

EXACT SCIENCES CORP  
Form 10-K  
February 28, 2014

Use these links to rapidly review the document

[Table of Contents](#)

[Item 8. Consolidated Financial Statements and Supplementary Data](#)

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 10-K**

ý **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934**

**For the fiscal year ended: December 31, 2013**

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934**

**Commission file number 000-32179**

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**EXACT SCIENCES CORPORATION**

(Exact name of registrant as specified in its charter)

**DELAWARE**

(State or other jurisdiction of  
incorporation or organization)

**02-0478229**

(IRS Employer  
Identification No.)

**441 Charmany Drive, Madison, WI**  
(Address of principal executive offices)

**53719**  
(Zip Code)

Registrant's telephone number, including area code: **(608) 284-5700**

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

**Common Stock, \$.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 ý No o

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 o No ý

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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       Smaller reporting company   
(Do not check if a  
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 \$972,055,226 (based on the closing price of the Registrant's Common Stock on June 28, 2013 of \$13.91 per share).

The number of shares outstanding of the Registrant's \$.01 par value Common Stock as of February 26, 2014 was 71,201,095.

### 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, 2013. 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, 2013

TABLE OF CONTENTS

|  | Page No.  |
|--|-----------|
| <b>Part I</b>  |           |
| <u>Item 1.</u> <u>Business</u>   | <u>1</u>  |
| <u>Item 1A.</u> <u>Risk Factors</u>  | <u>12</u> |
| <u>Item 1B.</u> <u>Unresolved Staff Comments</u>   | <u>21</u> |
| <u>Item 2.</u> <u>Properties</u>   | <u>21</u> |
| <u>Item 3.</u> <u>Legal Proceedings</u>  | <u>21</u> |
| <u>Item 4.</u> <u>Mine Safety Disclosures</u>  | <u>21</u> |
| <b>Part II</b>   |           |
| <u>Item 5.</u> <u>Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities</u> | <u>22</u> |
| <u>Item 6.</u> <u>Selected Financial Data</u>  | <u>22</u> |
| <u>Item 7.</u> <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>                        | <u>24</u> |
| <u>Item 7A.</u> <u>Quantitative and Qualitative Disclosures about Market Risk</u>  | <u>34</u> |
| <u>Item 8.</u> <u>Financial Statements and Supplementary Data</u>  | <u>35</u> |
| <u>Item 9.</u> <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>                         | <u>70</u> |
| <u>Item 9A.</u> <u>Controls and Procedures</u>   | <u>70</u> |
| <u>Item 9B.</u> <u>Other Information</u>   | <u>70</u> |
| <b>Part III</b>  |           |
| <u>Item 10.</u> <u>Directors, Executive Officers and Corporate Governance</u>  | <u>71</u> |
| <u>Item 11.</u> <u>Executive Compensation</u>  | <u>71</u> |
| <u>Item 12.</u> <u>Security and Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>          | <u>71</u> |
| <u>Item 13.</u> <u>Certain Relationships and Related Transactions, and Director Independence</u>                                   | <u>71</u> |
| <u>Item 14.</u> <u>Principal Accountant Fees and Services</u>  | <u>71</u> |
| <b>Part IV</b>   |           |
| <u>Item 15.</u> <u>Exhibits and Financial Statement Schedules</u>  | <u>71</u> |
| <u>SIGNATURES</u>  | <u>72</u> |

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," "plan," "estimate," "anticipate" or other comparable terms. Forward-looking statements in this Annual Report on Form 10-K may address the following subjects among others: statements regarding the sufficiency of our capital resources, expected operating losses, timing and anticipated results of the FDA's review of our pivotal clinical trial and our related FDA submissions, our ability to secure favorable reimbursement rates from Medicare and other third-party payors, our ability to establish a lab facility and secure the required certifications for that facility, timing of our launch of a commercial product, estimated markets for our products and expected revenues, expected research and development expenses, expected general and administrative expenses and our expectations concerning our business strategy. Forward-looking statements involve inherent risks and uncertainties which could cause actual results to differ materially from those in the forward-looking statements, as a result of various factors including those 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 report. We urge you to consider those risks and uncertainties in evaluating our forward-looking statements. We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made. Except as otherwise required by the federal securities laws, we disclaim any obligation or undertaking to publicly release any updates or revisions to any forward-looking statement contained herein (or elsewhere) to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

**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 an accurate, non-invasive, patient friendly screening test to meet our primary goal of becoming the market leader for a diagnostic screening product for the early detection of colorectal pre-cancer and cancer.

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

advance our product through the U.S. Food and Drug Administration (FDA) approval process;

commercialize an FDA-approved product that detects colorectal pre-cancer and cancer; and

secure favorable reimbursement for our product 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).

**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:

143,000 new cases in the U.S.

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52,000 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. 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 has meant that nearly two-thirds of colorectal cancer diagnoses are made in the disease's late stages. The five-year survival rates for stages 3 and 4 are 67 percent and 12 percent, respectively.

We believe the large underserved population of unscreened and inadequately screened patients represents a significant opportunity for a patient friendly screening test. A powerful preventive tool that detects pre-cancerous polyps and early stage colorectal cancer could significantly reduce colorectal cancer deaths and the health care costs associated with the disease. Pre-cancerous polyps are present in approximately 6 percent of average risk people 50 years of age and older who undergo routine colorectal cancer screening.

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.

### ***Our Solution***

Our Cologuard test is designed to detect pre-cancerous lesions or polyps, and each of the four stages of colorectal cancer and is expected to be 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 sDNA screening model has the potential to significantly reduce colorectal cancer deaths. The earlier pre-cancer or cancer is detected, the greater the reduction in mortality.

Our Cologuard test 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 will often represent DNA shed from cancerous or pre-cancerous lesions. Once the human DNA in the sample is isolated, sDNA detection looks for specific mutations and other abnormalities in that DNA known to

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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 would be for the patient to obtain a colonoscopy for confirmation and potentially have any polyps or lesions removed if confirmed.

We believe that sDNA screening in the general population offers an opportunity to increase screening rates, decrease deaths and lower health care costs from 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 our Cologuard test 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 would be conducted.

Our test is affordable, particularly relative to colonoscopy.

With repeat screening at regular intervals we believe our Cologuard test has the ability to achieve high cumulative sensitivity for pre-cancer detection. Given the importance of early detection of pre-cancer in the fight against colorectal cancer, we believe that an affordable, sensitive, non-invasive test has the potential to significantly reduce colorectal cancer deaths and the costs associated with the disease.

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*

Our current focus is on seeking FDA approval for our Cologuard test. We believe obtaining FDA approval is important to building broad demand and successfully commercializing our sDNA colorectal cancer screening technology. We are also in the process of developing our strategy for the ultimate commercialization of our Cologuard test.

In November 2012 we completed enrollment for our pivotal FDA clinical trial with over 10,000 patients enrolled at 90 enrollment sites in the U.S. and Canada. All patients provided a sample to be tested with our Cologuard test, and received a FIT test and a colonoscopy.

The FDA, as well as physicians and others assessing the effectiveness and value of our Cologuard test, will likely consider, among other things, our Cologuard test's sensitivity and specificity in identifying colorectal cancer and pre-cancerous polyps. "Sensitivity" (also called the true positive rate) measures the percentage of colorectal cancer or pre-cancerous polyps that our Cologuard test correctly identifies. "Specificity" (also called the true negative rate) measures the percentage of people who our Cologuard test correctly identifies as not having colorectal cancer or pre-cancerous polyps.

Preliminary top-line data from the clinical trial showed that our Cologuard test demonstrated 92 percent sensitivity for the detection of colorectal cancer and 42 percent sensitivity for the detection of pre-cancerous polyps, including 66 percent sensitivity for pre-cancerous polyps equal to or greater than 2 centimeters. The test achieved a specificity of 87 percent during the clinical trial.

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The clinical trial achieved all of its endpoints. The co-primary endpoints for the study were the sensitivity and specificity of the Cologuard screening test for colorectal adenocarcinoma. The clinical trial included two sets of co-secondary endpoints. The first included sensitivity and specificity of the test for advanced adenomas. The second included superiority of Cologuard to FIT for cancer and advanced adenoma sensitivity.

Each patient result from the Cologuard test was compared to the patient's colonoscopy result and the histopathologic diagnosis of any lesions that were discovered during colonoscopy and biopsied. The study population included 65 cancer patients and 752 patients with pre-cancerous polyps.

We submitted the results of our clinical trial to the FDA through a three part submission of a manufacturing module, analytical module, and clinical module. The manufacturing module was submitted to the FDA in December 2012, the analytical module was submitted to the FDA in February 2013, and the clinical module was submitted to the FDA in June 2013. Our submission is currently under review by the FDA.

The FDA's Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee is tentatively scheduled to review the premarket approval application (PMA) for our Cologuard stool-DNA-based, non-invasive colorectal cancer screening test on March 27, 2014. The date and details of the meeting are subject to confirmation by the FDA in a Federal Register notice.

We believe that obtaining a favorable national coverage decision and a favorable reimbursement rate from the Centers for Medicare & Medicaid Services (CMS) for our Cologuard test will be a necessary element in achieving material commercial success. With the goal of expediting receipt of a favorable coverage decision, we are working with CMS to coordinate the CMS coverage review with the FDA pre-market approval through a parallel review process. This program provides a pathway to a potential CMA national coverage determination shortly after an FDA approval decision, should it occur. With over 50% of our target patient population being covered by Medicare, receipt of a positive coverage decision from CMS would help speed adoption of our test after commercial launch. A favorable CMS outcome will also be critical to 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 our Cologuard test 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.

There are two elements to our targeting strategy for the early adoption of Cologuard. First, we are focused on large healthcare systems and groups. These networks employ a high percentage of the physicians in the United States and they typically have strong screening programs. Second, we plan to focus on primary care physicians who prescribe a high volume of FOBT and FIT tests since this physician group has displayed a partiality for stool based screenings methods.

As part of our commercialization strategy, we plan to establish a lab facility that will be certified pursuant to applicable Federal Clinical Laboratory Improvement Amendments (CLIA) regulations to process Cologuard tests and provide patient results. We expect a significant percentage of Cologuard test volume to be processed at our lab facility. We have leased a 29,000 square foot facility in Madison, Wisconsin to house our commercial lab operations and construction of the lab in that facility is substantially complete.

### *Competition*

The competitive landscape is favorable to sDNA screening. All of the colorectal cancer detection methods in use today are constrained by some combination of poor sensitivity, poor compliance and

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cost. Colonoscopy is 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, 66 percent detection rates for cancer and 27 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 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. In particular, we are aware of three companies Epigenomics AG, Gene News and Quest Diagnostics that are developing blood-based tests for the detection of colorectal cancer. It is our understanding that Epigenomics AG, has completed a large multi-center study designed to demonstrate the performance of its blood-based screening test for colorectal cancer and submitted those results to the FDA in the first quarter of 2013. It is also our understanding that Epigenomics AG has an FDA advisory committee meeting scheduled for March 26, 2014 to review their product.

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 existing and possibly improved traditional screening tests such as FOBT and FIT.

### ***Research and Development***

Research and development costs account for a substantial portion of our operating expenses. Our research and development expenses were \$27.7 million, \$42.1 million and \$22.0 million for the years ended December 31, 2013, 2012 and 2011, respectively.

### ***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***

We believe obtaining FDA approval for our Cologuard test is critical to building broad demand and successful commercialization for our sDNA colorectal cancer screening technologies. We are currently in the process of seeking a premarket approval (PMA) for our Cologuard test. The PMA process involves submitting extensive data to the FDA. This data allows 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 the FDA will continue to place considerable restrictions on products, including but not limited to registering manufacturing facilities, listing the products with the FDA, complying with labeling requirements, and meeting reporting 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. If we are able to commercialize our Cologuard test, we would expect to perform activities that may implicate HIPAA, such as providing clinical laboratory testing services or entering into specific kinds of relationships with a Covered Entity or a business associate of a Covered Entity.

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.* If our Cologuard test is successfully accepted by federal and state healthcare programs, we will be 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 could be 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 the federal 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

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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 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

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address methods for preventing and mitigating employee exposure, the use of personal protective equipment, and training.

*Specimen Transportation.* Our anticipated commercialization plans for our Cologuard test will 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, 2013, we owned 10 issued patents and 28 pending patent applications in the United States, and 62 issued patents and 26 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 26 patents issued and 7 pending patent applications in the U.S., and 29 patents issued and 12 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.

