when we incurred one-time severance costs related to an executive departure.

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Amounts in millions	2014	2013	Change
Professional fees	$ 22.6	$ 4.1	$ 18.5
Personnel expenses	12.4	3.1	9.3
Other sales and marketing	2.5	0.5	2.0
Stock-based compensation	1.4	1.9	(0.5)
Total sales and marketing expenses	$ 38.9	$ 9.6	$ 29.3

Investment income.

Investment income increased to $542.0 thousand for the year ended December 31, 2014 from $316.0 thousand for the year ended December 31, 2013. This increase was primarily due to an overall higher cash and marketable securities balance, due to our issuances of common stock, during the year ended December 31, 2014 as compared to the same period of 2013.

Interest expense.

Interest expense decreased to $51.0 thousand for the year ended December 31, 2014 from $69.0 thousand for the year ended December 31, 2013. This decrease is primarily due to less interest expense recognized for our capital lease during the year ended December 31, 2014 when compared to the same period in 2013.

Comparison of the years ended December 31, 2013 and 2012

Revenue.

Total revenue was $4.1 million for the year ended December 31, 2013 and $4.1 million for the year ended December 31, 2012. Revenue is composed of the amortization of up front technology license fee payments associated with our collaboration, license and purchase agreement with Genzyme. The unamortized Genzyme up front payment and holdback amounts are being amortized on a straight line basis over the initial Genzyme collaboration period, which ended in January 2014.

Research and development expenses.

Research and development expenses decreased to $27.7 million for the year ended December 31, 2013 from $42.1 million for the year ended December 31, 2012. This decrease was primarily due to a decrease in clinical trial costs, lab expenses, and professional fees due to the completion of the FDA clinical trial for Cologuard in April 2013, partially offset by an increase in personnel expenses due to increased headcount to help support our laboratory facility.

Amounts in millions	2013	2012	Change
Personnel expenses	$ 9.1	$ 7.4	$ 1.7
Clinical trial expenses	5.3	19.1	(13.8)

Other research and development	4.2	2.0	2.2
Lab expenses	2.8	4.9	(2.1)
Stock-based compensation	2.8	2.4	0.4
Research collaborations	1.8	1.3	0.5
Professional fees	1.3	3.6	(2.3)
License and royalty fees	0.4	1.4	(1.0)
Total research and development expenses	$ 27.7	$ 42.1	$ (14.4)

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General and administrative expenses.

General and administrative expenses increased to $13.6 million for the year ended December 31, 2013 from $9.9 million for the year ended December 31, 2012. The increase in general and administrative expenses was primarily a result of increased legal and professional fees in connection with FDA filing efforts, increased personnel costs and other general and administrative expenses to support the overall growth of the Company as we increased headcount and prepared for commercialization.

Amounts in millions	2013	2012	Change
Legal and professional fees	$ 4.1	$ 2.2	$ 1.9
Stock-based compensation	3.1	2.6	0.5
Personnel expenses	2.8	2.1	0.7
Other general and administrative	2.3	1.8	0.5
Information technology costs	0.5	0.4	0.1
Facility costs	0.5	0.4	0.1
Depreciation expense	0.3	0.4	(0.1)
Total general and administrative expenses	$ 13.6	$ 9.9	$ 3.7

Sales and marketing expenses.

Sales and marketing expenses increased to $9.6 million for the year ended December 31, 2013 from $4.8 million for the year ended December 31, 2012. The increase in sales and marketing expense was a result of hiring additional marketing personnel and increased professional fees in connection with the expanded use of consultants as we increased our efforts to prepare for the commercialization of Cologuard. The increase in stock based compensation and personnel costs is related to one-time severance costs incurred in June 2013 related to an executive departure.

Amounts in millions	2013	2012	Change
Professional fees	$ 4.1	$ 2.4	$ 1.8
Personnel expenses	3.1	1.6	1.5
Stock-based compensation	1.9	0.5	1.3
Other sales and marketing	0.5	0.3	0.2
Total sales and marketing expenses	$ 9.6	$ 4.8	$ 4.8

Investment income.

Investment income increased to $316.0 thousand for the year ended December 31, 2013 from $262.0 thousand for the year ended December 31, 2012. This increase was primarily due to an overall higher cash and marketable securities balance during the year ended December 31, 2013 as compared to the same period of 2012.

Interest expense.

Interest expense increased to $69.0 thousand for the year ended December 31, 2013 from $41.0 thousand for the year ended December 31, 2012. This increase was due to interest expense recognized from a capital lease which was entered into during September 2012.

Liquidity and Capital Resources

We have financed our operations primarily through private and public offerings of our common stock. As of December 31, 2014, we had approximately $58.1 million in unrestricted cash and cash equivalents and approximately $224.6 million in marketable securities.

All of our investments in marketable securities are comprised 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

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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 $80.9 million, $39.7 million, and $44.5 million for the years ended December 31, 2014, 2013 and 2012, respectively. The principal use of cash in operating activities for each of the years ended December 31, 2014, 2013 and 2012 was to fund our net loss. The increase in net cash used in operating activities for the years ended December 31, 2014 and December 31, 2013, as compared to prior years was primarily due to increased sales and marketing activities as well as general and administrative activities as we prepared 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 $117.8 million, $35.5 million, and $38.3 million for the years ended December 31, 2014, 2013, and, 2012, respectively. The increase in cash used in investing activities for the year ended December 31, 2014 when compared to the same period in 2013 was the result of increased purchases of marketable securities. Excluding the impact of purchases and maturities of marketable securities, net cash used in investing activities was $12.5 million for the year ended December 31, 2014, compared to net cash used in investing activities of $9.3 million for the year ended December 31, 2013 which was primarily the result of an increase 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, 2012 was primarily the result of purchases of property and equipment of $0.7 million.

Net cash provided by financing activities was $244.0 million, $74.8 million and $60.4 million for the years ended December 31, 2014, 2013 and 2012, respectively. The increase in cash provided by financing activities for the year ended December 31, 2014 when compared to the same period in 2013 was primarily the result of an increase in the proceeds from the sale of common stock from $73.3 million in 2013 to $238.6 million in 2014. Excluding the impact of the sale of common stock, net cash provided by financing activities was $5.4 million for the year ended December 31, 2014, compared to net cash provided by financing activities of $1.3 million for the same period in 2013. This increase in cash provided by financing activities was primarily due to proceeds received in connection to other long term liabilities, an increase in proceeds from the exercise of common stock options and an increase in proceeds in connection with the Company’s Employee Stock Purchase Plan for the year ended December 31, 2014. The increase in cash provided by financing activities for the year ended December 31, 2013 when compared to the same period in 2012 was primarily the result of an increase in proceeds from the sale of common stock from $57.8 million in 2012 to $73.3 million in 2013. Excluding the impact of the sale of common stock, net cash provided by financing activities was $1.3 million for the year ended December 31, 2013, compared to net cash provided by financing activities of $2.6 million for the same period in 2012. This decrease in cash provided by financing activities was primarily due to a decrease in proceeds from the exercise of common stock options for the year ended December 31, 2013.

We expect that cash and cash equivalents and marketable securities on hand at December 31, 2014, will be sufficient to fund our current operations for at least the next twelve months, based on current operating plans. However, since payments for Cologuard will be our only material revenue source and we have just begun to collect such payments and do not know the timing or amount of any such payments, it is possible that we may need to raise additional capital to fully fund our current strategic plan. If we are unable to obtain sufficient additional funds to enable us to fund our operations through the completion of such plan, our results of operations and financial condition would be materially adversely affected and we may be required to delay the implementation of our plan and otherwise scale back our operations. Even if we successfully raise sufficient funds to complete our plan, we cannot assure that our business will ever generate sufficient cash flow from operations to become profitable.

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The following table reflects our estimated fixed obligations and commitments as of December 31, 2014. This table does not include potential milestone payments due upon FDA approval of future products or future sales based royalty obligations and milestones:

		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)	$ 1,175	$ 97	$ 467	$ 467	$ 144
Other long-term liabilities(1)	2,727	46	94	94	2,493
Obligations under license and collaborative agreements(2)	3,497	698	512	512	1,775
Operating lease obligations	4,002	1,310	1,988	704	—
Capital lease obligations(1)	369	369	—	—	—
Total	$ 11,770	$ 2,520	$ 3,061	$ 1,777	$ 4,412

(1) Includes expected interest payments related to long term debt obligations.

(2) We have entered into license and collaborative agreements with the Mayo Foundation, Genzyme, MDx Health (formerly Oncomethylome Sciences), 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 and our office facility in London, United Kingdom. Capital leases reflect obligations under a capital equipment leasing arrangement.

Net Operating Loss Carryforwards

As of December 31, 2014, we had federal and state net operating loss carryforwards of approximately $422.7 million and $232.0 million, respectively. The Company also had federal and state research tax credit carryforwards of approximately $6.5 million and $15.6 million, respectively. The net operating loss and tax credit carryforwards will expire at various dates through 2033, 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. The deferred tax assets are still available for us to use in the future to offset taxable income, which would result in the recognition of tax benefit and a reduction to our effective tax rate.

