EXACT SCIENCES CORP Form 10-K March 01, 2013

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Item 8. Financial Statements and Supplementary Data

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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, 2012

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

Commission file number 000-32179

EXACT SCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

DELAWARE

02-0478229

(State or other jurisdiction of incorporation or organization)

(IRS Employer Identification No.)

441 Charmany Drive, Madison, WI

53719

(Address of principal executive offices)

(Zip Code)

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

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

Common Stock, \$.01 Par Value 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 o No ý

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

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 \circ No o

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 \(\gamma \) No o

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. ý

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 o Accelerated filer ý Non-accelerated filer o Smaller reporting company o

(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 o No ý

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 \$607,437,716 (based on the closing price of the Registrant's Common Stock on June 29, 2012 of \$10.72 per share).

The number of shares outstanding of the Registrant's \$.01 par value Common Stock as of February 26, 2013 was 64,031,106.

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, 2012. 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, 2012

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PART I

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange and Exchange Act of 1934, as amended, that are intended to be covered by the "safe harbor" created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "could," "seek," "intend," "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 our pivotal clinical trial and our related FDA submissions, 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.

52,000 deaths in the U.S.

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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. The target sensitivity rate of our Cologuard test for cancer is equal to or greater than 85 percent at a specificity of 90 percent. In preliminary validation studies our test was able to detect cancers at or above this target sensitivity rate and we were also able to demonstrate strong pre-cancer detection.

Our Cologuard test 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

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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 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. Patient enrollment included more than 55 colorectal cancer patients and more than 800 pre-cancer patients. All patients provided a sample to be tested with our Cologuard test, and received a FIT test and a colonoscopy. The results of the trial will establish the performance characteristics (sensitivity and specificity) of our Cologuard test.

We are currently in the process of submitting the results of our 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 and the analytical module was submitted in February 2013. We expect to submit the clinical module in the second quarter of 2013.

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We believe that obtaining a positive 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 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 plan to focus marketing efforts 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. Six percent of primary care physician prescribers are responsible for 60% of FOBT/FIT volume.

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.

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 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 2013. It demonstrated only 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. It is our understanding that one of these companies, 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.

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 \$42.1 million, \$22.0 million and \$9.0 million for the years ended December 31, 2012, 2011 and 2010, respectively.

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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 clearance or 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.

Other Regulations

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.

In addition, the specimen transport and storage containers that are used in connection with certain of our products are deemed to be a Class II medical device regulated by the FDA. Once a physician orders a test, the patient will need to receive a specimen container to collect and transport the patient's stool sample. Our collection kit will be submitted to the FDA in the first quarter of 2013 as a Class II de novo 510k.

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. In 2009, we expanded our intellectual property estate through our collaboration with the Mayo Clinic and licensed Invader detection technology from Hologic, which we have incorporated into our assay design. We have an extensive license to markers, digital PCR, and other technologies

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applicable to the detection of colorectal cancer from the Johns Hopkins University, and have additional licensed intellectual property from MDx Health (formerly Oncomethylome) and Case Western Reserve University.

Our success depends to a significant degree upon our ability to protect our technologies through patent coverage. As of December 31, 2012, we owned 14 issued patents and 12 pending patent applications in the United States, and 48 issued patents and 5 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 27 patents issued and 9 pending patent applications in the U.S., and 46 patents issued and 15 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.

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, 2012, we had eighty seven 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 financial statements and accompanying notes to the financial statements included elsewhere in this Form 10-K for information concerning revenues, profits and losses and total assets.

Available Information

We were incorporated in the State of Delaware on February 10, 1995. Our executive offices are located at 441 Charmany Drive, Madison, Wisconsin 53719. Our telephone number is 608-284-5700. Our Internet website address is *www.exactsciences.com*. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge through the investor relations page of our internet website as soon as

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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, 2012, we have accumulated a total deficit of approximately \$274.2 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 or cleared 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;

our ability to successfully execute on a clinical trial;

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.

We believe obtaining FDA approval or clearance is critical to building broad demand for and successfully commercializing our Cologuard test. The FDA approval path for our Cologuard test will take significant time and require significant research, development and clinical study expenditures. In addition, we are in the process of developing our strategy for the ultimate commercialization of our Cologuard test which will also take significant time and require significant expenditures.