### ***License Agreements***

We license, on a non-exclusive basis, 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 net revenues received using the technologies, and may require minimum royalty amounts or 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

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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 are also required to pay minimum annual royalty fees of \$10,000 on June 12, 2012 and \$25,000 on June 12, 2013 and each year thereafter through 2029. The MAYO license agreement required various other payments, including an upfront payment of \$80,000, which we paid in the third quarter of 2009, and 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. We will be required to pay MAYO \$500,000 upon FDA approval of our Cologuard test.

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.

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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 and \$100,000 when we began enrollment in our FDA trial in June 2011. We are required to pay Hologic a low single digit royalty on our net sales of products using the Covered Hologic IP, and to make a \$100,000 milestone payment upon FDA approval of our Cologuard test.

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. Under the 2009 Hologic license agreement, we agreed to meet certain commercialization milestones, of which the only remaining milestone is to commercialize a product using the Covered Hologic IP by April 14, 2014. Failure to meet this milestone, after certain cure periods, may result in the termination of the licenses.

### 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 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 \$100,000 upon the first commercial sale of a licensed product

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after the receipt of FDA approval, \$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 have identified a new opportunity for our sDNA colorectal cancer screening technology focused on the inflammatory bowel disease (IBD) patient population. The IBD screening population includes patients with Crohn's disease, ulcerative colitis and primary sclerosing cholangitis.

For IBD patients, inflammation obscures optical detection for colorectal cancer by colonoscopy. Therefore, we believe there is a significant opportunity for a patient friendly sDNA screening test for these patients. Approximately 50% of the patient population is not screened according to current guidelines for IBD. As part of our collaboration, the Mayo Clinic has conducted preliminary pre-clinical studies on this patient group using our sDNA screening technology which have shown promising results.

We initiated an IBD clinical trial in the first quarter 2013 that will focus on this specific patient group, and plan on enrolling around 300 IBD patients into the trial. We estimate the potential U.S. market for an IBD screening test to be approximately \$250 million.

Also, we are working with the Mayo Clinic on developing tests to detect other gastro-intestinal cancers, specifically esophageal and pancreatic cancer.

### ***Employees***

As of December 31, 2013, we had one hundred and two 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](http://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 which 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 successfully commercialize any of our technologies or become profitable.*

We have incurred losses since we were formed and have had only modest product and royalty fee revenues to date. From our date of inception on February 10, 1995 through December 31, 2013, we have accumulated a total deficit of approximately \$320.8 million. We expect that our losses will continue for at least the next several years and that we will be required to invest significant additional funds toward development and commercialization of our colorectal cancer screening technology. 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 based on our technologies will be sufficient to make us profitable.

Our future revenues will depend on our ability to successfully commercialize an FDA-approved product for sDNA colorectal cancer screening. Our ability to successfully commercialize our technologies may be affected by the following factors:

the scope of and progress made in our research and development activities;

threats posed by competing technologies;

acceptance, endorsement and formal policy approval of favorable reimbursement for our test by Medicare and other third-party payors; and

our ability to market our test through primary care physician awareness and consumer education and outreach.

There are many factors outside our control that may impact our ability to successfully commercialize a colorectal cancer screening test and we may not succeed in doing so.

*We may need additional capital to execute our business plan, and we may be unable to raise additional capital on acceptable terms.*

Although we believe that we have sufficient capital to fund our operations for at least the next twelve months, we may not have sufficient capital to fully fund the commercial development of our Cologuard test and related FDA submission and commercialization efforts. If we are unable to obtain needed financing on acceptable terms, we may not be able to implement our business plan, which could have a material adverse effect on our business, financial condition and results of operations. 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. Even if we successfully raise sufficient funds to continue our operations to fund development, FDA submission and commercialization of our Cologuard test, we cannot provide assurance that our business will ever generate sufficient cash flow from operations to become profitable.

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

Our ability to generate product sales will depend on the commercial success of our Cologuard test. We will need to obtain FDA approval before we can commercialize this product.

The commercial success of our Cologuard test and our ability to generate product sales will depend on several factors, including the following:

FDA approval;

acceptance in the medical community;

the number of patients tested for colorectal cancer in the U.S. as well as the number of patients who use Cologuard for this test;

sufficient coverage or reimbursement by third party payors;

our ability to successfully market Cologuard;

the amount and nature of competition from other colorectal cancer screening products and procedures; and

our ability to establish and maintain commercial manufacturing, distribution, sales force and CLIA laboratory testing capabilities.

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

***There can be no assurance that we will obtain FDA approval for our Cologuard test.***

We believe obtaining FDA approval for our Cologuard test is critical to building broad demand and successful commercialization for our sDNA colorectal cancer screening technologies. We are currently in the process of seeking a premarket approval (PMA) for our Cologuard test. The PMA process involves providing extensive data to the FDA to allow the FDA to find that the device is safe and effective for its intended use, which may also include providing additional data and updates to the FDA, the convening of expert panels, inspection of manufacturing facilities, and new or supplemented PMAs 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 the FDA will continue to place considerable restrictions on products, including but not limited to registering manufacturing facilities, listing the products with the FDA, complying with labeling requirements, and meeting reporting 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, and if it does not, we may not be able to successfully commercialize our Cologuard test.

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

The market for colorectal 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 cancer. We are aware of three companies Epigenomics AG, Gene News and Quest Diagnostics that are developing a blood-based test for the detection of colorectal cancer. It is our understanding that Epigenomics AG has completed a large multi-center study designed to demonstrate the performance of its blood-based screening test for colorectal cancer and submitted the results of that





study to the FDA in the first quarter of 2013. It is also our understanding that Epigenomics AG has an FDA advisory committee meeting scheduled for March 26, 2014 to review their product. 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 existing and possibly improved traditional screening tests such as FOBT and FIT. Our competitors may also be working on additional methods of detecting colorectal cancer that have not yet been announced. We may be unable to compete effectively against these competitors either because their test is superior or because they may have more expertise, experience, financial resources or stronger business relationships.

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

Successful commercialization of our Cologuard test depends, in large part, on the availability of adequate reimbursement from government insurance plans, managed care organizations and private insurance plans. In particular, we believe that obtaining a positive national coverage decision and favorable reimbursement rate from the Centers for Medicare and Medicaid (CMS) for our Cologuard test will be a necessary element in achieving material commercial success. These third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new healthcare products approved for marketing by the FDA. As a result, there is significant uncertainty surrounding whether the use of tests that incorporate new technology, such as our Cologuard test, will be eligible for coverage by third-party payors or, if eligible for coverage, what the reimbursement rates will be for those products. Reimbursement of stool-based DNA colorectal cancer screening by a third-party payor may depend on a number of factors, including a payor's determination that tests using our technologies are: sensitive for colorectal 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.

If we are unable to obtain positive policy decisions from third-party payors, including Medicare and managed care organizations, approving reimbursement for our Cologuard test at adequate levels, the commercial success of this product would be compromised and our revenues would be significantly limited. Moreover, coverage policies and reimbursement rates are subject to change and we cannot guarantee that even if we initially achieve adequate coverage and reimbursement rates that they will be applicable to our products in the future.

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

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, third-party payors and patients that our Cologuard test 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, our Cologuard test, which could prevent us from successfully commercializing it.

***We expect to rely on third parties to conduct any future studies of our technologies that may be required by the FDA, 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 our Cologuard test or other products we may develop.

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 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 regulatory approval for our Cologuard test.

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

The development and commercialization of our Cologuard test relies upon strategic collaborations and licensing agreements with third parties. We currently have a collaborative arrangement with the Mayo Clinic. In addition, we have licensing agreements with Hologic and MDx Health (formerly Oncomethylome Sciences, S.A.). Such arrangements provide us with intellectual property crucial to our product development, including technology that we have incorporated into our Cologuard test. Our dependence on licensing, collaboration and other similar agreements with third parties may subject us to a number of risks. There can be no assurance that any current contractual arrangements between us and third parties or between our strategic partners and other third parties will be continued, not breached or not terminated early or that we will be able to enter into the future relationships necessary to successfully commercialize our Cologuard test. Any failure to obtain or retain the rights to necessary technologies could require us to re-configure our Cologuard test, which could negatively impact its commercial sale or increase the associated costs, either of which could materially harm our business and adversely affect our future revenues.

As we seek to commercialize and market our Cologuard test, 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 development or commercialization of our Cologuard test.

***We have limited selling and marketing resources and lack manufacturing, distribution and commercial laboratory experience, which may restrict our success in commercializing products containing our colorectal cancer screening technology.***

To grow our business as planned, we must expand our sales, marketing and customer support capabilities. We must also establish satisfactory arrangements for the manufacture and distribution of our Cologuard test, which will involve the development of our commercial infrastructure and/or collaborative commercial arrangements and partnerships. In addition, as part of our commercialization strategy, we are planning to establish a CLIA certified lab facility to process Cologuard tests and provide patient results. Developing these functions will be time consuming and expensive. We have limited experience in these areas and we may encounter difficulties retaining and managing the

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specialized workforce these activities will 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.

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

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

its demonstrated sensitivity and specificity for detecting colorectal pre-cancer and cancer;

its price;

the availability of alternative screening methods;

the willingness of physicians to prescribe our Cologuard test; and

sufficient third-party coverage or reimbursement.

Even if our Cologuard test is superior to other colorectal cancer screening options, adequate third-party reimbursement is obtained and medical practitioners choose to order our Cologuard test, 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 will require people to collect a stool sample, which some people may be reluctant to do. If our products do not achieve an adequate level of acceptance, we may not generate material product revenues and we may not become profitable.

***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.***

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.

***We may be subject to substantial costs and liability, or be prevented from using technologies incorporated in our Cologuard test, as a result of litigation or other proceedings relating to patent 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 is designed to maximize our patent protection against third parties in the U.S. and, potentially, in certain foreign countries. We have filed patent applications that we believe cover the methods we have

designed to help detect colorectal cancer and other cancers. In order to protect or enforce our patent 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. 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 not be available on acceptable 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 our competitive advantage.***

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 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 our Cologuard test will be 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 fail to comply with any such applicable regulations and guidelines, we could incur significant liability and/or our partners could be forced to cease offering our products 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 our Cologuard test 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.

***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 restrictions on the marketing of pharmaceutical products, 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 pharmaceutical industry and to regulate billing practices and financial relationships with physicians and hospitals. 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 activities of manufacturers of medical devices by limiting the kinds of financial arrangements, including sales programs, that may be used with hospitals, physicians, laboratories and other potential purchasers of medical devices. 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 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, William Megan, our Senior Vice President and Principal Financial Officer, 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 an FDA approved product. While our management team has significant experience in

securing FDA approvals, we have considerably less experience in commercializing a product. The efforts of our management team will be critical to us as we develop our technologies and work towards the commercialization of an FDA approved product.

***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 move towards the commercialization of our Cologuard test could materially adversely affect our business, financial condition and results of operations.

***If we lose the support of our key scientific collaborators, it may be difficult to establish tests using our technologies as a standard of care for colorectal cancer screening, which may limit our revenue growth and profitability.***

We have established relationships with leading scientists at important research and academic institutions, such as the Mayo Clinic, Case Western Reserve University and Johns Hopkins University, that we believe are key to establishing tests using our technologies as a standard of care for colorectal cancer screening. If our collaborators determine that colorectal cancer screening tests using our technologies are not appropriate options for colorectal cancer screening, or superior to available colorectal cancer screening tests, or that alternative technologies would be more effective in the early detection of colorectal cancer, we would encounter significant difficulty establishing tests using our technologies as a standard of care for colorectal cancer screening, which would limit our revenue growth and profitability.

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

The sale and use of our Cologuard test could lead to product or professional liability claims based on 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. 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.

***Delaware law and our charter documents 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.

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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.

Delaware law, our charter documents and other agreements could have the effect of delaying, deferring or preventing a transaction or a change in control that might involve a premium for our common stock or otherwise be considered favorably by our stockholders.

### ***Our inability to manage growth could harm our business.***

As we work toward obtaining FDA approval for our Cologuard test and launching commercialization for this product we expect to require additional personnel in the areas of quality assurance, compliance, regulatory affairs, product development and sales and marketing. 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 our Cologuard test, we will also need to effectively manage our manufacturing 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.

### ***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 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 customers or investors. 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 the 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



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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, 2013, we occupied approximately 35,000 square feet of space in our headquarters located in Madison, Wisconsin under a lease which expires in October 2014, but can be extended to October 2019. In addition, we have leased a 29,000 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.