Critical Accounting Policies and Estimates

Management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United

States. 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, certain third party royalty obligations, accrued clinical trial costs, and stock based compensation. We base our estimates on historical experience and on

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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. The Company's revenues are primarily generated by the Cologuard test. Revenues are recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable, and collectability is reasonably assured. The Company assesses whether the fee is fixed or determinable and if the collectability is reasonable based on the nature of the fee charged for the laboratory services delivered and whether there are existing contractual arrangements with customers, third-party commercial payors (insurance carriers and health plans) or coverage of the test by Centers for Medicare & Medicaid Services (CMS). In addition, when evaluating collectability, the Company considers factors such as collection experience for the healthcare industry, the financial standing of customers or third-party commercial payors, and whether it has sufficient collection history to reliably estimate a payor's individual payment patterns.

A significant portion of laboratory service revenues earned by the Company will be initially recognized on a cash basis because the above criteria will not have been met at the time the test results are delivered. The Company generally bills third-party payors upon generation and delivery of a test result to the ordering physician following completion of a test. As such, the Company takes assignment of benefits and risk of collection with the third-party payor. Patients may have out-of-pocket costs for amounts not covered by their insurance reimbursement policies. Consequently, the Company pursues reimbursement on a case-by-case basis directly from the patient.

For laboratory services performed, where the collectability is not reasonably assured, the Company will continue to recognize revenues upon cash collection until it can reliably estimate the amount that would be ultimately collected for the Cologuard test. In order to begin to record revenue on an accrual basis in these scenarios, the Company expects to use at least several months of payment history, review the number of test paid against the number of tests billed, and consider the payor's outstanding balance for unpaid tests to determine whether payments are being made for a consistently high percentage of tests billed and at appropriate amounts given the contracted or historical payment amount. Cologuard became available upon FDA approval on August 11, 2014. The national coverage decision for Cologuard was released by CMS on October 9, 2014.

The Company recognized approximately $1.5 million in laboratory service revenue for the year ended December 31, 2014.

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

In connection with our January 2009 strategic transaction with Genzyme Corporation, Genzyme agreed to pay us 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. Our on going performance obligations to Genzyme under the Collaboration, License and Purchase Agreement (the "CLP Agreement"), as described below, including our obligation to deliver 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, we deferred the initial $16.65 million in cash received at closing and are amortizing that up front payment on a straight line basis into revenue over the initial five year collaboration period ending in January 2014. We received the first holdback amount of $962,000, which included accrued interest, due from Genzyme during the first quarter of 2010 and the second holdback amount of $934,250, 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.

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In addition, Genzyme purchased 3,000,000 shares of our common stock on January 27, 2009, for $2.00 per share, representing a premium of $0.51 per share above the closing price of our common stock on that date of $1.49 per share. The aggregate premium paid by Genzyme over the closing price of our 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, we 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.

In total, we 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.

Stock Based Compensation.

All stock based awards, 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 following assumptions are used in determining fair value for employee stock options and ESPP shares:

· Valuation and Recognition—The fair value of each option award is estimated on the date of grant using the Black Scholes option pricing model. The estimated fair value of employee stock options is recognized to expense using the straight line method over the vesting period.

  · Expected Term—The Company uses the simplified calculation of expected life, described in the SEC's Staff Accounting Bulletins 107 and 110, as the Company does not currently have sufficient historical exercise data on which to base an estimate of expected term. Using this method, the expected term 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 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 valuation method 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 fair value of 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 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. 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 $161.9 million and $124.5 million valuation allowance at December 31, 2014 and 2013 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, 2014 and 2013 was $37.4 million and $20.6 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.

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Recent Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes the revenue recognition requirements in Topic 605, Revenue Recognition, and most industry-specific guidance. The update also creates a new Subtopic 340-40, Other Assets and Deferred Costs – Contracts with Customers, which provides guidance for the incremental costs of obtaining a contract with a customer and those costs incurred in fulfilling a contract with a customer that are not in the scope of another topic. The new revenue standard requires that entities should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entities expect to be entitled in exchange for those goods or services. To achieve that core principle, the standard requires a five step process of identifying the contracts with customers, identifying the performance obligations in the contracts, determining the transaction price, allocating the transaction price to the performance obligations, and recognizing revenue when, or as, the performance obligations are satisfied. The amendment also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. This pronouncement is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. We are evaluating the impact that the adoption of this standard will have on our consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements—Going Concern (Subtopic 205-40), Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern . The amendment is effective for the annual period beginning after December 15, 2016, and for annual and interim periods thereafter, with early adoption permitted. The amendment requires an entity's management to evaluate for each annual and interim reporting period whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued or available to be issued. If substantial doubt is raised, further analysis and disclosures are required, including management's plans to mitigate the adverse conditions or events.

In July 2013, the FASB issued ASU 2013-11 regarding the presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. This standard requires entities to present an unrecognized tax benefit as a reduction of a deferred tax asset for a net operating loss ("NOL") or tax credit carryforward whenever the NOL or tax credit carryforward would be available to reduce the additional taxable income or tax due if the tax position is disallowed. This ASU requires entities to assess whether to net the unrecognized tax benefit with a deferred tax asset as of the reporting date. This guidance is effective for fiscal years beginning after December 15, 2013, with early adoption permitted. The Company adopted this guidance during the first quarter of 2014, and it did not have a material impact on the consolidated financial statements as we have a full valuation allowance against our deferred tax asset. Refer to footnote 13 for further description.

Off Balance Sheet Arrangements

As of December 31, 2014, 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, 2014 and December 31, 2013 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

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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, 2014 and 2013 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, 2014. 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, 2014 and 2013, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, 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, 2014, 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 27, 2015 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Milwaukee, Wisconsin

February 27, 2015

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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, 2014, 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, 2014, 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, 2014 and 2013, 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, 2014 and our report dated February 27, 2015 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Milwaukee, Wisconsin

February 27, 2015

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EXACT SCIENCES CORPORATION

Consolidated Balance Sheets

(Amounts in thousands, except share data)

	December 31, 2014	December 31, 2013
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 58,131	$ 12,851
Marketable securities	224,625	120,408
Accounts receivable	1,376	—
Inventory, net	4,017	—
Prepaid expenses and other current assets	3,528	2,199
Total current assets	291,677	135,458
Property and Equipment, at cost:		
Laboratory equipment	10,381	5,087
Assets under construction	1,552	2,592
Computer equipment and computer software	7,577	1,217
Leasehold improvements	5,937	5,043
Furniture and fixtures	939	268
	26,386	14,207
Less—Accumulated depreciation	(6,439)	(3,038)
Net property and equipment	19,947	11,169
Total assets	$ 311,624	$ 146,627
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,647	$ 873
Accrued liabilities	13,960	5,694
Capital lease obligation, current portion	360	351
Lease incentive obligation, current portion	554	540
Deferred license fees, current portion	—	294
Total current liabilities	17,521	7,752
Long-term debt	1,000	1,000
Long-term accrued interest	106	84
Other long-term liabilities	2,399	—
Capital lease obligation, less current portion	—	360
Lease incentive obligation, less current portion	1,614	2,115
Total liabilities	22,640	11,311
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.01 par value Authorized—5,000,000 shares Issued and outstanding—no shares at December 31, 2014 and December 31, 2013	—	—

Common stock, $0.01 par value Authorized—200,000,000 shares Issued and outstanding—88,626,042 and 71,071,838 shares at December 31, 2014 and December 31, 2013	887	711
Additional paid-in capital	709,019	455,239
Accumulated other comprehensive income	(115)	125
Accumulated deficit	(420,807)	(320,759)
Total stockholders' equity	288,984	135,316
Total liabilities and stockholders' equity	$ 311,624	$ 146,627

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,		
	2014	2013	2012
Laboratory service revenue	$ 1,504	$ —	$ —
License fees	294	4,144	4,144
Total revenue	1,798	4,144	4,144
Cost of sales	4,325	—	—
Gross margin	(2,527)	4,144	4,144
Operating expenses:			
Research and development	28,669	27,678	42,131
General and administrative	30,435	13,649	9,900
Sales and marketing	38,908	9,578	4,755
Total operating expenses	98,012	50,905	56,786
Loss from operations	(100,539)	(46,761)	(52,642)
Other income (expense)			
Investment income	542	316	262
Interest expense	(51)	(69)	(41)
Total other income (expenses)	491	247	221
Net loss	$ (100,048)	$ (46,514)	$ (52,421)
Net loss per share—basic and diluted	$ (1.25)	$ (0.69)	$ (0.88)
Weighted average common shares outstanding—basic and diluted	80,232	67,493	59,481

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,		
	2014	2013	2012
Net loss	$ (100,048)	$ (46,514)	$ (52,421)
Other comprehensive loss, net of tax:			
Unrealized gain (loss) on available-for-sale investments	(240)	47	92
Comprehensive loss	$ (100,288)	$ (46,467)	$ (52,329)