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

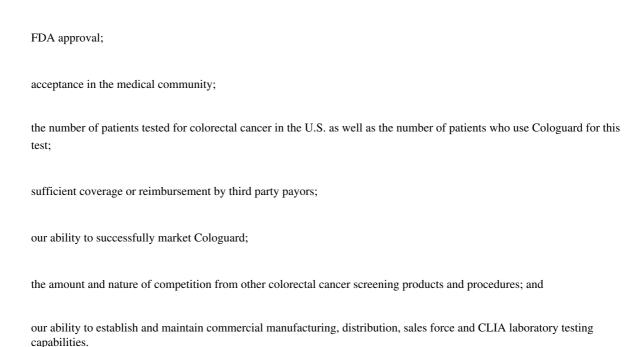
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needed financing on acceptable terms, we may not be able to implement our business plan, which could have a material adverse effect on our business, financial condition and results of operations. If we raise additional funds through the sale of equity, 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 assure you 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 complete a successful clinical trial and obtain FDA approval or clearance 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:



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.

Although in validation studies our Cologuard test detected both pre-cancers and cancers at target sensitivity rates, the FDA approval path for our Cologuard test will take significant time and require significant research, development and clinical study expenditures and ultimately may not succeed.

We have designed our Cologuard test with a goal of detecting both pre-cancers and cancers. The target sensitivity rate for cancer is equal to or greater than 85% at a specificity of 90%. In preliminary validation studies our test was able to detect cancers at or above this target sensitivity rate and we were also able to demonstrate strong pre-cancer detection. However, prior to commercialization of our Cologuard test, it will be necessary to obtain FDA approval or clearance, which will depend upon our ability to successfully complete a pivotal clinical trial. Unlike a clinical trial, our validation studies did not use a final product to test patient samples under real-life, clinical conditions. The results achieved in our clinical trial may differ materially from our validation study results. Even if our clinical trial is successful, FDA approval for our Cologuard test will take significant time and require significant research, development and clinical study expenditures and ultimately may not succeed.

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

We believe obtaining FDA clearance or 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. 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.

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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 clearance or 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 or other products we may develop.

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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, Johns Hopkins University, MDx Health (formerly Oncomethylome) and Case Western Reserve University. Such arrangements provide us with intellectual property crucial to our product development, including technology that 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 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 Cologua	ard test may not	gain market ac	ceptance by ph	ysicians,	healthcare pa	ayors and ot	thers in the	medical co	mmunity.	The de	gree of
market acceptance	e of our Cologua	ard test will de	pend on a num	ber of fact	tors, includir	ng:					

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

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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

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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.

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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 Chief Operating Officer and Chief Financial Officer, Laura Stoltenberg, our Chief Commercial 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.

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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 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 or any other product we develop could lead to product liability claims based on allegations that one of our products contained a design or manufacturing defect which resulted in the failure to detect the disease for which it was designed. A product 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 product liability insurance would protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product 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.

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.

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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 clearance or approval for our Cologuard test and developing our commercialization strategy 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 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 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

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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, 2012, 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. These facilities are adequate to meet our space requirements with respect to the development and commercialization of an FDA approved product for colorectal cancer screening.

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			
2012						
First quarter	\$	11.24	\$	7.90		
Second quarter		11.15		9.49		
Third quarter		11.69		9.80		
Fourth quarter		12.30		8.87		
2011						
First quarter	\$	7.37	\$	4.91		
Second quarter		8.65		6.87		
Third quarter		9.45		6.00		
Fourth quarter		8.84		6.06		

As of February 28, 2013, there were 52,191,501 shares of our common stock outstanding held by approximately 107 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, 2012, 2011 and 2010 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, 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, an independent registered public accounting firm. The selected historical

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financial data as of December 31, 2008 and for the year then ended are derived from financial statements not included elsewhere in this Form 10-K, which were audited by Ernst & Young, LLP, an independent registered public accounting firm.