### **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     |
|----------------|----------|---------|
| <b>2013</b>    |          |         |
| First quarter  | \$ 11.98 | \$ 9.62 |
| Second quarter | 14.42    | 6.93    |
| Third quarter  | 14.70    | 11.47   |
| Fourth quarter | 12.59    | 9.53    |
| <b>2012</b>    |          |         |
| First quarter  | \$ 11.24 | \$ 7.90 |
| Second quarter | 11.15    | 9.49    |
| Third quarter  | 11.69    | 9.80    |
| Fourth quarter | 12.30    | 8.87    |

As of February 26, 2014, there were 71,201,095 shares of our common stock outstanding held by approximately 100 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.

**Item 6. Selected Financial Data**

The selected historical financial data set forth below as of December 31, 2013, 2012, and 2011 and for the years then ended are derived from financial statements included elsewhere in this Form 10-K, which were audited by BDO USA, LLP, an independent registered public accounting firm. The selected historical financial data set forth below as of December 31, 2010 and for the year then ended are derived from financial statements not included elsewhere in this Form 10-K, which were audited by BDO USA, LLP. The selected historical financial data set forth below as of December 31, 2009 and for the year then ended are derived from financial statements not included elsewhere in this Form 10-K, which were audited by Grant Thornton, LLP. The selected historical financial data should be read in conjunction with, and are qualified by reference to "Management's Discussion and Analysis of

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Financial Condition and Results of Operations", our financial statements and notes thereto and the reports of independent registered public accountants included elsewhere in this Form 10-K.

|   | Year Ended December 31,                       |             |             |             |            |
|---|---|-------------|-------------|-------------|------------|
|   | 2013  | 2012        | 2011        | 2010        | 2009       |
|   | (Amounts in thousands, except per share data) |             |             |             |            |
| <b>Statements of Operations Data:</b>       |   |             |             |             |            |
| Revenue:                                    |   |             |             |             |            |
| Product royalty fees                        | \$  | \$          | \$ 20       | \$ 26       | \$ 25      |
| License fees                                | 4,144   | 4,144       | 4,143       | 5,318       | 4,733      |
|   | 4,144   | 4,144       | 4,163       | 5,344       | 4,758      |
| Cost of revenue                             |   |             | 24          | 24          | 20         |
| Gross profit                                | 4,144   | 4,144       | 4,139       | 5,320       | 4,738      |
| Operating expenses:                         |   |             |             |             |            |
| Research and development(1)                 | 27,678  | 42,131      | 21,968      | 9,023       | 4,213      |
| General and administrative(1)               | 13,649  | 9,900       | 8,137       | 6,330       | 9,549      |
| Sales and marketing(1)                      | 9,578   | 4,755       | 2,857       | 1,793       | 226        |
| Restructuring                               |   |             |             |             | (3)        |
|   | 50,905  | 56,786      | 32,962      | 17,146      | 13,985     |
| Loss from operations                        | (46,761)                                      | (52,642)    | (28,823)    | (11,826)    | (9,247)    |
| Investment income                           | 316   | 262         | 169         | 46          | 120        |
| Interest expense                            | (69)  | (41)        | (21)        | (20)        | (1)        |
| Other income                                |   |             |             | 244         |            |
| Net loss                                    | \$ (46,514)                                   | \$ (52,421) | \$ (28,675) | \$ (11,556) | \$ (9,128) |
| Net loss per share:                         |   |             |             |             |            |
| Basic and diluted                           | \$ (0.69)                                     | \$ (0.88)   | \$ (0.54)   | \$ (0.29)   | \$ (0.28)  |
| Weighted average common shares outstanding: |   |             |             |             |            |
| Basic and diluted                           | 67,493  | 59,481      | 52,512      | 40,455      | 32,791     |
| <b>Balance Sheet Data:</b>                  |   |             |             |             |            |
| Cash and cash equivalents                   | \$ 12,851                                     | \$ 13,345   | \$ 35,781   | \$ 78,752   | \$ 21,924  |
| Marketable securities                       | 120,408                                       | 94,776      | 57,580      | 16,663      | 2,404      |
| Total assets                                | 146,627                                       | 112,119     | 96,953      | 96,515      | 25,770     |

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|                      |         |        |        |        |        |
|----------------------|---------|--------|--------|--------|--------|
| Total long term debt | 1,000   | 1,000  | 1,000  | 1,000  | 1,000  |
| Total liabilities    | 11,311  | 13,524 | 13,458 | 16,761 | 19,676 |
| Stockholders' equity | 135,316 | 98,595 | 83,495 | 79,754 | 6,094  |

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(1)

Non-cash stock-based compensation expense included in these amounts are as follows:

|                            | 2013     | 2012     | 2011     | 2010     | 2009   |
|----------------------------|----------|----------|----------|----------|--------|
| Research and development   | \$ 2,817 | \$ 2,396 | \$ 1,685 | \$ 1,087 | \$ 319 |
| General and administrative | 3,054    | 2,579    | 1,622    | 993      | 2,308  |
| Sales and marketing        | 1,873    | 518      | 657      | 41       | 4      |

23

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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.*

**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 an accurate, non-invasive, patient friendly screening test to meet our primary goal of becoming the market leader for a diagnostic screening product for the early detection of colorectal pre-cancer and cancer.

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

- advance our product through U.S. Food and Drug Administration (FDA) clinical approval process;
- commercialize an FDA-approved product that detects colorectal pre-cancer and cancer; and
- secure favorable reimbursement for our product 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).

Colorectal cancer is the second leading cause of cancer deaths in the United States and the leading cause of cancer deaths among nonsmokers.

It is widely accepted that colorectal cancer is among the most preventable, yet least prevented cancers. Colorectal cancer typically takes 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 United States for whom routine colorectal cancer screening is recommended, nearly 47 percent have not been screened according to current guidelines. Poor compliance has meant that nearly two-thirds of colorectal cancer diagnoses are made in the disease's late stages. The five-year survival rates for stages 3 and 4 are 67 percent and 12 percent, respectively.

We believe the large population of unscreened and inadequately screened patients represents a significant opportunity for a patient friendly screening test like ours. A powerful preventive tool that detects pre-cancerous polyps and early stage colorectal cancer could significantly reduce colorectal cancer deaths and the health care costs associated with the disease. Pre-cancerous polyps are present in approximately 6 percent of average risk people 50 years of age and older who undergo routine colorectal cancer screening.

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.

Our current focus is on seeking FDA approval for our Cologuard test. We believe obtaining FDA approval is important to building broad demand and successfully commercializing our sDNA colorectal

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cancer screening technology. We are also in the process of developing our strategy for the ultimate commercialization of our Cologuard test.

In November 2012 we completed enrollment for our pivotal FDA clinical trial with over 10,000 patients enrolled at 90 enrollment sites in the U.S. and Canada. All patients provided a sample to be tested with our Cologuard test, and received a FIT test and a colonoscopy.

The FDA, as well as physicians and others assessing the effectiveness and value of our Cologuard test, will likely consider, among other things, our Cologuard test's sensitivity and specificity in identifying colorectal cancer and pre-cancerous polyps. "Sensitivity" (also called the true positive rate) measures the percentage of colorectal cancer or pre-cancerous polyps that our Cologuard test correctly identifies. "Specificity" (also called the true negative rate) measures the percentage of people who our Cologuard test correctly identifies as not having colorectal cancer or pre-cancerous polyps.

Preliminary, top-line data from the clinical trial showed that our Cologuard test demonstrated 92 percent sensitivity for the detection of colorectal cancer and 42 percent sensitivity for the detection of pre-cancerous polyps, including 66 percent sensitivity for pre-cancerous polyps equal to or greater than 2 centimeters. The test achieved a specificity of 87 percent during the clinical trial.

We submitted the results of our clinical trial to the FDA through a three part submission of a manufacturing module, analytical module, and clinical module. The manufacturing module was submitted to the FDA in December 2012, the analytical module was submitted to the FDA in February 2013, and the clinical module was submitted to the FDA in June 2013. Our submission is currently under review by the FDA.

The FDA's Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee is tentatively scheduled to review the premarket approval application (PMA) for our Cologuard test on March 27, 2014. The date and details of the meeting are subject to confirmation by the FDA in a Federal Register notice.

We believe that obtaining a favorable national coverage decision and a favorable reimbursement rate from the Centers for Medicare & Medicaid Services (CMS) for our Cologuard test will be a necessary element in achieving material commercial success. With the goal of expediting receipt of a favorable coverage decision, we are working with CMS to coordinate the CMS coverage review with the FDA pre-market approval through a parallel review process. This program provides a pathway to a potential CMS national coverage determination shortly after an FDA approval, should it occur. With over 50% of our target patient population being covered by Medicare, receipt of a positive coverage decision from CMS would help speed adoption of our test after commercial launch. A favorable CMS outcome will also be critical to 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 our Cologuard test 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.

There are two elements to our targeting strategy for the early adoption of Cologuard. First, we are focused on large healthcare systems and groups. These networks employ a high percentage of the physicians in the United States and they typically have strong screening programs. Second, we plan to focus on primary care physicians who prescribe a high volume of FOBT and FIT tests since this physician group has displayed a partiality for stool based screening methods.

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We have generated limited operating revenues since inception and, as of December 31, 2013, we had an accumulated deficit of approximately \$320.8 million. We expect to continue to incur losses for the next several years, and it is possible we may never achieve profitability.

### **2014 Priorities**

Our top priorities for 2014 include securing FDA approval and a favorable national coverage decision from CMS for our Cologuard test. If for any reason the FDA does not approve our PMA or such approval is substantially delayed, our business and prospects would likely be materially adversely impacted. Likewise it would be a material adverse event for our business if we do not receive a positive national coverage decision and favorable reimbursement rate from CMS or if for any other reason we are unable to successfully commercialize our Cologuard test.

Another priority is to secure favorable coverage and reimbursement from commercial payors.

In 2014 we also plan to continue implementing our commercialization plan, including building our manufacturing capacity, obtaining CLIA certification for our processing lab, integrating our IT infrastructure for ordering, processing, and billing, and deploying our sales and marketing teams.

We also have identified a new opportunity for our sDNA colorectal cancer screening technology focused on the inflammatory bowel disease (IBD) patient population. We initiated an IBD clinical trial in the first quarter 2013 that will focus on this specific patient group, and plan on enrolling around 300 IBD patients into the trial. Furthermore, we will work on developing enhancements to our Cologuard test and identifying and conducting research on other potential pipeline products targeting other cancers, such as esophageal and pancreatic cancer.

### **Results of Operations**

Our priorities during 2013 were completing the FDA submission of our Cologuard test and working toward launch readiness by building a marketing team and continuing our outreach and education efforts to physicians, third party payors and advocates. This led to a decrease in research and development costs during the year of \$14.4 million and an increase in marketing costs during the year of \$4.8 million. In addition to accomplishing these goals, we ensured that we were well capitalized to meet our 2014 goals by raising \$73.3 million net of issuance costs in June 2013 through a public offering of common stock.

#### ***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. Due to completion of the collaboration period in January 2014, we do not expect to recognize any further significant revenues under this agreement.