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 , 2012	56,624,763	$ 566	$ 304,767	$ (14)	$ (221,824)	$ 83,495
Issuance of common stock related to the Mayo Transaction (Note 4)	97,466	1	999	—	—	1,000
Issuance of common stock, net of issuance costs of $3.9 million	6,325,000	63	57,692	—	—	57,755
Exercise of common stock options and warrants	691,471	7	2,381	—	—	2,388
Issuance of common stock to fund the Company's 2011 401(k) match	32,872	—	274	—	—	274
Compensation expense related to issuance of stock options and restricted stock awards	74,617	1	5,492	—	—	5,493
Purchase of employee stock purchase plan shares	63,611	1	366	—	—	367
Expense related to warrants (Note 4)	—	—	152	—	—	152
Net loss	—	—	—	—	(52,421)	(52,421)
Accumulated other comprehensive income	—	—	—	92	—	92
Balance, December 31 , 2012	63,909,800	$ 639	$ 372,123	$ 78	$ (274,245)	$ 98,595
Issuance of common stock, net of issuance costs of $4.8 million	6,325,000	63	73,232	—	—	73,296
Exercise of common stock options and warrants	418,146	4	1,337	—	—	1,341
	30,538	1	354	—	—	354

Issuance of common stock to fund the Company's 2012 401(k) match						
Compensation expense related to issuance of stock options and restricted stock awards	328,422	3	7,741	—	—	7,744
Purchase of employee stock purchase plan shares	59,932	1	452	—	—	453
Net loss	—	—	—	—	(46,514)	(46,514)
Accumulated other comprehensive income	—	—	—	47	—	47
Balance, December 31 , 2013	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	1	455	—	—	456
Compensation expense related to issuance of stock options, restricted stock awards and warrants	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	$ 887	$ 709,019	$ (115)	$ (420,807)	$ 288,984

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,		
	2014	2013	2012
Cash flows from operating activities:			
Net loss	$ (100,048)	$ (46,514)	$ (52,421)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of fixed assets	3,710	1,418	985
Loss on disposal of property and equipment	49	100	—
Stock-based compensation	11,520	7,744	5,493
Amortization of deferred license fees	(294)	(4,144)	(4,144)
Warrant licensing expense	—	—	152
Restricted stock licensing expense	—	—	1,000
Amortization of premium on short-term investments	842	636	532
Changes in assets and liabilities:			
Prepaid expenses and other current assets	(1,329)	(1,606)	441
Accounts receivable	(1,376)	—	—
Inventory, net	(4,017)	—	—
Accounts payable	1,886	(2,891)	2,887
Accrued expenses	8,610	2,833	532
Lease incentive obligation	(487)	2,655	—
Accrued interest	22	21	21
Net cash used in operating activities	(80,912)	(39,748)	(44,522)
Cash flows from investing activities:			
Purchases of marketable securities	(209,471)	(98,510)	(96,047)
Maturities of marketable securities	104,172	72,289	58,411
Purchases of property and equipment	(12,537)	(9,282)	(681)
Net cash used in investing activities	(117,836)	(35,503)	(38,317)
Cash flows from financing activities:			
Proceeds from sale of common stock, net of issuance costs	238,580	73,296	57,755
Proceeds from exercise of common stock options	2,640	1,341	2,388
Proceeds in connection with the Company's Employee Stock Purchase Plan	760	453	367
Proceeds from New Market Tax Credit financing agreements	2,399	—	—
Payments on capital lease obligations	(351)	(333)	(107)
Net cash provided by financing activities	244,028	74,757	60,403
Net increase (decrease) in cash and cash equivalents	45,280	(494)	(22,436)
Cash and cash equivalents, beginning of period	12,851	13,345	35,781
Cash and cash equivalents, end of period	$ 58,131	$ 12,851	$ 13,345

Supplemental disclosure of non-cash investing and financing activities:			
Unrealized gain (loss) on available-for-sale investments	$ (240)	$ 47	$ 92
Issuance of 32,666, 30,538, and 32,872 shares of common stock to fund the Company's 401(k) matching contribution for 2013, 2012, and 2011, respectively	$ 456	$ 354	$ 274
Laboratory equipment acquired with a capital lease	$ —	$ —	$ 1,151

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 ("Exact" or the "Company") was incorporated in February 1995. Exact is a molecular diagnostics company currently focused on the early detection and prevention of colorectal cancer. The Company's non invasive stool based DNA (sDNA) screening technology includes proprietary and patented methods that isolate and analyze human DNA present in stool to screen for the presence of colorectal pre cancer and cancer.

(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, and variable interest entities. See Note 12 for the discussion of financing arrangements involving certain entities that are variable interest entities that are included in 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 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 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, 2014 and 2013.

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, 2014 and December 31, 2013 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. 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

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

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 $11,000, $9,639, and $6,231, net of insignificant realized losses, for the years ended December 31, 2014, 2013, and 2012, respectively. Unrealized losses on investments recorded in other comprehensive income were $159,908 and $7,190 for the years ended December 31, 2014 and 2013, respectively. Unrealized gains on investments recorded in other comprehensive income were $45,808 and $132,663 for the years ended December 31, 2014 and 2013, respectively.

Available for sale securities at December 31, 2014 consist of the following:

	December 31, 2014			
(In thousands)	Amortized Cost	Gains in Accumulated Other Comprehensive Income	Losses in Accumulated Other Comprehensive Income	Estimated Fair Value
Corporate bonds	$ 141,239	$ 21	$ (136)	$ 141,124
U.S. government agency securities	18,687	8	(7)	18,688
Asset backed securities	60,821	17	(18)	60,820
Commercial paper	3,993	—	—	3,993
Total available-for-sale securities	$ 224,740	$ 46	$ (161)	$ 224,625

Available for sale securities at December 31, 2013 consist of the following:

	December 31, 2013			
(In thousands)	Amortized Cost	Gains in Accumulated Other Comprehensive Income	Losses in Accumulated Other Comprehensive Income	Estimated Fair Value
Corporate bonds	$ 77,935	$ 82	$ (7)	$ 78,010
U.S. government agency securities	34,291	46	—	34,337
Certificates of deposit	6,558	4	—	6,562
Commercial paper	1,499	—	—	1,499

Total available-for-sale securities	$ 120,283	$ 132	$ (7)	$ 120,408

Changes in Accumulated Other Comprehensive Income (Loss)

The amount recognized in accumulated other comprehensive income (loss) (AOCI) for the years ended December 31, 2014 and 2013 were as follows (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Beginning balance	$ 125	$ 78	$ (14)
Other comprehensive (loss) income before reclassifications	(200)	90	84
Amounts reclassified from accumulated other comprehensive loss	(40)	(43)	8
Net current period change in accumulated other comprehensive income (loss)	(240)	47	92
Ending balance	$ (115)	$ 125	$ 78

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

Amounts reclassified from accumulated other comprehensive income (loss) for the years ended December 31, 2014 and 2013 were as follows (in thousands):

Details about AOCI Components	Affected Line Item in the Statement of Operations	Year Ended December 31, 2014	2013	2012
Change in value of available-for-sale investments				
Sales and maturities of available-for-sale investments	Investment income	$ (40)	$ (43)	$ 8
Total reclassifications		$ (40)	$ (43)	$ 8

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:

Asset Classification	Estimated Useful Life
Laboratory equipment	3 - 5 years
Office, computer equipment and computer software	3 years
Leasehold improvements	Lesser of the remaining lease term or useful life
Furniture and fixtures	3 years

Depreciation expense for the years ended December 31, 2014, 2013, and 2012 was $3.7 million, $1.4 million, and $1.0 million, respectively.

At December 31, 2014, the Company had $1.6 million of assets under construction which consisted of $1.2 million of capitalized costs related to software and computer hardware projects and $0.4 million of costs related to leasehold improvement projects. Depreciation will begin on these assets once they are placed into service. We expect that it will

cost $0.2 million to complete the leasehold improvement projects and $0.1 million to complete the software projects, and these projects are expected to be completed in 2015.

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 in the application development stage that meet the criteria for capitalization are capitalized and amortized using the straight line basis over the estimated economic useful life of the software.

Patent Costs

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. The capitalized patents are amortized beginning when patents are approved over an estimated useful life of five years. Capitalized patent costs are expensed upon disapproval, upon a decision by the Company to no longer pursue the patent or when the related intellectual property is either sold or deemed to be no longer of value to the Company. The Company determined that all

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

patent costs incurred during the year ended December 31, 2014, 2013 and 2012 should be expensed and not capitalized as the future economic benefit derived from the transactions cannot be determined.

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 (amounts are in thousands):

	2014	2013	2012
Shares issuable upon exercise of stock options	4,934	6,063	6,182
Shares issuable upon exercise of outstanding warrants(1)	—	155	325
Shares issuable upon the release of restricted stock awards	1,541	1,151	814
Shares issuable upon the vesting of restricted stock awards related to licensing agreement	24	49	73
	6,499	7,418	7,394

(1) At December 31, 2013, represents warrants to purchase 80,000 shares of common stock issued under a license agreement and warrants to purchase 75,000 shares of common stock issued under a consulting agreement. At December 31, 2012, represents warrants to purchase 250,000 shares of common stock issued under a licensing agreement and warrants to purchase 75,000 shares of common stock issued under a consulting agreement.

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 revenues are primarily generated by the Cologuard test. Revenues are recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered,

the price is fixed or determinable, and collectability is reasonably assured. The Company assesses whether the fee is fixed or determinable and if the collectability is reasonable based on the nature of the fee charged for the laboratory services delivered and whether there are existing contractual arrangements with customers, third-party commercial payors (insurance carriers and health plans) or coverage of the test by Centers for Medicare & Medicaid Services (CMS). In addition, when evaluating collectability, the Company considers factors such as collection experience for the healthcare industry, the financial standing of customers or third-party commercial payors, and whether it has sufficient collection history to reliably estimate a payor's individual payment patterns.