The selected historical financial data should be read in conjunction with, and are qualified by reference to "Management's Discussion and Analysis of 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,									
		2012		2011		2010		2009		2008
		(4	Amo	unts in thou	ısan	ds, except p	er sl	hare data)		
Statements of Operations Data:										
Revenue:										
Product royalty fees	\$		\$	20	\$	26	\$	25	\$	(2,234)
License fees		4,144		4,143		5,318		4,733		1,351
Product										16
		4,144		4,163		5,344		4,758		(867)
Cost of revenue				24		24		20		1
Gross profit (loss)		4,144		4,139		5,320		4,738		(868)
Operating expenses:										
Research and development(1)		42,131		21,968		9,023		4,213		2,034
General and administrative(1)		9,900		8,137		6,330		9,549		6,469
Sales and marketing(1)		4,755		2,857		1,793		226		
Restructuring(1)								(3)		602
		56,786		32,962		17,146		13,985		9,105
Loss from operations		(52,642)		(28,823)		(11,826)		(9,247)		(9,973)
		(==,= !=)		(==,===)		(,)		(,,= 11)		(2,2.0)
Investment income		262		169		46		120		232
Interest expense		(41)		(21)		(20)		(1)		
Other income						244				
Net loss	\$	(52,421)	\$	(28,675)	\$	(11,556)	\$	(9,128)	\$	(9,741)
	-	(==, ===)	7	(==,=,=)	-	(,)	-	(,,,	-	(2,1.1-)
Net loss per share:										
Basic and diluted	\$	(0.88)	\$	(0.54)	\$	(0.29)	\$	(0.28)	\$	(0.36)
Busic and direct	Ψ	(0.00)	Ψ	(0.51)	Ψ	(0.2)	Ψ	(0.20)	Ψ	(0.50)
Weighted average common shares outstanding:										
Basic and diluted		59,481		52,512		40,455		32,791		27,212
Dasic and unucu		J7, 4 01		32,312		40,433		32,791		21,212
Polomos Chast Dotos										
Balance Sheet Data: Cash and cash equivalents	\$	13,345	\$	35,781	\$	78,752	\$	21,924	\$	4,937
Marketable securities	Ф	94,776	Ф	57,580	Ф	16,663	Ф		Ф	4,937
Total assets		112,119		96,953		96,515		2,404 25,770		5,898
Total long term debt		1,000		1,000		1,000		1,000		2,090
Total liabilities		13,524		13,458		16,761		19,676		8,331
Stockholders' equity (deficit)		98,595		83,495		79,754		6,094		(2,433)
		70,373		03,473		17,134		0,054		(4,433)

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

	2012	2011	2010	2009	2008
Research and development	\$ 2,396	\$ 1,685	\$ 1,087	\$ 319	\$ 89

General and administrative	2,579	1,622	993	2,308	918
Sales and marketing	518	657	41	4	
Restructuring					3
			18	8	

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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 financial statements and should be read together with our 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 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.

Our Cologuard test is designed to detect pre-cancerous lesions or polyps, and each of the four stages of colorectal cancer. The target sensitivity rate of our Cologuard test for cancer is equal to or greater than 85 percent at a specificity of 90 percent. In preliminary validation studies our test was able to detect cancers at or above this target sensitivity rate and we were also able to demonstrate strong pre-cancer detection.

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 screening provide a significant market opportunity. Assuming a 30-percent test adoption rate and a three-year screening interval, we estimate the potential

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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 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. Patient enrollment included more than 55 colorectal cancer patients and more than 800 pre-cancer patients. All patients provided a sample to be tested with our Cologuard test, and received a FIT test and a colonoscopy. The results of the trial will establish the performance characteristics (sensitivity and specificity) of our Cologuard test.

We are currently in the process of submitting the results of our 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 and the analytical module was submitted in February 2013. We expect to submit the clinical module in the second quarter of 2013.

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.

We plan to focus marketing efforts 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. Six percent of primary care physician prescribers are responsible for 60% of FOBT/FIT volume.

We have generated limited operating revenues since inception and, as of December 31, 2012, we had an accumulated deficit of approximately \$274.2 million. We expect to continue to incur losses for the next several years, and it is possible we may never achieve profitability.

2013 Priorities

Our top priorities for 2013 include completing the FDA submission and CMS coverage application for our Cologuard test. If for any reason our FDA submission is substantially delayed, 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.

In 2013 we also plan to focus on building our manufacturing capacity which includes continuous improvements to our FDA compliant quality management system.

We currently expect that upon initial commercial launch we will process a significant percentage of Cologuard test volume. Accordingly, another 2013 priority for us is establishing a CLIA certified lab facility to process Cologuard tests and provide patient results.

In addition, in 2013 we plan to work toward launch readiness through building and deploying a top notch marketing team and continuing our outreach and education efforts to physicians, third party payors and advocates.

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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 primary focus during 2012 was completing the development of our Cologuard screening test and finishing enrollment for our clinical trial. This led to an increase in research and development costs during the year of \$20.1 million. In addition to accomplishing these goals, we ensured that we were well capitalized to meet our 2013 goals by raising \$57.8 million net of issuance costs in August 2012 through issuing common stock to the public.