##### ***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

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clinical trial for our Cologuard test 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 reasearch and development                | 4.2            | 2.0            | 2.2              |
| Lab expenses                                   | 2.8            | 4.9            | (2.1)            |
| Stock-based compensation                       | 2.7            | 2.4            | 0.3              |
| Research collaborations                        | 1.8            | 1.3            | 0.5              |
| Professional fees                              | 1.4            | 3.6            | (2.2)            |
| License and royalty fees                       | 0.4            | 1.4            | (1.0)            |
| <b>Total research and development expenses</b> | <b>\$ 27.7</b> | <b>\$ 42.1</b> | <b>\$ (14.4)</b> |

### *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                      | \$ 4.2         | \$ 2.2        | \$ 2.0        |
| Stock-based compensation                         | 3.0            | 2.6           | 0.4           |
| Personnel expenses                               | 2.8            | 2.1           | 0.7           |
| Other general and administrative                 | 2.1            | 1.9           | 0.2           |
| Facility costs                                   | 1.5            | 1.1           | 0.4           |
| <b>Total general and administrative expenses</b> | <b>\$ 13.6</b> | <b>\$ 9.9</b> | <b>\$ 3.7</b> |

### *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 our Cologuard test. The increase in stock-based compensation and personnel costs is related to the severance costs as a result of the June 7, 2013 resignation of Laura Stoltenberg, the Company's former Chief Commercial Officer.

| Amounts in millions                       | 2013          | 2012          | Change        |
|---|---------------|---------------|---------------|
| Professional fees                         | \$ 4.2        | \$ 2.4        | \$ 1.8        |
| Personnel expenses                        | 3.1           | 1.6           | 1.5           |
| Stock-based compensation                  | 1.8           | 0.5           | 1.3           |
| Other sales and marketing                 | 0.5           | 0.3           | 0.2           |
| <b>Total sales and marketing expenses</b> | <b>\$ 9.6</b> | <b>\$ 4.8</b> | <b>\$ 4.8</b> |





**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.

**Comparison of the years ended December 31, 2012 and 2011****Revenue.**

Total revenue was \$4.1 million for the year ended December 31, 2012 and \$4.2 million for the year ended December 31, 2011. 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 increased to \$42.1 million for the year ended December 31, 2012 from \$22.0 million for the year ended December 31, 2011. This increase was primarily due to increased efforts focused on completing enrollment for our clinical trial and preparing the FDA submissions for our Cologuard test. We added key personnel to our clinical and research and development teams and the related expenses increased accordingly. Lab expenses consist of purchasing costs related to assay development and lab operations, and there was additional cost in this area as we finalized the assay design in 2012.

| Amounts in millions                            | 2012           | 2011           | Change         |
|--|----------------|----------------|----------------|
| Clinical trial expenses                        | \$ 19.1        | \$ 8.1         | \$ 11.0        |
| Personnel expenses                             | 7.4            | 5.3            | 2.1            |
| Lab expenses                                   | 4.9            | 2.6            | 2.3            |
| Professional fees                              | 3.6            | 1.1            | 2.5            |
| Stock-based compensation                       | 2.4            | 1.7            | 0.7            |
| Other reasearch and development                | 2.0            | 1.2            | 0.8            |
| License and royalty fees                       | 1.4            | 0.8            | 0.6            |
| Research collaborations                        | 1.3            | 1.2            | 0.1            |
| <b>Total research and development expenses</b> | <b>\$ 42.1</b> | <b>\$ 22.0</b> | <b>\$ 20.1</b> |

**General and administrative expenses.**

General and administrative expenses increased to \$9.9 million for the year ended December 31, 2012 from \$8.1 million for the year ended December 31, 2011. This increase was primarily a result of

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increased payroll and related expenses due to new general and administrative hires and increased operations at the Company.

| Amounts in millions              | 2012   | 2011   | Change |
|----------------------------------|--------|--------|--------|
| Stock-based compensation         | \$ 2.6 | \$ 1.6 | \$ 1.0 |
| Legal and professional fees      | 2.2    | 2.8    | (0.6)  |
| Personnel expenses               | 2.1    | 1.8    | 0.3    |
| Other general and administrative | 1.9    | 1.0    | 0.9    |
| Facility costs                   | 1.1    | 0.9    | 0.2    |

|   |        |        |        |
|---|--------|--------|--------|
| Total general and administrative expenses | \$ 9.9 | \$ 8.1 | \$ 1.8 |
|---|--------|--------|--------|

### *Sales and marketing expenses.*

Sales and marketing expenses increased to \$4.8 million for the year ended December 31, 2012 from \$2.9 million for the year ended December 31, 2011. The increase in sales and marketing expenses was a result of hiring additional marketing personnel and increased expenses incurred as a result of implementing a go-to-market strategy, branding and other marketing expenses.

| Amounts in millions       | 2012   | 2011   | Change |
|---------------------------|--------|--------|--------|
| Professional fees         | \$ 2.4 | \$ 0.9 | \$ 1.5 |
| Personnel expenses        | 1.6    | 1.1    | 0.5    |
| Stock-based compensation  | 0.5    | 0.7    | (0.2)  |
| Other sales and marketing | 0.3    | 0.2    | 0.1    |

|                                    |        |        |        |
|------------------------------------|--------|--------|--------|
| Total sales and marketing expenses | \$ 4.8 | \$ 2.9 | \$ 1.9 |
|------------------------------------|--------|--------|--------|

### *Investment income.*

Investment income increased to \$262.0 thousand for the year ended December 31, 2012 from \$169.0 thousand for the year ended December 31, 2011. This increase was primarily due to an overall higher cash and marketable securities balance during the year ended December 31, 2012 as compared to the same period of 2011.

### *Interest expense.*

Interest expense increased to \$41.0 thousand for the year ended December 31, 2012 from \$21.0 thousand for the year ended December 31, 2011. This increase was due to interest expense recognized from a capital lease which was entered into in 2012.

### *Liquidity and Capital Resources*

We have financed our operations primarily through private and public offerings of our common stock and cash received in January 2009 from Genzyme in connection with the Genzyme strategic transaction. As of December 31, 2013, we had approximately \$12.9 million in unrestricted cash and cash equivalents and approximately \$120.4 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 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.



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Net cash used in operating activities was \$39.3 million, \$44.2 million, and \$27.5 million for the years ended December 31, 2013, 2012 and 2011, respectively. The principal use of cash in operating activities for each of the years ended December 31, 2013, 2012 and 2011 was to fund our net loss. The decrease in net cash used in operating activities for the years ended December 31, 2013 and December 31, 2012, as compared to prior years was primarily due to decreased research and development activities. 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 \$35.5 million, \$38.3 million, and \$43.4 million for the years ended December 31, 2013, 2012, and, 2011, respectively. The decrease in cash used in investing activities for the year ended December 31, 2013 when compared to the same period in 2012 was the result of increased maturities of marketable securities. Excluding the impact of purchases and maturities of marketable securities, net cash used in investing activities was \$9.3 million for the year ended December 31, 2013, compared to net cash used in investing activities of \$0.7 million for the year ended December 31, 2012 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, 2011 was primarily the result of purchases of property and equipment of \$2.1 million.

Net cash provided by financing activities was \$74.3 million, \$60.0 million and \$27.9 million for the years ended December 31, 2013, 2012 and 2011, respectively. 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 the 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 \$1.0 million for the year ended December 31, 2013, compared to net cash provided by financing activities of \$2.3 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. The increase in cash provided by financing activities for the year ended December 31, 2012 when compared to the same period in 2011 was primarily the result of an increase in proceeds from the sale of common stock from \$27.2 million in 2011 to \$57.8 million in 2012. Excluding the impact of the sale of common stock, net cash provided by financing activities was \$2.3 million for the year ended December 31, 2012, compared to net cash provided by financing activities of \$0.7 million for the same period in 2011. This increase in cash provided by financing activities was primarily due to an increase in proceeds from the exercise of common stock options for the year ended December 31, 2012.

We expect that cash and cash equivalents and marketable securities on hand at December 31, 2013, will be sufficient to fund our current operations for at least the next twelve months, based on current operating plans. However, since we have no current sources of material ongoing revenue, it is possible that we may need to raise additional capital to fully fund our current strategic plan, the primary goal of which is commercializing our FDA approved non-invasive sDNA colorectal pre-cancer and cancer screening test. 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, 2013. This table does not include potential milestone payments due upon FDA approval or future sales-based royalty obligations:

| Description   | Total           | Less Than<br>One Year | Payments Due by Period |                 | More Than<br>5 Years |
|---|-----------------|-----------------------|------------------------|-----------------|----------------------|
|   |                 |                       | 1 - 3 Years            | 3 - 5 Years     |                      |
|   |                 |                       | (in Thousands)         |                 |                      |
| Long-term debt obligations(1)                             | \$ 1,158        | \$ 39                 | \$ 463                 | \$ 463          | \$ 193               |
| Obligations under license and collaborative agreements(2) | 3,691           | 596                   | 552                    | 512             | 2,031                |
| Operating lease obligations                               | 3,812           | 1,124                 | 1,364                  | 1,324           |                      |
| Capital lease obligations(1)                              | 750             | 381                   | 369                    |                 |                      |
| <b>Total</b>  | <b>\$ 9,411</b> | <b>\$ 2,140</b>       | <b>\$ 2,748</b>        | <b>\$ 2,299</b> | <b>\$ 2,224</b>      |

(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. Capital leases reflect obligations under a capital equipment leasing arrangement.

### *Net Operating Loss Carryforwards*

As of December 31, 2013, we had federal and state net operating loss carryforwards of approximately \$300.1 million and \$115.4 million, respectively. The Company also had federal and state research tax credit carryforwards of approximately \$5.6 million and \$18.7 million, respectively. The net operating loss and tax credit carryforwards will expire at various dates through 2032, 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

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obligations, accrued clinical trial costs, and stock-based compensation. We base our estimates on historical experience and on various other factors that are believed to be appropriate under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our financial statements included in this report, we believe that the following accounting policies and judgments are most critical to aid in fully understanding and evaluating our reported financial results.

### *Revenue Recognition.*

**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 are being 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 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 are amortizing 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 \$4.1 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, 2013.

### *Clinical Trial Accrual*

Accruals are recorded for clinical trial patient site costs when the liability is probable and reasonably estimable. For our pivotal FDA clinical trial and other sample procurement studies we undertake periodically, an accrual is made for a patient site cost once the patient has progressed past certain steps in the patient assessment and sample processing procedure. The accrual is estimated based on historical average patient reimbursement fees. Management has not recorded an accrual for clinical trial costs at December 31, 2013 as our clinical trial is complete. Management recorded an accrual of \$0.4 million at December 31, 2012 and 2011, respectively, for clinical trial costs related to site payments.

***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 \$124.5 million and \$103.9 million valuation allowance at December 31, 2013 and 2012 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 the current year is \$20.6 million. Due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact the Company's effective tax rate.

***Recent Accounting Pronouncements*** In December 2011, the FASB issued ASU No. 2011-11, *Balance Sheet (Topic 210) Disclosures about Offsetting Assets and Liabilities*. ASU 2011-11 requires an entity to disclose information about offsetting and related arrangements to enable users of its financial statements to understand the effect of those arrangements on its financial position. Entities are required to disclose both gross and net information about these instruments. ASU 2011-11 was effective for annual reporting periods beginning on or after January 1, 2013, and interim periods within those annual periods. The adoption of this ASU did not have a material impact on our consolidated financial statements.

***Off-Balance Sheet Arrangements***

As of December 31, 2013, 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, 2013 and December 31, 2012 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.

**Item 8. Consolidated Financial Statements and Supplementary Data**

**EXACT SCIENCES CORPORATION**  
**Index to Financial Statements**

|   | <b>Page</b> |
|---|-------------|
| <u>Reports of Independent Registered Public Accounting Firm</u>   | <u>36</u>   |
| <u>Consolidated Balance Sheets as of December 31, 2013 and 2012</u>   | <u>38</u>   |
| <u>Consolidated Statements of Operations for the Years Ended December 31, 2013, 2012 and 2011</u>           | <u>39</u>   |
| <u>Consolidated Statements of Comprehensive Loss for the Years Ended December 31, 2013, 2012 and 2011</u>   | <u>40</u>   |
| <u>Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2013, 2012 and 2011</u> | <u>41</u>   |
| <u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2013, 2012 and 2011</u>           | <u>42</u>   |
| <u>Notes to Consolidated Financial Statements</u>   | <u>43</u>   |

**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, 2013 and 2012 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, 2013. 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, 2013 and 2012, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2013, 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, 2013, based on criteria established in *Internal Control - Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated February 28, 2014 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Milwaukee, Wisconsin  
February 28, 2014

**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, 2013, based on criteria established in *Internal Control - Integrated Framework (1992)* 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, 2013, 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, 2013 and 2012, 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, 2013 and our report dated February 28, 2014 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Milwaukee, Wisconsin  
February 28, 2014