A significant portion of laboratory service revenues earned by the Company will be initially recognized on a cash basis because the above criteria will not have been met at the time the test results are delivered. The Company generally bills third-party payors upon generation and delivery of a test result to the ordering physician following completion of a

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test. As such, the Company takes assignment of benefits and risk of collection with the third-party payor. Patients may have out-of-pocket costs for amounts not covered by their insurance reimbursement policies. Consequently, the Company pursues reimbursement on a case-by-case basis directly from the patient.

For laboratory services performed, where the collectability is not reasonably assured, the Company will continue to recognize revenues upon cash collection until it can reliably estimate the amount that would be ultimately collected for the Cologuard test. In order to begin to record revenue on an accrual basis in these scenarios, the Company expects to use at least several months of payment history, review the number of test paid against the number of tests billed, and consider the payor's outstanding balance for unpaid test to determine whether payments are being made for a consistently high percentage of tests billed and at appropriate amounts given the contracted or historical payment amount. Cologuard became available upon FDA approval on August 11, 2014. The national coverage decision for Cologuard was released by CMS on October 9, 2014.

The Company recognized approximately $1.5 million in laboratory service revenue for the year ended December 31, 2014.

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 is amortizing 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 $934,250 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 recognized approximately $0.3 million in license fee revenue for the year ended December 31, 2014 and $4.1 million in license fee revenue in connection with the amortization of the up front payments from Genzyme during the years ended December 31, 2013, and 2012, respectively.

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

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

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

Direct and indirect manufacturing costs incurred during process validation and for other research and development activities, which are not permitted to be sold, have been expensed to research and development. Raw material inventory that was purchased in prior periods, and expensed to research and development, may still be on hand and used toward the production of commercial Cologuard, provided it has an appropriate remaining shelf life. This inventory is expected to provide a gross margin benefit to the Company in future periods of $0.7 million if the entirety of those balances were allocated to inventory produced for resale and not allocated to research and development activities.

The Company has invested in its manufacturing operations to support future demand for Cologuard. Because of this investment in the future, the Company is not currently operating at normal capacity. Charges related to excess capacity are included as current period charges to cost of sales, and are not capitalized into inventory. Total excess capacity charged to cost of sales during the year ended December 31, 2014 was $1.6 million.

Inventory consists of the following (amount in thousands):

	December 31,	
	2014	2013
Raw Materials	$ 1,019	$ —
Semi-finished and finished goods	2,998	—
Total inventory	$ 4,017	$ —

Advertising Costs

The Company expenses the costs of media advertising at the time the advertising takes place. The Company expensed approximately $5.3 million, $0.1 million and $0.1 million of media advertising during the years ended December 31, 2014, 2013, and 2012, respectively.

Fair Value Measurements

The FASB has issued authoritative guidance which requires that fair value should 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 the 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.

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

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 change from period to period.

The following table presents the Company's fair value measurements as of December 31, 2014 along with the level within the fair value hierarchy in which the fair value measurements in their entirety fall. Amounts in the table are in thousands.

		Fair Value Measurement at December 31, 2014 Using:		
Description	Fair Value at December 31, 2014	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	$ 53,569	$ 53,569	$ —	$ —
Corporate bonds	4,562	—	4,562	—
Available-for-Sale Marketable securities				
Corporate bonds	141,124	—	141,124	—
U.S. government agency securities	18,688	—	18,688	—
Asset backed securities	60,820	—	60,820	—
Commercial paper	3,993	—	3,993	—
Total	$ 282,756	$ 53,569	$ 229,187	$ —

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

The following table presents the Company's fair value measurements as of December 31, 2013 along with the level within the fair value hierarchy in which the fair value measurements in their entirety fall. Amounts in the table are in thousands.

		Fair Value Measurement at December 31, 2013 Using:		
Description	Fair Value at December 31, 2013	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	$ 12,851	$ 12,851	$ —	$ —
Available-for-Sale Marketable securities				
Corporate bonds	78,010	—	78,010	—
U.S. government agency securities	34,338	—	34,338	—
Certificates of deposit	6,561	—	6,561	—
Commercial paper	1,499	—	1,499	—
Total	$ 133,259	$ 12,851	$ 120,408	$ —

The Company monitors investments for other-than-temporary impairment. It was determined that unrealized gains and losses at December 31, 2014 and 2013, 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.

The following table summarizes the gross unrealized losses and fair values of investments in an unrealized loss position as of December 31, 2014, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position:

	December 31, 2014					
	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	$ 113,960	$ (136)	$ —	$ —	$ 113,960	$ (136)
Asset backed securities	33,073	(18)	—	—	33,073	(18)
U.S. government agency securities	5,641	(7)	—	—	5,641	(7)
Total	$ 152,674	$ (161)	$ —	$ —	$ 152,674	$ (161)

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The following table summarizes the gross unrealized losses and fair value of investments in an unrealized loss position as of December 31, 2013, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position:

	December 31, 2013					
	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	$ 7,379	$ (6)	$ —	$ —	$ 7,379	$ (6)
Asset backed securities	5,062	(1)	—	—	5,062	(1)
Commercial paper	1,499	—	—	—	1,499	—
Total	$ 13,940	$ (7)	$ —	$ —	$ 13,940	$ (7)

The following table summarizes contractual underlying maturities of the Company's available for sale investments at December 31, 2014 (in thousands):

	Due one year or less		Due after one year through two years	
Description	Cost	Fair Value	Cost	Fair Value
Marketable Securities				
U.S. government agency securities	$ 14,788	$ 14,796	$ 3,899	$ 3,892
Corporate bonds	81,461	81,423	59,777	59,701
Commercial paper	3,993	3,993	—	—
Asset backed securities	—	—	60,821	60,820

Total	$ 100,242	$ 100,212	$ 124,497	$ 124,413

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 hedging arrangements. Financial instruments that subject the Company to credit risk consist of cash, cash equivalents and marketable securities. As of December 31, 2014, 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 $57.1 million. The Company has not experienced any losses in such accounts and management believes it is not exposed to any significant credit risk.

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.

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Recent Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes the revenue recognition requirements in Topic 605, Revenue Recognition, and most industry-specific guidance. The update also creates a new Subtopic 340-40, Other Assets and Deferred Costs – Contracts with Customers, which provides guidance for the incremental costs of obtaining a contract with a customer and those costs incurred in fulfilling a contract with a customer that are not in the scope of another topic. The new revenue standard requires that entities should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entities expect to be entitled in exchange for those goods or services. To achieve that core principle, the standard requires a five step process of identifying the contracts with customers, identifying the performance obligations in the contracts, determining the transaction price, allocating the transaction price to the performance obligations, and recognizing revenue when, or as, the performance obligations are satisfied. The amendment also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. This pronouncement is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. We are evaluating the impact that the adoption of this standard will have on our consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements—Going Concern (Subtopic 205-40), Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern . The amendment is effective for the annual period beginning after December 15, 2016, and for annual and interim periods thereafter, with early adoption permitted. The amendment requires an entity’s management to evaluate for each annual and interim reporting period whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are issued or available to be issued. If substantial doubt is raised, further analysis and disclosures are required, including management’s plans to mitigate the adverse conditions or events.

In July 2013, the FASB issued ASU 2013-11 regarding the presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. This standard requires entities to present an unrecognized tax benefit as a reduction of a deferred tax asset for a net operating loss ("NOL") or tax credit carryforward whenever the NOL or tax credit carryforward would be available to reduce the additional taxable income or tax due if the tax position is disallowed. This ASU requires entities to assess whether to net the unrecognized tax benefit with a deferred tax asset as of the reporting date. This guidance is effective for fiscal years beginning after December 15, 2013, with early adoption permitted. The Company adopted this guidance during the first quarter of 2014, and it did not have a material impact on the consolidated financial statements as we have a full valuation allowance against the deferred tax asset. Refer to footnote 13 for further description.

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,

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Notes to Consolidated Financial Statements (Continued)

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

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 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, including the obligation to deliver 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 is amortizing 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 $934,250 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 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. The Company

recognized approximately $4.1 million in license fee revenue in connection with the amortization of the up front payments and holdback amounts from Genzyme during each of the years ended December 31, 2013 and 2012.