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. Total revenue is primarily 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 ends 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 is primarily due to increased efforts focused on completing enrollment for our clinical trial and preparing for our submission to the FDA with significant increases in clinical trial expenses and associated professional fees. 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		nange
Clinical trial expenses	\$ 19.	\$	8.1	\$	11.0
Personnel expenses	7.4	1	5.3		2.1
Lab expenses	4.9)	2.6		2.3
Professional fees	3.0	5	1.1		2.5
Stock-based compensation	2.4	1	1.7		0.7
Other research and development	2.0)	1.2		0.8
License and royalty fees	1.4	1	0.8		0.6
Research collaborations	1.3	3	1.2		0.1
Total research and development expenses	\$ 42.	\$	22.0	\$	20.1

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.

Amounts in millions	2012		2011		Cł	nange
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		Ch	ange
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 \$262,000 for the year ended December 31, 2012 from \$169,000 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 \$41,000 for the year ended December 31, 2012 from \$21,000 for the year ended December 31, 2011. This increase was due to interest expense recognized from a capital lease entered into in 2012.

Comparison of the years ended December 31, 2011 and 2010

Revenue.

Total revenue decreased to \$4.2 million for the year ended December 31, 2011 from \$5.3 million for the year ended December 31, 2010. Total revenue is primarily composed of the amortization of up-front technology license fee payments associated with our amended license agreement with LabCorp and our collaboration, license and purchase agreement with Genzyme. The unamortized LabCorp up-front payment was amortized on a straight-line basis over the exclusive license period, which ended in December 2010. The unamortized Genzyme up-front payment and holdback amounts are being amortized on a straight-line basis over the initial Genzyme collaboration period, which ends in January 2014. Revenues also include royalties on LabCorp's sales of ColoSure as well as charges for our third-party royalty reimbursement obligation to LabCorp which are recorded as reductions to revenue under financial accounting guidance.

The decrease in total revenue for the year ended December 31, 2011 when compared to the same period of 2010 was primarily the result of the LabCorp up-front payment being fully amortized into revenue at December 31, 2010.

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Research and development expenses.

Research and development expenses increased to \$22.0 million for the year ended December 31, 2011 from \$9.0 million for the year ended December 31, 2010. The increase in research and development expenses was primarily to support our efforts to develop and seek FDA approval or clearance for our Cologuard test. This included hiring additional personnel and funding lab operation expenses.

Amounts in millions	2011		2010		Ch	ange
Clinical trial expenses	\$	8.1	\$	0.1	\$	8.0
Personnel expenses		5.3		2.8		2.5
Lab expenses		2.6		1.5		1.1
Stock-based compensation		1.7		1.1		0.6
Other research and development		1.2		0.5		0.7
Research collaborations		1.2		1.5		(0.3)
Professional fees		1.1		1.1		
License and royalty fees		0.8		0.4		0.4
Total research and development expenses	\$	22.0	\$	9.0	\$	13.0

General and administrative expenses.

General and administrative expenses increased to \$8.1 million for the year ended December 31, 2011, compared to \$6.3 million for the year ended December 31, 2010. The increase in general and administrative expenses was primarily a result of hiring additional personnel and supporting the overall growth of the Company.

Amounts in millions	2011		2010		Ch	ange
Legal and professional fees	\$	2.8	\$	2.1	\$	0.7
Personnel expenses		1.8		1.6		0.2
Stock-based compensation		1.6		1.0		0.6
Other general and administrative		1.0		1.0		
Facility costs		0.9		0.6		0.3
Total general and administrative expenses	\$	8.1	\$	6.3	\$	1.8

Sales and marketing expenses.

Sales and marketing expenses increased to \$2.9 million for the year ended December 31, 2011 from \$1.8 million for the year ended December 31, 2010. The increase in sales and marketing expense was a result of hiring additional marketing personnel.

Amounts in millions	2011		2010		Change	
Personnel expenses	\$	1.1	\$	0.2	\$	0.9
Professional fees		0.9		1.5		(0.6)
Stock-based compensation		0.7				0.7
Other sales and marketing		0.2		0.1		0.1
Total sales and marketing expenses	\$	2.9	\$	1.8	\$	1.1

Investment income. Investment income increased to \$169,000 for the year ended December 31, 2011 from \$46,000 for the year ended December 31, 2010. This increase was primarily due to an overall higher cash and marketable securities balance during the year ended December 31, 2011 as compared to the same period of 2010.

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Interest expense. Interest expense increased to \$21,000 for the year ended December 31, 2011 from \$20,000 for the year ended December 31, 2010. This slight increase was due to additional interest expense recognized from our loan from the Wisconsin Department of Commerce.

Other income. There was no other income for the year ended December 31, 2011 compared to \$244,000 for the year ended December 31, 2010. This decrease was due to the receipt of a Qualifying Therapeutic Discover Project grant issued by the federal government in 2010 which was not available in 2011.