## EXACT SCIENCES CORPORATION

## Consolidated Balance Sheets

(Amounts in thousands, except share data)

|  | December 31,<br>2013 | December 31,<br>2012 |
|--|----------------------|----------------------|
| <b>ASSETS</b>                                    |                      |                      |
| Current Assets:                                  |                      |                      |
| Cash and cash equivalents                        | \$ 12,851            | \$ 13,345            |
| Marketable securities                            | 120,408              | 94,776               |
| Prepaid expenses and other current assets        | 2,199                | 593                  |
| <br>   |                      |                      |
| Total current assets                             | 135,458              | 108,714              |
| Property and Equipment, at cost:                 |                      |                      |
| Laboratory equipment                             | 5,087                | 4,051                |
| Assets under construction                        | 2,592                |                      |
| Office and computer equipment                    | 1,217                | 824                  |
| Leasehold improvements                           | 5,043                | 283                  |
| Furniture and fixtures                           | 268                  | 28                   |
| <br>   |                      |                      |
|  | 14,207               | 5,186                |
| Less Accumulated depreciation                    | (3,038)              | (1,781)              |
| <br>   |                      |                      |
|  | 11,169               | 3,405                |
| <br>   |                      |                      |
|  | \$ 146,627           | \$ 112,119           |
| <br><b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>  |                      |                      |
| Current Liabilities:                             |                      |                      |
| Accounts payable                                 | \$ 761               | \$ 3,652             |
| Accrued liabilities                              | 5,806                | 3,327                |
| Capital lease obligation, current portion        | 351                  | 333                  |
| Lease incentive obligation, current portion      | 540                  |                      |
| Deferred license fees, current portion           | 294                  | 4,143                |
| <br>   |                      |                      |
| Total current liabilities                        | 7,752                | 11,455               |
| <br>   |                      |                      |
| Long-term debt                                   | 1,000                | 1,000                |
| Long-term accrued interest                       | 84                   | 63                   |
| Capital lease obligation, less current portion   | 360                  | 711                  |
| Lease incentive obligation, less current portion | 2,115                |                      |
| Deferred license fees, less current portion      |                      | 295                  |
| <br>   |                      |                      |
| Commitments and contingencies                    |                      |                      |
| <br>   |                      |                      |
| Stockholders' Equity:                            |                      |                      |
| Preferred stock, \$0.01 par value                |                      |                      |
| Authorized 5,000,000 shares                      |                      |                      |

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Issued and outstanding no shares at December 31, 2013 and December 31, 2012

|  |           |           |
|--|-----------|-----------|
| Common stock, \$0.01 par value   |           |           |
| Authorized 100,000,000 shares  |           |           |
| Issued and outstanding 71,071,838 and 63,909,800 shares at December 31, 2013 and December 31, 2012 | 711       | 639       |
| Additional paid-in capital   | 455,239   | 372,123   |
| Accumulated other comprehensive income   | 125       | 78        |
| Accumulated deficit  | (320,759) | (274,245) |
| <br>   |           |           |
| Total stockholders' equity   | 135,316   | 98,595    |

\$ 146,627 \$ 112,119

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

## EXACT SCIENCES CORPORATION

## Consolidated Statements of Operations

(Amounts in thousands, except per share data)

|  | Year Ended December 31, |             |             |
|--|-------------------------|-------------|-------------|
|  | 2013                    | 2012        | 2011        |
| Revenue:   |                         |             |             |
| Product royalty fees   | \$                      | \$          | \$ 20       |
| License fees   | 4,144                   | 4,144       | 4,143       |
|  | 4,144                   | 4,144       | 4,163       |
| Cost of revenue:   |                         |             |             |
| Product royalty fees   |                         |             | 24          |
| Gross profit   | 4,144                   | 4,144       | 4,139       |
| Operating expenses:  |                         |             |             |
| Research and development                                     | 27,678                  | 42,131      | 21,968      |
| General and administrative                                   | 13,649                  | 9,900       | 8,137       |
| Sales and marketing  | 9,578                   | 4,755       | 2,857       |
|  | 50,905                  | 56,786      | 32,962      |
| Loss from operations   | (46,761)                | (52,642)    | (28,823)    |
| Investment income  | 316                     | 262         | 169         |
| Interest expense   | (69)                    | (41)        | (21)        |
| Net loss   | \$ (46,514)             | \$ (52,421) | \$ (28,675) |
| Net loss per share basic and diluted                         | \$ (0.69)               | \$ (0.88)   | \$ (0.54)   |
| Weighted average common shares outstanding basic and diluted | 67,493                  | 59,481      | 52,512      |

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





**EXACT SCIENCES CORPORATION**

**Consolidated Statements of Comprehensive Loss**

(Amounts in thousands)

| (In Thousands)   | December 31,    |                 |                 |
|--|-----------------|-----------------|-----------------|
|  | 2013            | 2012            | 2011            |
| Net loss   | \$ (46,514)     | \$ (52,421)     | \$ (28,675)     |
| Other comprehensive income (loss), net of tax:           |                 |                 |                 |
| Unrealized gain (loss) on available-for-sale investments | 47              | 92              | (15)            |
| <br>Comprehensive loss                                   | <br>\$ (46,467) | <br>\$ (52,329) | <br>\$ (28,690) |

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

## EXACT SCIENCES CORPORATION

## Consolidated Statements of Stockholders' Equity

(Amounts in thousands, except share data)

|   | Common Stock |        | Other Comprehensive |         | Total        |               |
|---|--------------|--------|---------------------|---------|--------------|---------------|
|   | Number of    | \$0.01 | Additional          | Income  | Accumulated  | Stockholders' |
|   | Shares       | Par    | Paid In             | (Loss)  | Deficit      | Equity        |
|   |              | Value  | Capital             |         |              |               |
| Balance, January 1, 2011  | 52,163,629   | \$ 522 | \$ 272,380          | \$ 1    | \$ (193,149) | \$ 79,754     |
| Issuance of common stock, net of issuance costs of \$1.5 million                      | 3,593,750    | 36     | 27,179              |         |              | 27,215        |
| Exercise of common stock options and warrants   | 708,590      | 7      | 678                 |         |              | 685           |
| Issuance of common stock to fund the Company's 2010 401(k) match                      | 27,872       |        | 169                 |         |              | 169           |
| Compensation expense related to issuance of stock options and restricted stock awards | 79,065       | 1      | 3,963               |         |              | 3,964         |
| Purchase of employee stock purchase plan shares                                       | 51,857       |        | 291                 |         |              | 291           |
| Expense related to warrants (Note 4)  |              |        | 107                 |         |              | 107           |
| Net loss  |              |        |                     |         | (28,675)     | (28,675)      |
| Accumulated other comprehensive loss  |              |        |                     | (15)    |              | (15)          |
| Balance, December 31, 2011  | 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         |
| Issuance of common stock to fund the Company's 2012 401(k) match                      | 30,538       | 1      | 354                 |         |              | 354           |
|   | 328,422      | 3      | 7,741               |         |              | 7,744         |

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Compensation expense related to issuance of stock options and restricted stock awards

|   |        |   |     |          |          |
|---|--------|---|-----|----------|----------|
| 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

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

## EXACT SCIENCES CORPORATION

## Consolidated Statements of Cash Flows

(Amounts in thousands, except share data)

|   | Year Ended December 31, |             |             |
|---|-------------------------|-------------|-------------|
|   | 2013                    | 2012        | 2011        |
| Cash flows from operating activities:                                       |                         |             |             |
| Net loss  | \$ (46,514)             | \$ (52,421) | \$ (28,675) |
| Adjustments to reconcile net loss to net cash used in operating activities: |                         |             |             |
| Depreciation and amortization of fixed assets                               | 1,418                   | 985         | 411         |
| Loss on disposal of property and equipment                                  | 100                     |             |             |
| Stock-based compensation  | 7,744                   | 5,493       | 3,964       |
| Amortization of deferred license fees                                       | (4,144)                 | (4,144)     | (4,143)     |
| Warrant licensing expense   |                         | 152         | 107         |
| Restricted stock licensing expense  |                         | 1,000       |             |
| Amortization of premium on short-term investments                           | 636                     | 532         | 360         |
| Changes in assets and liabilities:  |                         |             |             |
| Prepaid expenses and other current assets                                   | (1,606)                 | 441         | (788)       |
| Accounts payable  | (2,891)                 | 2,887       | (263)       |
| Accrued liabilities   | 3,286                   | 899         | 1,542       |
| Lease incentive obligation  | 2,655                   |             |             |
| Accrued interest  | 21                      | 21          | 21          |
| Net cash used in operating activities                                       | (39,295)                | (44,155)    | (27,464)    |
| Cash flows from investing activities:                                       |                         |             |             |
| Purchases of marketable securities  | (98,510)                | (96,047)    | (87,017)    |
| Maturities of marketable securities   | 72,289                  | 58,411      | 45,725      |
| Purchases of property and equipment   | (9,282)                 | (681)       | (2,115)     |
| Net cash used in investing activities                                       | (35,503)                | (38,317)    | (43,407)    |
| Cash flows from financing activities:                                       |                         |             |             |
| Proceeds from sale of common stock, net of issuance costs                   | 73,296                  | 57,755      | 27,215      |
| Proceeds from exercise of common stock options                              | 1,341                   | 2,388       | 685         |
| Payments on capital lease obligations                                       | (333)                   | (107)       |             |
| Net cash provided by financing activities                                   | 74,304                  | 60,036      | 27,900      |
| Net decrease in cash and cash equivalents                                   | (494)                   | (22,436)    | (42,971)    |
| Cash and cash equivalents, beginning of period                              | 13,345                  | 35,781      | 78,752      |
| Cash and cash equivalents, end of period                                    | \$ 12,851               | \$ 13,345   | \$ 35,781   |
| Supplemental disclosure of non-cash investing and financing activities:     |                         |             |             |
| Unrealized gain (loss) on available-for-sale investments                    | \$ 47                   | \$ 92       | \$ (15)     |

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|   |    |     |    |     |    |     |
|---|----|-----|----|-----|----|-----|
| Issuance of 30,538, 32,872, and 27,872 shares of common stock to fund the Company's 401(k) matching contribution for 2012, 2011, and 2010, respectively | \$ | 354 | \$ | 274 | \$ | 169 |
|---|----|-----|----|-----|----|-----|

|  |    |     |    |     |    |     |
|--|----|-----|----|-----|----|-----|
| Conversion of accrued expenses into 59,932, 63,611 and 51,857 shares of common stock in connection with the Company's ESPP for 2013, 2012 and 2011, respectively | \$ | 453 | \$ | 367 | \$ | 291 |
|--|----|-----|----|-----|----|-----|

|  |    |  |    |       |    |  |
|--|----|--|----|-------|----|--|
| Laboratory equipment acquired with a capital lease | \$ |  | \$ | 1,151 | \$ |  |
|--|----|--|----|-------|----|--|

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

**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 subsidiary, Exact Sciences Laboratories, LLC. 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 subsidiary, Exact Sciences Laboratories, LLC.

**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, 2013 and 2012.

**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, 2013 and December 31, 2012 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

## EXACT SCIENCES CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## (2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer. Investments in which the Company has the ability and intent, if necessary, to liquidate in order to support its current operations (including those with a contractual term greater than one year from the date of purchase) are classified as current. All of the Company's investments are considered current. Realized gains were \$9,639, \$6,231, and \$419 for the years ended December 31, 2013, 2012, and 2011, respectively. Unrealized gains on investments recorded in other comprehensive income were \$125,473 and \$77,808 for the years ended December 31, 2013 and 2012. Unrealized losses on investments recorded in other comprehensive income were \$13,784 for the year ended December 31, 2011.

The amounts reclassified from accumulated other comprehensive income to investment income during 2013, 2012 and 2011 related to the unrealized change in the value of marketable securities, were not significant.

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

| (In thousands)                             | Amortized<br>Cost | December 31, 2013   |  | Estimated<br>Fair<br>Value |
|--|-------------------|---|--|----------------------------|
|  |                   | Gains in<br>Accumulated<br>Other<br>Comprehensive<br>Income | Losses in<br>Accumulated<br>Other<br>Comprehensive<br>Income |                            |
| Corporate bonds                            | \$ 77,935         | \$ 75   | \$   | \$ 78,010                  |
| U.S. government agency securities          | 34,291            | 47  |  | 34,338                     |
| Certificates of deposit                    | 6,558             | 3   |  | 6,561                      |
| Commercial paper                           | 1,499             |   |  | 1,499                      |
| <b>Total available-for-sale securities</b> | <b>\$ 120,283</b> | <b>\$ 125</b>   | <b>\$</b>  | <b>\$ 120,408</b>          |

Available-for-sale securities at December 31, 2012 consist of the following:

| (In thousands)                             | Amortized<br>Cost | December 31, 2012   |  | Estimated<br>Fair<br>Value |
|--|-------------------|---|--|----------------------------|
|  |                   | Gains in<br>Accumulated<br>Other<br>Comprehensive<br>Income | Losses in<br>Accumulated<br>Other<br>Comprehensive<br>Income |                            |
| U.S. government agency securities          | \$ 44,270         | \$ 38   | \$   | \$ 44,308                  |
| Corporate bonds                            | 43,303            | 27  |  | 43,330                     |
| Certificates of deposit                    | 5,926             | 13  |  | 5,939                      |
| Commercial paper                           | 1,199             |   |  | 1,199                      |
| <b>Total available-for-sale securities</b> | <b>\$ 94,698</b>  | <b>\$ 78</b>  | <b>\$</b>  | <b>\$ 94,776</b>           |

**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:

| <b>Asset Classification</b>   | <b>Estimated Useful Life</b>                         |
|-------------------------------|--|
| Laboratory equipment          | 3 - 5 years  |
| Office and computer equipment | 3 years  |
| Leasehold improvements        | Lesser of the remaining<br>lease term or useful life |
| Furniture and fixtures        | 3 years  |

44



**EXACT SCIENCES CORPORATION**

**Notes to Consolidated Financial Statements (Continued)**

**(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

Depreciation expense for the years ended December 31, 2013, 2012, and 2011 was \$1.4 million, \$1.0 million, and \$0.4 million, respectively.