(4) MAYO LICENSE AGREEMENT

Overview

On June 11, 2009, the Company entered into a license agreement (the “License Agreement”) with MAYO Foundation for Medical Education and Research (“MAYO”). Under the License Agreement, MAYO granted the Company an exclusive, worldwide license within the field (the “Field”) of stool or blood based cancer diagnostics and screening (excluding a specified proteomic target) with regard to certain MAYO patents, and a non exclusive worldwide license within the Field with regard to certain MAYO know how. The licensed patents cover advances in sample processing, analytical testing and data analysis associated with non invasive, stool based DNA screening for colorectal cancer. Under the License Agreement, the Company assumes the obligation and expense of prosecuting and maintaining the licensed patents and is obligated to make commercially reasonable efforts to bring products covered by the license to market. Pursuant to the License Agreement, the Company granted MAYO two common stock purchase warrants with an

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exercise price of $1.90 per share covering 1,000,000 and 250,000 shares of common stock, respectively. The Company is also required to make payments to MAYO for up front fees, fees once certain milestones are reached by the Company, and other payments as outlined in the License Agreement. In addition to the license to intellectual property owned by MAYO, the Company receives product development and research and development efforts from MAYO personnel. The Company is also obligated to make royalty payments to MAYO on potential future net sales of any products developed from the licensed technology. The Company sought rights to the MAYO intellectual property for the specific purpose of developing a non invasive, stool based DNA screening test for colorectal cancer. At the time the license agreement was executed, the sole focus of the Company was the development of such a test. Accordingly, the Company recognized the initial payments and expense related to the warrants at the time of the transaction and the amounts were expensed to research and development as there were no anticipated alternative future uses associated with the intellectual property.

Warrants

The warrants granted to MAYO were valued using a Black Scholes pricing model at the date of the grant. The warrants were granted with an exercise price of $1.90 per share of common stock. The grant to purchase 1,000,000 shares was immediately exercisable and the grant to purchase 250,000 shares vests and became exercisable over a four year period.

The warrant covering 1,000,000 shares was fully exercised as of September 2011.

In January of 2013, MAYO partially exercised its warrant covering 250,000 shares by utilizing the cashless exercise provision contained in the warrant. As a result of this exercise for a gross amount of 85,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its right with respect to 14,008 shares leaving it with a net amount of 70,992 shares.

In June of 2013, MAYO partially exercised this warrant by utilizing the cashless exercise provision contained in the warrant. As a result of this exercise for a gross amount of 85,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its right with respect to 12,765 shares leaving it with a net amount of 72,235 shares.

In June of 2014, MAYO exercised the remaining shares of this warrant by utilizing the cashless exercise provision contained in the warrant. As a result of this exercise for a gross amount of 80,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its right with respect to 10,587 shares leaving it with a net amount of 69,413 shares.

Following this exercise, all of MAYO's warrants to purchase the Company's common stock were fully exercised.

Royalty Payments

The Company will make royalty payments to MAYO based on a percentage of net sales of products developed from the licensed technology starting in the third year of the agreement. Minimum royalty payments were $10,000 in 2012, $25,000 in each of 2013 and 2014 and will be $25,000 per year thereafter through 2033, the year the last patent expires.

Other Payments

Other payments under the License Agreement include an upfront payment of $80,000, a milestone payment of $250,000 on the commencement of patient enrollment in a human cancer screening clinical, and a $500,000 payment upon FDA approval of the Company's Cologuard test. The upfront payment of $80,000 was made in the third quarter of 2009 and expensed to research and development in the second quarter of 2009. The Company began enrollment in its FDA trial in June 2011 and the milestone payment of $250,000 was made and expensed to research and development in June 2011. The Company received FDA approval for its Cologuard test in August 2014 and the milestone payment of $500,000 was made and expensed to research and development in August 2014.

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Notes to Consolidated Financial Statements (Continued)

In addition, the Company is paying MAYO for research and development efforts. As part of the Company's research collaboration with MAYO, the Company has incurred charges of $2.3 million and has made payments of $0.7 million for the year ended December 31, 2014. The Company has recorded an estimated liability in the amount of $1.4 million for research and development efforts as of December 31, 2014. The Company incurred $1.7 million and made payments of $1.0 million for the year ended December 31, 2013. The Company recorded an estimated liability in the amount of $0.7 million for research and development efforts at December 31, 2013. The Company incurred charges of $1.2 million and made payments of $1.1 million for the year ended December 31, 2012.

May 2012 Amendment

In May 2012 the Company expanded the relationship with MAYO through an amendment to the License Agreement. As part of the amendment, MAYO expanded the Company's license to include all gastrointestinal cancers and diseases, and new cancer screening applications of stool and blood based testing. As consideration for the expanded license, the Company granted MAYO 97,466 shares of restricted stock, one quarter of which vested immediately, with the remainder to vest in three equal annual installments. The Company recognized $1.0 million in research and development licensing expense during the twelve months ended December 31, 2012 in connection with the restricted stock grant. The Company sought rights to the Mayo intellectual property for the specific purpose of developing future non invasive, stool based DNA screening tests for gastrointestinal diseases other than colorectal cancer. The Company does not believe there are alternative future uses for the intellectual property. In addition, at the time the restricted stock grant expense was recorded for the intellectual property license, the Company believed it was unlikely they would proceed with the tests for other gastrointestinal diseases unless the significant risks related to the colorectal cancer screening test receiving FDA approval were mitigated. Because of the significant uncertainty of receiving FDA approval for the colorectal cancer diagnostic, coupled with the uncertainty associated with funding future development of tests for other gastrointestinal diseases, the Company could not conclude that commencement of any future projects related to the acquired intellectual property was reasonably expected at the time of this license agreement amendment.

As part of the amendment, the Company will also be responsible for making additional restricted stock grants to MAYO as certain milestones are met with respect to commercial launch of the Company's second and third licensed products. Additionally, the Company will make milestone payments once certain sales levels are reached on the second and third licensed products. It is uncertain as to when or if these milestones will be met; therefore, the milestone payments have not been recorded as a liability. The Company evaluates the status of the milestone payments at each reporting date to determine if a liability should be recorded for the milestone payment.

(5) ISSUANCES OF EQUITY

Underwritten Public Offerings

On August 13, 2012, the Company completed an underwritten public offering of 6.3 million shares of common stock at a price of $9.75 per share to the public. The Company received approximately $57.8 million of net proceeds from the offering, after deducting $3.9 million for the underwriting discount and other stock issuance costs paid by the Company.

On June 21, 2013, the Company completed an underwritten public offering of 6.3 million shares of common stock at a price of $12.35 per share to the public. The Company received approximately $73.3 million of net proceeds from the offering, after deducting $4.8 million for the underwriting discount and other stock issuance costs paid by the Company.

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 the $8.9 million for the underwriting discount 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 from the offering, after deducting $2.1 million for the underwriting discount and other stock issuance costs paid by the Company.

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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 and the 2000 Stock Option and Incentive Plan (collectively, the "Stock Plans").

2000 Stock Option and Incentive Plan The Company adopted the 2000 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, 2014, options to purchase 3,358,800 shares were outstanding under the 2000 Option Plan. There were no shares of restricted stock outstanding under the 2000 Option Plan.

2010 Omnibus Long Term Incentive Plan The Company adopted the 2010 Omnibus Long Term Incentive Plan (the "2010 Stock Plan") on July 16, 2010. The 2010 Stock Plan will expire on July 16, 2020 and after such date no further awards may be granted under the plan. Under the terms of the 2010 Stock Plan, the Company is authorized to grant

incentive stock options, as defined under the Internal Revenue Code, non qualified options, restricted stock awards and other stock awards to employees, officers, directors, consultants and advisors. Options granted under the 2010 Stock Plan expire ten years from the date of grant. Grants made from the 2010 Stock Plan generally vest over a period of three to four years.

The 2010 Stock Plan is administered by the compensation committee of the Company's board of directors, which selects the individuals to whom equity based awards will be granted and determines the option exercise price and other terms of each award, subject to the provisions of the 2010 Stock Plan. The 2010 Stock Plan provides that upon an acquisition of the Company, all equity will accelerate by a period of one year. In addition, upon the termination of an employee without cause or for good reason prior to the first anniversary of the completion of the acquisition, all equity awards then outstanding under the 2010 Stock Plan held by that employee will immediately vest. At December 31, 2014,

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options to purchase 1,575,517 shares were outstanding under the 2010 Stock Plan and 1,541,114 shares of restricted stock and restricted stock units were outstanding. At December 31, 2014, there were 1,638,187 shares available for future grant under the 2010 Stock Plan.

2010 Employee Stock Purchase Plan The 2010 Employee Stock Purchase Plan (the "2010 Purchase Plan") was adopted by the Company on July 16, 2010. The 2010 Purchase Plan provides participating employees the right to purchase 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 stockholders of Exact Sciences Corporation approved an amendment to the 2010 Employee Stock Purchase Plan to increase the number of shares available for purchase thereunder by 500,000 shares. At December 31, 2014, there were 540,177 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, 2014, there were 259,823 cumulative shares issued under the 2010 Purchase Plan, and 88,166 shares were issued in the year ended December 31, 2014, as follows:

Offering period ended	Number of Shares	Weighted Average price per Share
April 30, 2014	40,846	$ 8.25
October 31, 2014	47,320	$ 8.95

Stock Based Compensation Expense

The Company recorded approximately $11.5 million in stock based compensation expense during the year ended December 31, 2014, 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. The Company recorded $7.7 million in stock based compensation expense during the year ended December 31, 2013 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 and non employee directors. The Company recorded approximately

$5.5 million in stock based compensation expense during the year ended December 31, 2012 in connection with the amortization of awards of common stock, restricted common stock and stock options granted to employees, non employee directors and non employee consultants. Non cash stock based compensation expense by department for the years ended December 31, 2014, 2013, and 2012 are as follows, and amounts included in the table are in thousands:

	December 31,		
	2014	2013	2012
Cost of sales	$ 279	$ —	$ —
Research and development	4,135	2,817	2,396
General and administrative	5,589	3,054	2,579
Sales and marketing	1,517	1,873	518
Total stock-based compensation	$ 11,520	$ 7,744	$ 5,493

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Notes to Consolidated Financial Statements (Continued)

In connection with the June 7, 2013 resignation of the Company's former Chief Commercial Officer, the Company modified the vesting of 100,000 shares of her previously unvested restricted stock units of which 41,250 of the restricted stock units vested upon the execution of the separation agreement, 10,000 will vest in March 2014, and the remaining 48,750 will vest in twenty four equal monthly installments beginning in April 2014, subject to her continuing compliance with the terms of the separation agreement. She forfeited all other unvested restricted stock units and stock option awards. It was determined that the continuing compliance and service to be provided to the Company under the separation agreement was not substantive and, as a result, the Company recorded the full value of the modified restricted stock units as additional stock based compensation expense in the second quarter of 2013.

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 based on the assumptions in the table below. The estimated fair value of employee stock options is recognized to expense using the straight line method over the vesting period.

Expected Term—The Company uses the simplified calculation of expected life, described in the SEC's Staff Accounting Bulletins 107 and 110, as the Company does not currently have sufficient historical exercise data on which to base an estimate of expected life. Using this method, the expected term 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 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 valuation model 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, 2014, 2013 and 2012 was 4.99%, 2.76%, and 1.38%, respectively.

The fair value of each restricted stock and restricted stock unit award is determined on the date of grant using the closing stock price on that day. 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 in the following table:

	December 31,		
	2014	2013	2012
Option Plan Shares			
Risk-free interest rates	1.96% - 2.01%	0.94% - 1.73%	0.81% - 1.00%

Expected term (in years)	6	6	6
Expected volatility	77.6% - 80.8%	82.9% - 84.0%	85% - 92%
Dividend yield	0 %	0 %	0 %
Weighted average fair value per share of options granted during the period	$ 10.05	$ 8.12	$ 6.90
ESPP Shares			
Risk-free interest rates	0.1% - 0.5%	0.1% - 0.33%	0.18% - 0.30%
Expected term (in years)	0.5 - 2	0.5 - 2	0.5 - 2
Expected volatility	42.5% - 62.7%	39.1% - 45.6%	34.0% - 54.9%
Dividend yield	0 %	0 %	0 %
Weighted average fair value per share of stock purchase rights granted during the period	$ 6.3	$ 3.13	$ 2.84

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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 2014, 2013 and 2012 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, 2012	6,453,584	$ 2.27		
Granted	499,198	9.18		
Exercised	(691,471)	3.45		
Forfeited	(79,375)	7.6		
Outstanding, December 31, 2012	6,181,936	$ 2.62		
Granted	290,570	11.36		
Exercised	(274,919)	5.17		
Forfeited	(135,000)	10.08		
Outstanding, December 31, 2013	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	$ 117,503
Exercisable, December 31, 2014	4,186,502	$ 2.27	4.7	$ 105,384
Vested and expected to vest, December 31, 2014	4,897,001	$ 3.57	5.2	$ 116,898

(1) The aggregate intrinsic value of options outstanding at December 31, 2014 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 4,934,317 options that had exercise prices that were lower than the $27.44 market price of our common stock at December 31, 2014. The aggregate intrinsic value of options exercisable at December 31, 2014 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 4,186,502 options that had exercise prices that were lower than the $27.44 market price of our common stock at December 31, 2014. The total intrinsic value of options exercised during the years ended December 31, 2014, 2013 and 2012 was $29.2 million, $1.9 million, $4.5 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

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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.

A summary of restricted stock and restricted stock unit activity under the Stock Plans during the years ended December 31, 2014, 2013 and 2012 is as follows:

	Restricted Shares	Weighted Average Grant Date Fair Value
Outstanding, January 1, 2012	401,490	$ 6.24
Granted	602,268	9.47
Released	(185,116)	5.67
Forfeited	(4,687)	7.69
Outstanding, December 31, 2012	813,955	$ 8.51
Granted	1,147,553	11.76
Released	(344,611)	8.56
Forfeited	(466,203)	9.73
Outstanding, December 31, 2013	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

As of December 31, 2014, there was approximately $19.5 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 2.8 years.

The Company received approximately $2.6 million, $1.3 million and $2.4 million from stock option exercises during the years ended December 31, 2014, 2013 and 2012, respectively. During the years ended December 31, 2014, 2013 and 2012, 88,166, 59,932 and 63,611 shares of common stock, respectively, were issued under the Company's 2010 Purchase Plan resulting in proceeds to the company of $0.8 million, $0.5 million and $0.4 million, respectively.

The following table summarizes information relating to currently outstanding and exercisable stock options as of December 31, 2014:

Outstanding			Exercisable	
	Weighted Average Remaining	Weighted Average		Weighted Average

Exercise Price	Number of Options	Contractual Life (Years)	Exercise Price	Number of Options	Exercise Price
$0.00 - $1.00	2,887,500	4.2	$ 0.83	2,887,500	$ 0.83
$1.01 - $3.00	438,000	4.6	2.79	438,000	2.79
$3.01 - $5.00	319,347	5.5	3.95	319,347	3.95
$5.01 - $7.00	184,960	6.2	5.94	122,273	6.01
$7.01 - $9.00	141,248	6.5	8.16	127,623	8.22
$9.01 - $11.00	646,785	7.5	9.65	279,259	9.49
$11.01 - $15.00	283,000	9.0	14.04	12,500	14.4
$15.01- $16.52	33,477	9.6	16.52	—	—
	4,934,317	5.2	$ 3.63	4,186,502	$ 2.27

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

During the first quarter of 2012, the Company granted a total of 262,500 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 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 $0.6 million was recognized during the year ended December 31, 2012. The service and performance conditions were not met and the expense of $0.6 million was reversed in the first quarter of the year ended December 31, 2013.

During the first quarter of 2013, the Company granted a total of 180,750 restricted stock units to certain executives that vest based upon the satisfaction of certain 2013 performance conditions. Based on the conditions that were met 100,800 shares were earned. The shares vest equally over three years with the first vesting date at December 31, 2013. The company recognized $0.4 million during the year ended December 31, 2013 related to this restricted stock unit grant.

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, 2014, as follows:

Shares reserved for issuance	
2010 Option Plan	1,638,187
2010 Purchase Plan	540,177
	2,178,364

(7) COMMITMENTS AND CONTINGENCIES

Operating Leases

During November 2009, the Company entered into a five year lease for a 17,500 square foot laboratory office facility in Madison, Wisconsin. This lease contains periodic rent escalation adjustments. During November 2010, the Company entered into an amended lease agreement to lease an additional 7,072 square feet of laboratory and office space for a total of 24,572 square feet The amended agreement covers the same term as the original term and is also subject to periodic rent escalation adjustments. During March 2012, the Company entered into an amended lease agreement to lease an additional 10,428 square feet of laboratory and office space for a total of 35,000 square feet. The amended agreement covers the same term as the original term and is also subject to periodic rent escalation adjustments. During November 2014, the Company entered into an amended lease agreement to extend the terms of the lease on the 35,000 square feet of laboratory and office space. The lease is not subject to periodic rent escalation adjustments.

During the second quarter of 2013, the Company entered into a five year lease for a 29,000 square foot facility in Madison, Wisconsin that is to house its commercial lab operations. This lease contains periodic rent escalation adjustments and includes provisions for tenant improvements. During August 2014, the Company entered into an amended lease agreement to lease an additional 3,189 square feet of office space to house its contact center operations. The amended agreement covers the same term as the original term and is also subject to periodic rent escalation adjustments. During November 2014, the Company entered into an amended lease agreement to lease to lease adjacent land for the construction of a parking lot. The amended agreement covers the same term as the original term and is also

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

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 agreement, the landlord agreed to pay for a portion of leasehold improvements constructed. These payments are recorded as a lease incentive obligation and will be amortized over the five year term of the lease as a reduction of rent expense. As of December 31, 2014, the lease incentive obligation was $2.7 million. Construction of the laboratory facility was substantially complete at December 31, 2013 and the leasehold improvements related to the laboratory were placed into service. The amortization of the lease incentive obligation began in December of 2013. As part of August 2014 amendment, the landlord has agreed to pay for a portion of leasehold improvements constructed. These payments are recorded as a lease incentive obligation and will be amortized over the remaining lease term as a reduction of rent expense. As of December 31, 2014, the lease incentive obligation was $53.0 thousand. The amortization of the lease incentive obligation began in November of 2014.

During November 2014, the Company entered into a two year lease agreement for a 620 square foot office facility in London, United Kingdom that is to house European operations. This lease contains periodic rent escalation adjustments.

Future minimum payments under operating leases as of December 31, 2014 are as follows. Amounts included in the table are in thousands.

Year Ending December 31,	
2015	$ 1,310
2016	1,225
2017	763
2018	704
2019	—
Thereafter	—
Total lease obligations	$ 4,002

Rent expense included in the accompanying consolidated statements of operations was approximately $1.0 million, $0.7 million, and $0.4 million for the years ended December 31, 2014, 2013 and 2012, respectively.