At December 31, 2013, the Company had \$2.6 million of assets under construction which consisted of \$1.7 million of capitalized costs related to software projects and \$0.9 million of costs related to an equipment project. Depreciation will begin on these assets once they are placed into service. We expect that it will cost \$0.5 million to complete the equipment project and \$1.0 million to complete the software projects, and these projects are expected to be completed in 2014.

**Software Capitalization Policy**

Software development costs related to internal use software are incurred in three stages of development: the preliminary project stage, the application development stage, and the post-implementation stage. Costs incurred during the preliminary project and post-implementation stages are expensed as incurred. Costs 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 patent costs incurred during the year ended December 31, 2013, 2012 and 2011 should be expensed and not capitalized as the future economic benefit derived from the transactions cannot be determined.

**Clinical Trial Accrual**

Accruals are recorded for clinical trial patient site costs when the liability is probable and reasonably estimable. For our pivotal FDA clinical trial and other sample procurement studies we undertake periodically, an accrual is made for a patient site cost once the patient has progressed past certain steps in the patient assessment and sample processing procedure. The accrual is estimated based on historical average patient reimbursement fees. Management has not recorded an accrual for clinical trial costs at December 31, 2013 as our clinical trial is complete. Management recorded an accrual of \$0.4 million at December 31, 2012 and 2011, respectively, for clinical trial costs related to site payments.

**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.

## EXACT SCIENCES CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## (2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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):

|   | 2013  | 2012  | 2011  |
|---|-------|-------|-------|
| Shares issuable upon exercise of stock options  | 6,063 | 6,182 | 6,454 |
| Shares issuable upon exercise of outstanding warrants(1)                                | 155   | 325   | 325   |
| Shares issuable upon the release of restricted stock awards                             | 1,151 | 814   | 401   |
| Shares issuable upon exercise of restricted stock awards related to licensing agreement | 49    | 73    |       |
|   | 7,418 | 7,394 | 7,180 |

(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 and December 31, 2011, 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**

**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 are being 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



**EXACT SCIENCES CORPORATION**

**Notes to Consolidated Financial Statements (Continued)**

**(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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 is amortizing that amount on a straight line basis into revenue over the initial five-year collaboration period ending in January 2014.

The Company recognized approximately \$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, 2012, and 2011.

**Product royalty fees.** The Company has licensed certain of its technologies, including improvements to such technologies, on an exclusive basis to LabCorp. LabCorp developed and commercially offered a non-invasive stool-based DNA colorectal cancer screening service for the average-risk population based on the Company's technology. The Company is entitled to certain royalties on any sales of this product. Accordingly, the Company records product royalty fees based on the specified contractual percentage of LabCorp's net revenues from its sales of such colorectal cancer screening tests, as reported to the Company each month by LabCorp. The current royalty rate is subject to an increase in the event that LabCorp achieves a specified significant threshold of annual net revenues from the sales of such colorectal cancer screening tests. No sales of this product were reported to the Company during the year ended December 31, 2013 and December 31, 2012 and no product royalty fees were recorded. Product royalty fees were \$20,000 for the year ended December 31, 2011.

**Advertising Costs**

The Company expenses the costs of media advertising at the time the advertising takes place. The Company expensed approximately \$97.7 thousand, \$57.4 thousand and \$110.0 thousand of media advertising during the years ended December 31, 2013, 2012, and 2011, 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.

## EXACT SCIENCES CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## (2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

The three levels of the fair value hierarchy established are as follows:

- Level 1** Quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access as of the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis.
- Level 2** Pricing inputs other than quoted prices in active markets included in Level 1, which are either directly or indirectly observable as of the reporting date. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.
- Level 3** Unobservable inputs that reflect the Company's assumptions about the assumptions that market participants would use in pricing the asset or liability. Unobservable inputs shall be used to measure fair value to the extent that observable inputs are not available.
- Fixed-income securities and mutual funds are valued using a third party pricing agency. The valuation is based on observable inputs including pricing for similar assets and other observable market factors. There has been no material change from period to period.

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.

| Description                       | Fair Value Measurement at December 31, 2013 |                  |  |   |   |
|-----------------------------------|---|------------------|--|---|---|
|                                   | Fair Value at December 31, 2013             | Using:           | 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   |   |
| <b>Total</b>                      | <b>\$ 133,259</b>                           | <b>\$ 12,851</b> | <b>\$ 120,408</b>  | <b>\$</b>                                     | <b>\$</b>                                 |

## EXACT SCIENCES CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## (2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

The following table presents the Company's fair value measurements as of December 31, 2012 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.

| Description                       | Fair Value at<br>December 31,<br>2012 | Fair Value Measurement at December 31, 2012<br>Using:                      |  |  |
|-----------------------------------|---------------------------------------|--|--|--|
|                                   |                                       | Quoted Prices<br>in Active<br>Markets for<br>Identical Assets<br>(Level 1) | Significant Other<br>Observable<br>Inputs<br>(Level 2) | Significant<br>Unobservable<br>Inputs<br>(Level 3) |
| <b>Cash and cash equivalents</b>  |                                       |  |  |  |
| Cash and money market             | \$ 13,095                             | \$ 13,095  | \$   | \$   |
| Corporate bonds                   | 250                                   |  | 250  |  |
| <b>Available-for-Sale</b>         |                                       |  |  |  |
| <b>Marketable securities</b>      |                                       |  |  |  |
| U.S. government agency securities | 44,308                                |  | 44,308   |  |
| Certificates of deposit           | 5,939                                 |  | 5,939  |  |
| Corporate bonds                   | 43,330                                |  | 43,330   |  |
| Commercial paper                  | 1,199                                 |  | 1,199  |  |
| <b>Total</b>                      | <b>\$ 108,121</b>                     | <b>\$ 13,095</b>   | <b>\$ 95,026</b>                                       | <b>\$</b>  |

As of December 31, 2013 and 2012 there were available for sale securities in a continuous unrealized loss position for less than twelve months where the total unrealized losses were \$7.2 thousand and \$4.8 thousand respectively. At December 31, 2013 and 2012 there were no available for sale securities in a continuous unrealized loss position for greater than twelve months.

The following summarizes contractual underlying maturities of the Company's available-for-sale investments at December 31, 2013 (in thousands):

|                                      | Cost              | Fair Value        |
|--------------------------------------|-------------------|-------------------|
| Due in one year or less              | \$ 53,843         | \$ 53,871         |
| Due after one year through two years | 66,440            | 66,537            |
|                                      | <b>\$ 120,283</b> | <b>\$ 120,408</b> |

**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, 2013, 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 \$12.1 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.

**EXACT SCIENCES CORPORATION**

**Notes to Consolidated Financial Statements (Continued)**

**(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

**Recent Accounting Pronouncements**

In December 2011, the FASB issued ASU No. 2011-11, *Balance Sheet (Topic 210) Disclosures about Offsetting Assets and Liabilities*. ASU 2011-11 requires an entity to disclose information about offsetting and related arrangements to enable users of its financial statements to understand the effect of those arrangements on its financial position. Entities are required to disclose both gross and net information about these instruments. ASU 2011-11 was effective for annual reporting periods beginning on or after January 1, 2013, and interim periods within those annual periods. The adoption of this ASU did not have a material impact on our consolidated financial statements.

**Reclassifications**

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

**(3) GENZYME STRATEGIC TRANSACTION**

**Transaction summary**

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

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



**EXACT SCIENCES CORPORATION**

**Notes to Consolidated Financial Statements (Continued)**

**(3) GENZYME STRATEGIC TRANSACTION (Continued)**

\$934,250 which included accrued interest due, from Genzyme during the third quarter of 2010. The amounts were deferred and are being 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 is amortizing 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 \$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, 2012, and 2011.

**(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 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.

**EXACT SCIENCES CORPORATION**

**Notes to Consolidated Financial Statements (Continued)**

**(4) MAYO LICENSE AGREEMENT (Continued)**

**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 becomes exercisable over a four year period.

In March of 2010, MAYO partially exercised its warrant covering 1,000,000 shares by utilizing the cashless exercise provision contained in the agreement. As a result of this exercise for a gross amount of 200,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its rights with respects to 86,596 shares leaving it with a net amount of 113,404 shares.

In September of 2010, MAYO partially exercised its warrant covering the remaining 800,000 shares by utilizing the cashless exercise provision contained in the agreement. As a result of this exercise for a gross amount of 300,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its rights with respect to 97,853 shares leaving it with a net amount of 202,147 shares.

In June of 2011, MAYO partially exercised its warrant covering the remaining 500,000 shares by utilizing the cashless exercise provision contained in the warrant. As a result of this exercise for a gross amount of 250,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its rights with respect to 60,246 shares leaving it with a net amount of 189,754 shares.

In September of 2011, MAYO partially exercised its warrant covering the remaining 250,000 shares by utilizing the cashless exercise provision contained in the warrant. As a result of this exercise for a gross amount of 250,000 shares, in lieu or paying a cash exercise price, MAYO forfeited its right with respect to 56,641 shares leaving it with a net amount of 193,359 shares. Following this exercise, the warrant covering 1,000,000 shares was fully exercised.

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. Following this exercise, the warrant originally covering 250,000 covered a total of 80,000 shares at December 31, 2013.

**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 will be \$10,000 in 2012 and \$25,000 per year thereafter through 2029, 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

**EXACT SCIENCES CORPORATION**

**Notes to Consolidated Financial Statements (Continued)**

**(4) MAYO LICENSE AGREEMENT (Continued)**

\$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. It is uncertain as to when or if the FDA will approve the Company's Cologuard test; therefore the \$500,000 milestone payment has not been recorded as a liability. The Company evaluates the status of the timing of FDA approval at each reporting date to determine if a liability should be recorded for the milestone payment.

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 \$1.7 million and has made payments of \$1.0 million for the year ended December 31, 2013. The Company has recorded an estimated liability in the amount of \$0.7 million for research and development efforts as of December 31, 2013. The Company incurred \$1.2 million and made payments of \$1.1 million for the year ended December 31, 2012. The Company recorded an estimated liability in the amount of \$0.1 million for research and development efforts at 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.

**EXACT SCIENCES CORPORATION**

**Notes to Consolidated Financial Statements (Continued)**

**(5) ISSUANCES OF EQUITY**

**Underwritten Public Offerings**

On December 6, 2011, the Company completed an underwritten public offering of 3.6 million shares of common stock at a price of \$8.00 per share to the public. The Company received approximately \$27.2 million of net proceeds from the offering, after deducting \$1.5 million for the underwriting discount and other stock issuance costs paid by the Company.

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.

**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.

**EXACT SCIENCES CORPORATION**

**Notes to Consolidated Financial Statements (Continued)**

**(6) STOCK-BASED COMPENSATION (Continued)**

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, 2013, options to purchase 4,582,064 shares and 27,000 shares of restricted stock were 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, 2013, options to purchase 1,480,523 shares were outstanding under the 2010 Stock Plan and 1,123,694 shares of restricted stock and restricted stock units were outstanding. On July 25, 2013 the stockholders of Exact Sciences Corporation approved an amendment to the 2010 Stock Plan to increase the number of shares reserved for issuance thereunder by 2,800,000 shares. At December 31, 2013, there were 2,852,078 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. At December 31, 2013, there were 128,343 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

## EXACT SCIENCES CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## (6) STOCK-BASED COMPENSATION (Continued)

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, 2013, there were 171,657 cumulative shares issued under the 2010 Purchase Plan, and 59,932 shares were issued in the year ended December 31, 2013, as follows:

| Offering period ended | Number of Shares | Weighted Average price per Share |      |
|-----------------------|------------------|----------------------------------|------|
| April 30, 2013        | 33,338           | \$                               | 7.56 |
| October 31, 2013      | 26,594           | \$                               | 7.55 |

**Stock-Based Compensation Expense**

The Company recorded approximately \$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, non-employee consultants and non-employee directors. The Company recorded \$5.5 million in stock-based compensation expense during the year ended December 31, 2012 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 \$4.0 million in stock-based compensation expense during the year ended December 31, 2011 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, 2013, 2012, and 2011 are as follows, and amounts included in the table are in thousands:

|                            | December 31, |          |          |
|----------------------------|--------------|----------|----------|
|                            | 2013         | 2012     | 2011     |
| Research and development   | \$ 2,817     | \$ 2,396 | \$ 1,685 |
| General and administrative | 3,054        | 2,579    | 1,622    |
| Sales and marketing        | 1,873        | 518      | 657      |

In connection with the December 31, 2011 resignation of the Company's Senior Vice President of Sales and Marketing, the Company accelerated the vesting of 131,250 shares under his previously unvested stock options. This acceleration was done in accordance with his employment agreement. He had a two year period from December 31, 2011 to exercise these options. The remaining 168,750 stock options from his initial grant were forfeited. As a result of this accelerated vesting, the Company recorded additional stock compensation expense in 2011 to ensure that the total grant date fair value of the actual vested awards was amortized to expense.