During the fourth quarter of 2009, the Company entered into a sublease agreement (the “2009 Sublease Agreement”) with an unrelated party to sublease approximately 5,086 square feet of rentable area in the Company’s Madison facility. The term of the 2009 Sublease Agreement, which commenced on November 1, 2009, was 36 months. The Company has received approximately $0.2 million in sublease payments over the life of the 2009 Sublease Agreement. Pursuant to the Sublease Agreement, the unrelated party has no rights to renew or extend the 2009 Sublease Agreement. The Company did not receive sublease payments in 2014 or 2013. The Company received $66,800 in sublease payments in 2012. The 2009 Sublease Agreement expired on November 1, 2012.

License Agreements

The Company licenses, on a non exclusive basis, 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

On June 11, 2009, the Company entered into a patent licensing agreement with MAYO. Under the license agreement, MAYO granted the Company an exclusive, worldwide license within the field of stool or blood based cancer diagnostics and screening (excluding a specified proteomic target) with regard to certain MAYO patents and patent

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applications, as well as a non exclusive, worldwide license within such field with regard to certain MAYO know how. 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. 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. The Company agreed to pay MAYO a low single digit royalty on the Company's net sales of products using the licensed MAYO intellectual property. The Company was also required to pay minimum annual royalty fees of $10,000 on June 12, 2012 and $25,000 on June 12, 2013 and June 12, 2014. The Company is required to continue to pay minimum annual royalty fees of $25,000 each year through 2033.. The MAYO license agreement required various other payments, including an upfront payment of $80,000, which the Company paid in the third quarter of 2009, a milestone payment of $250,000 on the commencement of patient enrollment in FDA trials for the Company's Cologuard pre cancer and cancer screening test, which the Company paid in June 2011 The Company received FDA approval for its Cologuard test in August 2014, and the milestone payment of $500,000 was made and expensed to research and development in August 2014.

In May 2012 the Company expanded its relationship with MAYO through an amendment to the license agreement. As part of the amendment, MAYO expanded the license to include all gastrointestinal cancers and diseases, and new cancer screening applications of stool and blood based testing. As consideration for the expanded license, the Company granted MAYO 97,466 shares of its common stock, one quarter of which vested immediately, with the remainder to vest in three equal annual installments. The Company sought rights to the MAYO intellectual property for the specific purpose of developing future non invasive, stool based DNA screening tests for gastrointestinal diseases other than colorectal cancer. In addition, the Company agreed to issue MAYO shares of the Company's common stock with a value of $200,000 upon commercial launch of the Company's second and third products that use the licensed MAYO intellectual property. Additionally, the Company agreed in the amendment to pay MAYO, for each of the Company's products that use licensed MAYO intellectual property, $200,000 cash upon such product reaching $5 million in cumulative net sales, $750,000 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.

See Note 4 for additional 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.

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

The Company paid Hologic $50,000 upon executing the license agreement in 2009 and $100,000 when the Company began enrollment in its FDA trial in June 2011. 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. The Company received FDA approval for its Cologuard test in August 2014, and the milestone payment of $100,000 was made and expensed to research and development in August 2014.

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 $100,000 on each anniversary of the agreement for the life of the contract. The Company also agreed to pay $100,000 upon the first commercial sale of a licensed product after the receipt of FDA approval and $150,000 after the Company has reached net sales of $10 million of a licensed product after receipt of FDA approval, $750,000 after the Company has reached net sales of $50 million, and $1 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 royalty fee based on a certain percentage of the Company's net sales of the licensed products.

The Company has recorded research and development expense associated with license agreements of $2.3 million, $1.8 million, and $1.4 million, respectively, for the years ended December 31, 2014, 2013 and 2012. Future minimum payments due under the Company's technology licenses as of December 31, 2014 are as follows. Amounts included in the table are in thousands.

Year ending December 31,	
2015	$ 698
2016	256
2017	256
2018	256
2019	256
Thereafter	1,775
	$ 3,497

Capital Lease

In 2012 the Company entered into a lease agreement which is accounted for as a capital lease. 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 is depreciated over the three year lease term, and the expense is recorded as depreciation expense. Accumulated depreciation of the leased equipment at December 31, 2014 was approximately $674.5 thousand. The Company is required to make principal and interest payments of approximately $32,000 per month over the three year term of the lease agreement.

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

The future minimum lease payments required under the capital lease and the present value of the net minimum lease payments as of December 31, 2014 are as follows (in thousands):

Year ending December 31,	
2015	$ 369
Total lease obligations	$ 369
Less imputed interest	(9)
Present value of minimum lease payments	360
Less current maturities of capital lease obligations	(360)
Long term capital lease obligations	$ —

(8) RELATED PARTY TRANSACTIONS

In August 2013, the Company renewed a one year consulting agreement with a non employee director for an additional year. In accordance with the agreement, the Company granted a restricted stock award for 4,277 shares of common stock that vests over one year, and will make cash payments totaling $60,000 over the one year term of the agreement. The Company recorded expense related to this consulting agreement of $25,000 in 2013.

In August 2012, the Company entered into a one year consulting agreement with a non employee director under which the director agreed to provide advisory services in support of the Company’s commercialization activities. In accordance with the agreement, the Company granted a restricted stock award for 4,873 shares of common stock that vested over one year, and made cash payments totaling $60,000 over the initial one year term of the agreement. The Company recorded expense related to this consulting agreement of $35,000 in 2013 and $25,000 in 2012.

(9) ACCRUED LIABILITIES

Accrued liabilities at December 31, 2014 and 2013 consisted of the following. Amounts included in the table are in thousands.

	December 31,	
	2014	2013
Compensation	$ 5,668	$ 2,838
Professional fees	5,764	826
Research and trial related expenses	1,447	689
Licenses	646	539
Miscellaneous taxes	261	24
Other	122	58
Occupancy costs	52	71
Assets under construction	—	649
	$ 13,960	$ 5,694

(10) LONG TERM DEBT

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 million to the Company subject to the Company’s satisfaction of certain conditions. The Company received the $1 million in December 2009. The terms of

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Notes to Consolidated Financial Statements (Continued)

the loan are such that portions of the loan become forgivable if the Company meets certain job creation requirements at a specified wage rate. After the Company creates 100 full time positions, the principal shall be reduced at the rate of $5,405 for each new position created thereafter during the measurement period. If the Company has created 185 new full time positions as of June 30, 2015, the full amount of principal shall be forgiven. The loan bears an interest rate of 2%, which is subject to an increase to 4% if the Company does not meet certain job creation requirements. Both principal and interest payments under the loan agreement are deferred for five years. Based on the Company's estimation of the loan obligation, the table below represents the future principal obligations as of December 31, 2014:

Year ending December 31,	
2015	$ —
2016	145
2017	217
2018	221
2019	225
Thereafter	192
	$ 1,000

(11) EMPLOYEE BENEFIT PLAN

The Company maintains a qualified 401(k) retirement savings plan (the "401(k) Plan") covering all employees. Under the terms of the 401(k) Plan, participants may elect to defer a portion of their compensation into the 401(k) Plan, subject to certain limitations. Company matching contributions may be made at the discretion of the Board of Directors.

The Company's Board of Directors approved 401(k) Plan matching contributions for the years ended December 31, 2014, 2013 and 2012 in the form of Company common stock equal to 100% up to 6% of the participant's salary for that year. The Company recorded compensation expense of approximately $0.8 million, $0.5 million, and $0.4 million, respectively, in the statements of operations for the years ended December 31, 2014, 2013 and 2012 in connection with 401(k) Plan matching contributions.

(12) NEW MARKET TAX CREDIT

During the fourth quarter of 2014, the Company received approximately $2.4 million in net proceeds from financing agreements related to working capital and capital improvements at one of its Madison, Wisconsin facilities. This financing arrangement was structured with an unrelated third party financial institution (the “Investor”), an investment fund, and its majority owned community development entity in connection with the Company’s participation in transactions qualified under the federal New Markets Tax Credit 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 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 which becomes enforceable at the end of the seven-year compliance period, whereby we may be obligated or entitled to repurchase the Investor’s interest in the investment fund. The value attributable to the put/call is nominal.

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Notes to Consolidated Financial Statements (Continued)

The Investor is subject to 100% recapture of the New Markets Tax Credits 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 New Markets Tax Credit 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 New Markets Tax Credits 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.

Also in the fourth quarter, in connection with the New Markets Tax Credit transaction, the Company entered into an agreement that grants it the option to purchase certain real property adjacent to its current Madison, Wisconsin facilities. The option is renewable annually in exchange for a fee. If the Company decides not to exercise its option, it must, at that time, repay $1.2 million of the $2.4 million previously received from the Investor which could be applied to the repayment of the $2.4 million loan.

At December 31, 2014, the net loan balance of $2.4 million is recorded in Other Long Term Liabilities on the consolidated balance sheets. 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 investment fund and the 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. The Investor's contribution of $2.4 million is included in Cash and Cash Equivalents at December 31, 2014 and the offsetting Investor interest in the financing arrangement is included in Other Long Term Liabilities in the accompanying consolidated balance sheets.