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.

## EXACT SCIENCES CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## (6) STOCK-BASED COMPENSATION (Continued)

## Determining Fair Value

**Valuation and Recognition** The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model 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, 2013 was 2.76%. The Company's forfeiture rate used in the twelve months ended December 31, 2012 was 1.38%.

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,  |               |               |
|--|---------------|---------------|---------------|
|  | 2013          | 2012          | 2011          |
| <b>Option Plan Shares</b>  |               |               |               |
| Risk-free interest rates   | 0.94% - 1.73% | 0.81% - 1.00% | 0.88% - 2.3%  |
| Expected term (in years)   | 6             | 6             | 6             |
| Expected volatility  | 82.9% - 84.0% | 85% - 92%     | 92%           |
| Dividend yield   | 0%            | 0%            | 0%            |
| Weighted average fair value per share of options granted during the period               | \$8.12        | \$6.90        | \$4.78        |
| <b>ESPP Shares</b>   |               |               |               |
| Risk-free interest rates   | 0.10% - 0.33% | 0.18% - 0.30% | 0.13% - 0.61% |
| Expected term (in years)   | 0.5 - 2       | 0.5 - 2       | 0.5 - 2       |
| Expected volatility  | 39.1% - 45.6% | 34.0% - 54.9% | 48% - 63%     |
| Dividend yield   | 0%            | 0%            | 0%            |
| Weighted average fair value per share of stock purchase rights granted during the period | \$3.13        | \$2.84        | \$2.83        |

## EXACT SCIENCES CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## (6) STOCK-BASED COMPENSATION (Continued)

## Stock Option, Restricted Stock, and Restricted Stock Unit Activity

A summary of stock option activity under the Stock Plans during the years ended 2013, 2012 and 2011 is as follows:

| Options   | Shares    | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term (Years) | Aggregate<br>Intrinsic<br>Value(1) |
|---|-----------|--|---|------------------------------------|
| <i>(Aggregate intrinsic value in thousands)</i> |           |  |   |                                    |
| Outstanding, January 1, 2011                    | 6,217,139 | \$ 1.93                                  |   |                                    |
| Granted   | 814,424   | 6.26                                     |   |                                    |
| Exercised                                       | (325,477) | 2.11                                     |   |                                    |
| Forfeited                                       | (252,502) | 7.15                                     |   |                                    |
| Outstanding, December 31, 2011                  | 6,453,584 | \$ 2.27                                  |   |                                    |
| Granted   | 499,198   | 9.18                                     |   |                                    |
| Exercised                                       | (691,471) | 3.45                                     |   |                                    |
| Forfeited                                       | (79,375)  | 7.60                                     |   |                                    |
| Outstanding, December 31, 2012                  | 6,181,936 | \$ 2.62                                  | 6.6   |                                    |
| Granted   | 290,570   | 11.36                                    |   |                                    |
| Exercised                                       | (274,919) | 5.17                                     |   |                                    |
| Forfeited                                       | (135,000) | 10.08                                    |   |                                    |
| Outstanding, December 31, 2013                  | 6,062,587 | \$ 2.78                                  | 5.9   | \$ 54,537                          |
| Exercisable, December 31, 2013                  | 5,209,057 | \$ 1.79                                  | 5.5   | \$ 51,879                          |
| Vested and expected to vest, December 31, 2013  | 6,039,030 | \$ 2.79                                  | 5.9   | \$ 54,333                          |



(1)

The aggregate intrinsic value of options outstanding at December 31, 2013 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 6,012,587 options that had exercise prices that were lower than the \$11.75 market price of our common stock at December 31, 2013. The aggregate intrinsic value of options exercisable at December 31, 2013 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 5,209,057 options that had exercise prices that were lower than the \$11.75 market price of our common stock at December 31, 2013. The total intrinsic value of options exercised during the years ended December 31, 2013, 2012 and 2011 was \$1.9 million, \$4.5 million, \$1.9 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. The warrants contain a performance condition and vest if the Company successfully receives FDA approval for Cologuard. The Company is uncertain if the performance condition will be attained, and therefore no expense has been recorded on this warrant as of December 31, 2013. The exercise price of the warrant is \$0.01.

## EXACT SCIENCES CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## (6) STOCK-BASED COMPENSATION (Continued)

A summary of restricted stock and restricted stock unit activity under the Stock Plans during the years ended December 31, 2013, 2012 and 2011 is as follows:

|                                | Restricted<br>Shares | Weighted<br>Average Grant<br>Date Fair Value |
|--------------------------------|----------------------|--|
| Outstanding, January 1, 2011   | 263,630              | \$ 6.20                                      |
| Granted                        | 335,716              | 6.06   |
| Released                       | (192,856)            | 5.89   |
| Forfeited                      | (5,000)              | 5.61   |
| Outstanding, December 31, 2011 | 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                                     |

As of December 31, 2013, there was approximately \$13.5 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 2.6 years.

The Company received approximately \$1.3 million, \$2.4 million and \$0.7 million from stock option exercises during the years ended December 31, 2013, 2012 and 2011, respectively. During the years ended December 31, 2013, 2012 and 2011, 56,189, 63,611 and 51,857 shares of common stock, respectively, were issued under the Company's 2010 Purchase Plan resulting in proceeds to the company of \$0.5 million, \$0.4 million and \$0.3 million, respectively.

## EXACT SCIENCES CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## (6) STOCK-BASED COMPENSATION (Continued)

The following table summarizes information relating to currently outstanding and exercisable stock options as of December 31, 2013:

| Exercise Price   | Number of Options | Outstanding   |                                 | Exercisable       |                                 |
|------------------|-------------------|---|---------------------------------|-------------------|---------------------------------|
|                  |                   | Weighted Average Remaining Contractual Life (Years) | Weighted Average Exercise Price | Number of Options | Weighted Average Exercise Price |
| \$ - \$1.00      | 3,765,000         | 5.2   | \$ 0.83                         | 3,765,000         | \$ 0.83                         |
| \$1.01 - \$2.00  | 72,000            | 5.3   | 1.42                            | 72,000            | 1.42                            |
| \$2.01 - \$3.00  | 697,000           | 5.5   | 2.83                            | 697,000           | 2.83                            |
| \$3.01 - \$4.00  | 124,506           | 6.5   | 3.51                            | 119,256           | 3.49                            |
| \$4.01 - \$5.00  | 256,814           | 6.5   | 4.17                            | 190,064           | 4.17                            |
| \$5.01 - \$7.00  | 241,825           | 7.2   | 5.88                            | 108,950           | 5.95                            |
| \$7.01 - \$9.00  | 181,424           | 7.5   | 8.22                            | 122,126           | 8.30                            |
| \$9.01 - \$14.00 | 724,018           | 8.6   | 9.96                            | 134,661           | 9.33                            |
|                  | 6,062,587         | 5.9   | \$ 2.78                         | 5,209,057         | \$ 1.79                         |

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, 2013, as follows:

**Shares reserved for issuance**

|                    |           |
|--------------------|-----------|
| 2010 Option Plan   | 2,852,078 |
| 2010 Purchase Plan | 128,343   |
|                    | 2,980,421 |



## EXACT SCIENCES CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## (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 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. The Company has two options to extend the term of the lease for five years each.

As part of the lease agreement, 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 five year term of the lease as a reduction of rent expense. As of December 31, 2013, the lease incentive obligation was \$2.7 million. Construction of the laboratory facility was substantially complete at December 31, 2013 and the laboratory was placed into service. The amortization of the lease incentive obligation began in December of 2013.

Future minimum payments under operating leases as of December 31, 2013 are as follows. Amounts included in the table are in thousands.

| Year Ending December 31, |          |
|--------------------------|----------|
| 2014                     | \$ 1,124 |
| 2015                     | 680      |
| 2016                     | 684      |
| 2017                     | 689      |
| 2018                     | 577      |
| Thereafter               |          |

|                         |          |
|-------------------------|----------|
| Total lease obligations | \$ 3,754 |
|-------------------------|----------|

Rent expense included in the accompanying consolidated statements of operations was approximately \$0.7 million, \$0.4 million, and \$0.3 million for the years ended December 31, 2013, 2012 and 2011, 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 2013. The Company received \$66,800 and \$78,500 in sublease payments in 2012 and 2011, respectively. The 2009 Sublease Agreement expired on November 1, 2012.

**EXACT SCIENCES CORPORATION**

**Notes to Consolidated Financial Statements (Continued)**

**(7) COMMITMENTS AND CONTINGENCIES (Continued)**

**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 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 is also required to pay minimum annual royalty fees of \$10,000 on June 12, 2012 and \$25,000 on June 12, 2013 and each year thereafter through 2029. 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, and 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 will be required to pay MAYO \$500,000 upon FDA approval of the Company's Cologuard test.

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

**EXACT SCIENCES CORPORATION**

**Notes to Consolidated Financial Statements (Continued)**

**(7) COMMITMENTS AND CONTINGENCIES (Continued)**

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.

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, and to make a \$100,000 milestone payment upon FDA approval of the Company's Cologuard test.

It is uncertain as to when the FDA will approve the Company's Cologuard test. Therefore, the \$100,000 milestone payment has not been recorded as a liability. The Company evaluates the status of the FDA trial at each reporting date to determine if a liability should be recorded for the milestone payment.

**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.

## EXACT SCIENCES CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## (7) COMMITMENTS AND CONTINGENCIES (Continued)

The Company has recorded research and development expense associated with license agreements of \$1.8 million, \$1.4 million, and \$0.8 million, respectively, for the years ended December 31, 2013, 2012 and 2011. Future minimum payments due under the Company's technology licenses as of December 31, 2013 are as follows. Amounts included in the table are in thousands.

|                          |          |
|--------------------------|----------|
| Year ending December 31, |          |
| 2014                     | \$ 596   |
| 2015                     | 296      |
| 2016                     | 256      |
| 2017                     | 256      |
| 2018                     | 256      |
| Thereafter               | 2,031    |
|                          | \$ 3,691 |

**Research collaborations**

The Company has also entered into several clinical research agreements, under which it is obligated to fund certain research activities for purposes of technology development. As of December 31, 2013, 2012 and 2011, the Company had no outstanding sample collection commitments. The Company has recorded research and development expense associated with clinical research agreements of approximately \$1.7 million, \$1.2 million, and \$1.0 million, respectively, for the years ended December 31, 2013, 2012 and 2011. As of December 31, 2013, the Company did not have any remaining obligation under these agreements.

**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 at December 31, 2013. 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, 2013 was approximately \$511.6 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.



## EXACT SCIENCES CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## (7) COMMITMENTS AND CONTINGENCIES (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, 2013 are as follows (in thousands):

|  |        |
|--|--------|
| Year Ending December 31,                             |        |
| 2014   | \$ 381 |
| 2015   | 369    |
| <br>   |        |
| Total lease obligations                              | \$ 750 |
| Less imputed interest                                | (39)   |
| Present value of minimum lease payments              | 711    |
| <br>   |        |
| Less current maturities of capital lease obligations | (351)  |
| <br>   |        |
| Long term capital lease obligations                  | \$ 360 |

## (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, 2013 and 2012 consisted of the following. Amounts included in the table are in thousands.

|                                     | December 31, |          |
|-------------------------------------|--------------|----------|
|                                     | 2013         | 2012     |
| Compensation                        | \$ 2,838     | \$ 1,985 |
| Professional fees                   | 826          | 351      |
| Research and trial related expenses | 801          | 576      |
| Assets under construction           | 649          |          |
| Licenses                            | 539          | 373      |
| Other                               | 82           | 19       |
| Occupancy costs                     | 71           | 23       |
|                                     |              |          |
|                                     | \$ 5,806     | \$ 3,327 |



**EXACT SCIENCES CORPORATION****Notes to Consolidated Financial Statements (Continued)****(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 the loan are such that portions of the loan become forgivable if the Company meets certain job creation requirements. 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, 2013:

| Year ending December 31, |     |
|--------------------------|-----|
| 2014                     | \$  |
| 2015                     | 145 |
| 2016                     | 217 |
| 2017                     | 221 |
| 2018                     | 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, 2013, 2012 and 2011 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 \$0.5 million, \$0.4 million, and \$0.3 million, respectively, in the statements of operations for the years ended December 31, 2013, 2012 and 2011 in connection with 401(k) Plan matching contributions.

**(12) 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, 2013, the Company had federal net

## EXACT SCIENCES CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## (12) INCOME TAXES (Continued)

operating loss and state net operating loss carryforward of approximately \$300.1 million and \$115.4 million, respectively for financial reporting purposes, which may be used to offset future taxable income. The Company also had federal and state research tax credit carryforwards of \$5.6 million and \$18.7 million, respectively which may be used to offset future income tax liability. The federal and state carryforwards expire beginning 2013 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, 2013 and 2012, the Company had \$16.5 million and \$14.2 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, |           |
|---------------------------------------|--------------|-----------|
|                                       | 2013         | 2012      |
| Deferred tax assets:                  |              |           |
| Operating loss carryforwards          | \$ 101,942   | \$ 88,532 |
| Tax credit carryforwards              | 18,061       | 10,184    |
| Deferred revenue                      | 117          | 1,758     |
| Other temporary differences           | 4,429        | 3,445     |
| <br>                                  |              |           |
| Tax assets before valuation allowance | 124,549      | 103,919   |
| Less Valuation allowance              | (124,549)    | (103,919) |
| <br>                                  |              |           |
| 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 \$124.5 million and \$103.9 million valuation allowance at December 31, 2013 and 2012 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 the current year is \$20.6 million. Due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact the Company's effective tax rate.

## EXACT SCIENCES CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## (12) INCOME TAXES (Continued)

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

|                                     | December 31, |        |        |
|-------------------------------------|--------------|--------|--------|
|                                     | 2013         | 2012   | 2011   |
| U.S. Federal statutory rate         | 34.0%        | 34.0%  | 34.0%  |
| State taxes                         | 4.8          | 1.7    | 5.6    |
| Research and development tax credit | 16.9         | 5.1    | 1.7    |
| Stock-based compensation expense    | (1.1)        | (0.6)  | (2.4)  |
| Other adjustments                   | (0.3)        | (0.1)  | 0.1    |
| Valuation allowance                 | (54.3)       | (40.1) | (39.0) |
| Effective tax rate                  | 0.0%         | 0.0%   | 0.0%   |

There are no unrecognized tax benefits as of December 31, 2013, 2012 and 2011, 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, 2013.

As of December 31, 2013, 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 2013, and to 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, 2013, 2012 and 2011.

## (13) 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, 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.

## EXACT SCIENCES CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## (13) QUARTERLY RESULTS OF OPERATIONS (UNAUDITED) (Continued)

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) |             |               |              |
| <b>2013</b>  |   |             |               |              |
| 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       |

|                            |          |          |          |          |
|----------------------------|----------|----------|----------|----------|
| <b>2012</b>                |          |          |          |          |
| 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   | 8,999    | 12,202   | 10,491   | 10,439   |
| General and administrative | 2,145    | 2,393    | 2,547    | 2,815    |
| Sales and marketing        | 594      | 1,331    | 1,006    | 1,824    |

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|                      |          |          |          |          |
|----------------------|----------|----------|----------|----------|
| Loss from operations | (10,702) | (14,890) | (13,008) | (14,042) |
| Investment income    | 62       | 59       | 67       | 74       |
| Interest expense     | (5)      | (5)      | (11)     | (20)     |

Net loss \$ (10,645) \$ (14,836) \$ (12,952) \$ (13,988)

Net loss per share basic and diluted \$ (0.19) \$ (0.26) \$ (0.21) \$ (0.22)

Weighted average common shares outstanding basic and diluted 56,718 57,037 60,531 63,582

**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, 2013 to provide reasonable assurance that information required to be disclosed by us in reports that we file under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in Securities and Exchange Commission rules and forms and that material information relating to the Company is accumulated and communicated to management, including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

*Changes in Internal Control over Financial Reporting.*

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2013, 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, 2013. 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*. Based on our assessment, we concluded that, as of December 31, 2013, 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, 2013, which is included herein.

**Item 9B. Other Information**

None.



**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance**

The information required under this item is incorporated by reference to the following sections of our proxy statement for our 2014 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 2014 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 2014 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 2014 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 2014 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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| Name  | Title    | Date              |
|---|----------|-------------------|
| <u>/s/ DANIEL J. LEVANGIE</u><br>Daniel J. Levangie | Director | February 28, 2014 |
| <u>/s/ KATHERINE NAPIER</u><br>Katherine Napier     | Director | February 28, 2014 |
| <u>/s/ LIONEL STERLING</u><br>Lionel Sterling       | Director | February 28, 2014 |
| <u>/s/ DAVID THOMPSON</u><br>David Thompson         | Director | February 28, 2014 |

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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 our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)   |
| 3.2            | Amended and Restated By-Laws of the Registrant (previously filed as Exhibit 3.1 to our Report on Form 10-Q for the period ended March 31, 2009, which is incorporated herein by reference)  |
| 3.3            | Certificate of Designations of Series A Junior Participating Preferred Stock of Exact Sciences Corporation (previously filed as Exhibit 3.1 to our Registration Statement on Form 8-A filed on February 23, 2011, which is incorporated herein by reference)                                  |
| 4.1            | Specimen certificate representing the Registrant's Common Stock (previously filed as Exhibit 4.1 to our Registration Statement on Form S-1 (File No. 333-48812), which is 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 our Report on Form 10-Q for the period ended June 30, 2009, which is incorporated herein by reference)   |
| 4.4            | Rights Agreement, dated as of February 22, 2011, by and between Exact Sciences Corporation and American Stock Transfer & Trust Company, LLC (previously filed as Exhibit 4.1 to our Registration Statement on Form 8-A filed on February 23, 2011, which is incorporated herein by reference) |
| 10.1*          | 2000 Stock Option and Incentive Plan (previously filed as Exhibit 10.2 to our Annual Report on Form 10-K filed for the period ended December 31, 2008, which is 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 our Annual Report on Form 10-K for the period ended December 31, 2007, which is incorporated herein by reference)   |
| 10.3**         | Collaboration, License and Purchase Agreement between Genzyme Corporation and the Registrant, dated January 27, 2009 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on January 28, 2009, which is incorporated herein by reference)  |
| 10.4*          | Employment Agreement by and between Kevin T. Conroy and the Registrant, dated as of March 18, 2009 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on March 18, 2009, which is incorporated herein by reference)  |
| 10.5*          | Employment Agreement by and between Maneesh Arora and the Registrant, dated as of March 18, 2009 (previously filed as Exhibit 10.2 to our Report on Form 8-K filed on March 18, 2009, which is incorporated herein by reference)  |
| 10.6*          | Employment Agreement by and between Graham Lidgard and the Registrant, dated as of August 1, 2009 (previously filed as Exhibit 10 to our Report on Form 10-Q for the period ended September 30, 2009, which is incorporated herein by reference)  |
| 10.7**         | License Agreement by and between MAYO Foundation for Medical and Educational Research and the Registrant, dated June 11, 2009 (previously filed as Exhibit 10.2 to our Report on Form 10-Q for the period ended June 30, 2009, which is incorporated herein by reference)                     |

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| Exhibit Number | Description  |
|----------------|--|
| 10.8**         | Technology License Agreement by and between Hologic, Inc., Third Wave Technologies, Inc., and the Registrant, dated as of October 14, 2009 (previously filed as Exhibit 10.39 to our Annual Report on Form 10-K filed for the period ended December 31, 2009, which is incorporated herein by reference)           |
| 10.9           | Loan Agreement, dated November 10, 2009, between the Wisconsin Department of Commerce and the Registrant (previously filed as Exhibit 10.13 to our Annual Report on Form 10-K filed for the period ended December 31, 2009, which is incorporated herein by reference)   |
| 10.10          | Lease Agreement, dated November 11, 2009, between University Research Park Incorporated and the Registrant (previously filed as Exhibit 10.13 to our Annual Report on Form 10-K filed for the period ended December 31, 2009, which is incorporated herein by reference)   |
| 10.11*         | The Registrant's 2010 Omnibus Long-Term Incentive Plan (previously filed as Appendix A to the Proxy Statement for the Company's 2010 Annual Meeting of Stockholders filed on April 30, 2010)   |
| 10.12*         | The Registrant's 2010 Employee Stock Purchase Plan (previously filed as Appendix B to the Proxy Statement for the Company's 2010 Annual Meeting of Stockholders filed on April 30, 2010)   |
| 10.13*         | 2010 Omnibus Long-Term Incentive Plan Form Stock Option Award Agreement (previously filed as Exhibit 4.5 to our Registration Statement on Form S-8 (File No. 333-168909), which is incorporated herein by reference)   |
| 10.14*         | 2010 Omnibus Long-Term Incentive Plan Form Restricted Stock Award Agreement (previously filed as Exhibit 4.6 to our Registration Statement on Form S-8 (File No. 333-168909), which is incorporated herein by reference)   |
| 10.15*         | 2010 Omnibus Long-Term Incentive Plan Form Restricted Stock Unit Award Agreement (previously filed as Exhibit 10.35 our Annual Report on Form 10-K filed for the period ended December 31, 2010, which is incorporated herein by reference)  |
| 10.16*         | Employment Agreement by and between Laura Stoltenberg and the Registrant, dated as of March 19, 2012 (previously filed as Exhibit 10.1 to our Report on Form 10-Q for the period ended March 31, 2012, which is incorporated herein by reference)  |
| 10.17          | Amendment No. 4 to the Research License Agreement dated June 12, 2009 between the Registrant and Mayo Foundation for Medical Education and Research dated May 15, 2012 (previously filed as Exhibit 10.1 to our Report on Form 10-Q for the period ended June 30, 2012, which is incorporated herein by reference) |
| 10.18*         | Consulting Agreement dated August 27, 2013 between the Registrant and James P. Connelly (previously filed as Exhibit 10.2 to our Report on Form 10-Q for the period ended September 30, 2013, which is incorporated herein by reference)   |
| 10.19**+       | Amendment to Technology License Agreement by and between Hologic, Inc., Third Wave Technologies, Inc., and the Registrant, dated as of December 7, 2012 (previously filed as Exhibit 10.37 to our Report on Form 10-K for the period ended December 31, 2013, which is incorporated herein by reference)           |

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| Exhibit Number | Description   |
|----------------|---|
| 10.20*         | Employment Letter Agreement by and between William J. Megan and the Registrant, dated as of August 7, 2013 (previously filed as Exhibit 10.1 to our Report on Form 10-Q for the period ended September 30, 2013, which is incorporated herein by reference) |
| 10.21*         | First Amendment to the Exact Sciences Corporation 2010 Omnibus Long-Term Incentive Plan (previously filed as Appendix A to the Proxy Statement for the Company's 2013 Annual Meeting of Stockholders, which is incorporated herein by reference)            |
| 10.22*         | Exact Sciences Corporation Non-employee Director Compensation Policy dated July 25, 2013 (previously filed as Exhibit 10.4 to our Report on Form 10-Q for the period ended September 30, 2013, which is incorporated herein by reference)                   |
| 10.23          | Separation Agreement and General Release between Laura S. Stoltenberg and Exact Sciences Corporation dated June 7, 2013 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on June 7, 2013, which is incorporated herein by reference)       |
| 10.24          | Lease Agreement between The Alexander Company and Exact Sciences Laboratories, Inc. dated June 25, 2013 (previously filed as Exhibit 10.2 to our Report on Form 10-Q for the period ended June 30, 2013, which is incorporated herein by reference)         |
| 10.25**+       | License Agreement by and between MDx Health S.A. and the Registrant, dated as of July 26, 2010  |
| 10.26**+       | Addendum to License Agreement by and between MDx Health S.A. and the Registrant, dated May 6, 2011  |
| 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   |

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

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

+ Filed herewith.