(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, 2014, the Company had federal net operating loss and state net operating loss carryforwards of approximately $422.7 million and $232.0 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 $6.5 million and $15.6 million, respectively which may be used to offset future income tax liability. The federal and state

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

carryforwards expire beginning 2014 through 2032 and are subject to review and possible adjustment by the Internal Revenue Service. 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, 2014 and 2013, the Company had $39.8 million and $16.5 million, respectively, in excess tax benefit stock option deductions. The excess tax benefit arising from these deductions is credited to additional paid in capital as the benefit is realized.

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. Amounts included in the table are in thousands.

	December 31,	
	2014	2013
Deferred tax assets:		
Operating loss carryforwards	$ 140,471	$ 101,942
Tax credit carryforwards	16,915	18,061
Deferred revenue	11	117
Other temporary differences	4,543	4,429
Tax assets before valuation allowance	161,940	124,549
Less—Valuation allowance	(161,940)	(124,549)
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 $161.9 million and $124.5 million valuation allowance at December 31, 2014 and 2013 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, 2014 and 2013 was $37.4 million and $20.6 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,		
	2014	2013	2012
U.S. Federal statutory rate	34.0 %	34.0 %	34.0 %
State taxes	5.5	4.8	1.7
Research and development tax credit	(1.1)	16.9	5.1
Stock-based compensation expense	(0.5)	(1.1)	(0.6)
Other adjustments	(0.8)	(0.3)	(0.1)
Valuation allowance	(37.1)	(54.3)	(40.1)
Effective tax rate	0.0 %	0.0 %	0.0 %

There are no unrecognized tax benefits as of December 2014, 2013 and 2012, 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, 2014.

As of December 31, 2014, due to the carryforward of unutilized net operating losses and research and development credits, the Company is subject to U.S. Federal income tax examinations for the tax years 1995 through 2014, and to

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Notes to Consolidated Financial Statements (Continued)

state income tax examinations for the tax years 1995 through 2013. 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, 2014, 2013 and 2012.

(14) SUBSEQUENT EVENT

In February 2015 the Company amended and restated its license agreement with MAYO to extend the arrangement with MAYO for an additional five years and broaden the Company's and MAYO's collaboration efforts to develop screening, surveillance and diagnostic tests and tools for use in connection with gastrointestinal cancers, precancers, diseases and conditions. MAYO agreed to continue to make available personnel during the additional five year period to provide the Company product development and research and development assistance. The amended and restated license agreement defines "gastrointestinal" to include certain airway organs (including the pharynx, larynx, trachea, bronchi and lungs) and certain head and neck organs (including nasal passages, mouth and throat). The amended and restated license agreement also reflects an expanded list of patent rights that MAYO licenses to the Company.

Pursuant to the amended and restated license agreement, the Company agreed to pay MAYO an additional $5,000,000, payable in five annual installments, the first of which was due February 10, 2015.

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

(15) 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, 2014 and 2013. 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)			
2014				
Laboratory service revenue	$ —	$ —	$ —	$ 1,504
License fee revenue	294	—	—	—
Cost of revenue	—	—	924	3,401
Gross profit	294	—	(924)	(1,897)
Research and development	7,430	7,174	9,073	4,992
General and administrative	4,586	6,230	8,994	10,625
Sales and marketing	4,456	6,166	13,217	15,069
Loss from operations	(16,178)	(19,570)	(32,208)	(32,583)
Investment income	86	146	160	150
Interest expense	(15)	(13)	(12)	(11)
Net loss	$ (16,107)	$ (19,437)	$ (32,060)	$ (32,444)
Net loss per share—basic and diluted	$ (0.23)	$ (0.24)	$ (0.39)	$ (0.38)
Weighted average common shares outstanding—basic and diluted	70,987	82,048	82,941	84,734
2013				
Revenue	$ 1,036	$ 1,036	$ 1,036	$ 1,036
Cost of revenue	—	—	—	—
Gross profit	1,036	1,036	1,036	1,036
Research and development	7,526	6,457	6,982	6,713
General and administrative	2,648	3,628	3,686	3,687
Sales and marketing	1,759	3,302	1,615	2,902
Loss from operations	(10,897)	(12,351)	(11,247)	(12,266)
Investment income	62	55	103	96
Interest expense	(19)	(18)	(16)	(16)
Net loss	$ (10,854)	$ (12,314)	$ (11,160)	$ (12,186)
Net loss per share—basic and diluted	$ (0.17)	$ (0.19)	$ (0.16)	$ (0.17)

Weighted average common shares outstanding—basic and diluted	63,836	64,699	70,559	70,757

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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 Securities Exchange Act of 1934. 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, 2014 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.

On May 14, 2013, the Committee of Sponsoring Organizations of the Treadway Commission (COSO) published an updated Internal Control – Integrated Framework (2013) and related illustrative documents. The Company adopted the new framework in 2014. Other than the implementation of these new internal controls and policies, there have been no significant changes in internal control over financial reporting 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. 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, 2014. 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, 2014, the Company's 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, 2014, 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 2015 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 2015 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 2015 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 2015 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 2015 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).

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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 27, 2015 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 27, 2015
/s/ MANEESH K. ARORA Maneesh K. Arora	Senior Vice President and Chief Operating Officer and Director	February 27, 2015

/s/ William J. Megan William J. Megan	Principal Financial Officer	February 27, 2015
/s/ Thomas D. Carey Thomas D. Carey	Director	February 27, 2015
/s/ Sally W. Crawford Sally W. Crawford	Director	February 27, 2015
/s/ Daniel J. Levangie Daniel J. Levangie	Director	February 27, 2015
/s/ Katherine Napier Katherine Napier	Director	February 27, 2015
/s/ Lionel Sterling Lionel Sterling	Director	February 27, 2015
/s/ David Thompson David Thompson	Lead Independent Director	February 27, 2015
/s/ MICHAEL S. WYZGA Michael S. Wyzga	Director	February 27, 2015

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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	Amended and Restated By-Laws of the Registrant (previously filed as Exhibit 3.1 to the Registrant's Report on Form 10-Q for the period ended March 31, 2009 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)
4.3	Warrant No. W 2 issued to MAYO Foundation for Medical and Educational Research dated June 11, 2009 (previously filed as Exhibit 4.2 to the Registrant's Quarterly Report on Form 10 Q for the period ended June 30, 2009 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 our 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 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)
10.7**	License Agreement dated June 11, 2009 by and between MAYO Foundation for Medical and Educational Research and the Registrant (previously filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the period ended June 30, 2009 and incorporated herein by reference)
10.8**	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)
10.9	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)
10.10	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)
10.11*	The Registrant's 2010 Omnibus Long Term Incentive Plan (previously filed as Appendix A to the Definitive Proxy Statement for the Registrant's 2010 Annual Meeting of Stockholders filed on April 30, 2010 and incorporated herein by reference)
10.12*	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)
10.13*	First Amendment to the Registrant's 2010 Employment Stock Purchase Plan (previously filed as Appendix B to the Definitive Proxy Statement for the Registrant's 2014 Annual Meeting of Stockholders filed of June 20, 2014, and incorporated herein by reference)
10.14*	2010 Omnibus Long Term Incentive Plan Form Stock Option Award Agreement (previously filed as Exhibit 4.5 to the Registrant's Registration Statement on Form S 8 (File No. 333 168909) and incorporated herein by reference)

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10.15*	2010 Omnibus Long Term Incentive Plan Form Restricted Stock Award Agreement (previously filed as Exhibit 4.6 to the Registrant's Registration Statement on Form S 8 (File No. 333 168909) and incorporated herein by reference)
10.16*	2010 Omnibus Long Term Incentive Plan Form Restricted Stock Unit Award Agreement (previously filed as Exhibit 10.35 to the Registrant's Annual Report on Form 10 K filed for the period ended December 31, 2010 and incorporated herein by reference)
10.17	Amendment No. 4 dated May 15, 2012 to the License Agreement dated June 12, 2009 by and 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 June 30, 2012 and incorporated herein by reference)
10.18*	Consulting Agreement dated August 27, 2013 by and between the Registrant and James P. Connelly (previously filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10 Q for the period ended September 30, 2013 and incorporated herein by reference)

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10.19**	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)
10.20*+	Employment Agreement by and between William J. Megan and the Registrant, dated as of November 10, 2014.
10.21*	First Amendment to the Exact Sciences Corporation 2010 Omnibus Long Term Incentive Plan (previously filed as Appendix A to the Definitive Proxy Statement for the Registrant's 2013 Annual Meeting of Stockholders filed April 30, 2013 and incorporated herein by reference)
10.22*	Exact Sciences Corporation Non employee Director Compensation Policy dated April 28, 2014 (previously filed as Exhibit 10 to the Registrant's Quarterly Report on Form 10 Q for the period ended June 30, 2014 and incorporated herein by reference)
10.23	Separation Agreement and General Release dated June 7, 2013 by and between Laura S. Stoltenberg and the Registrant (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8 K filed on June 7, 2013 and incorporated herein by reference)

10.24	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)
10.25**	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)
10.26**	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)
10.27+	Amendment One to Lease dated November 1, 2010 by and between University Research Park Incorporated and the Registrant.
10.28+	Lease Agreement dated April 16, 2014 by and between Ultratec, Inc. and the Registrant
10.29+	First Amendment to Lease dated September 26, 2014 by and between Ultratec, Inc. and the Registrant.
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.