Liquidity and Capital Resources

We have financed our operations since inception primarily through private and public offerings of our common stock, cash received from LabCorp in connection with our license agreement with LabCorp, and cash received in January 2009 from Genzyme in connection with the Genzyme strategic transaction. As of December 31, 2012, we had approximately \$13.3 million in unrestricted cash and cash equivalents and approximately \$94.8 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.

Net cash used in operating activities was \$44.2 million, \$27.5 million, and \$13.4 million for the years ended December 31, 2012, 2011 and 2010, respectively. The principal use of cash in operating activities for each of the years ended December 31, 2012, 2011 and 2010 was to fund our net loss. The increase in net cash used in operating activities for the year ended December 31, 2012 as compared to the year ended December 31, 2011 was primarily due to increased research and development activities. The increase for the year ended December 31, 2011 as compared to the year ended December 31, 2010, was also primarily due to increases in 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 \$38.4 million, \$43.4 million, and \$14.9 million for the years ended December 31, 2012, 2011, and, 2010, respectively. The decrease in cash used in investing activities for the year ended December 31, 2012 when compared to the same period in 2011 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 \$0.7 million for the year ended December 31, 2012, compared to net cash used in investing activities of \$2.1 million for the year ended December 31, 2011 which was primarily the result of a decrease in purchases of property and equipment. Excluding the impact of purchases and maturities of marketable securities, net cash used in investing activities for the year ended December 31, 2010 was primarily the result of purchases of property and equipment

Net cash provided by financing activities was \$60.0 million, \$27.9 million and \$85.2 million for the years ended December 31, 2012, 2011 and 2010, respectively. 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 the 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. The decrease in cash provided by

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financing activities for the year ended December 31, 2011 when compared to the same period in 2010 was primarily the result of a decrease in proceeds from the sale of common stock from \$82.3 million in 2010 to \$27.2 million in 2011. Excluding the impact of the sale of common stock, the decrease in net cash provided by financing activities was primarily due to a decrease in proceeds from the Genzyme strategic transaction from \$1.9 million for the year ended December 31, 2010 to none for the year ended December 31, 2011, and an increase in proceeds from the exercise of common stock options from \$0.5 million for the year ended December 31, 2010 to \$0.7 million for the year ended December 31, 2011, slightly offset by the decrease in restricted cash of \$0.5 million during the year ended December 31, 2010.

We expect that cash and cash equivalents and marketable securities on hand at December 31, 2012, 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.

In order to complete our clinical trial for our Cologuard test, we expect to spend approximately \$3.0 million to \$4.0 million in 2013. Expenditures include costs for personnel, consultants, lab testing and clinical trial sites. We believe we have enough cash on hand to fund these planned clinical trial expenditures. 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.

The table below reflects our estimated fixed obligations and commitments as of December 31, 2012:

			Payments Due by Period							
Description	,	Γotal		s Than e Year	1 - 3	3 Years	3 - :	5 Years		re Than Years
				(in Thousands)						
Long-term debt obligations(1)	\$	1,158	\$		\$	270	\$	463	\$	425
Obligations under license and collaborative agreements(2)		3,887		496		592		512		2,287
Operating lease obligations		976		527		449				
Capital lease obligations(1)		1,131		381		750				
Total	\$	7,152	\$	1,404	\$	2,061	\$	975	\$	2,712

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

We have entered into license and collaborative agreements with Johns Hopkins University, the Mayo Foundation, Genzyme, MDx Health (formerly Oncomethylome Sciences), and Hologic, Inc. See Note 7 in the notes to the 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 facility at our headquarters in Madison, WI. Capital leases reflect obligations under a capital equipment leasing arrangement.

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Net Operating Loss Carryforwards

As of December 31, 2012, we had federal and state net operating loss carryforwards of approximately \$250.7 million and \$158.7 million, respectively. The Company also had federal and state research tax credit carryforwards of approximately \$4.2 million and \$9.0 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 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. On June 27, 2007, we entered into an amendment to our exclusive license agreement with LabCorp, which, among other modifications to the terms of the license, extended the exclusive license period of the license with LabCorp from August 2008 through December 2010. Accordingly, we amortized the remaining deferred revenue balance at the time of the amendment of \$4.7 million on a straight-line basis over the remaining exclusive license period, which ended in December 2010.

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

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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, 2012.

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 recorded an accrual of \$0.4 million at December 31, 2012 and 2011 for clinical trial costs related to site payments. We do not expect that actual amounts paid for these patient costs will materially differ from the amounts accrued.

Stock-Based Compensation.

All stock-based payments, including grants of employee stock options, restricted stock and restricted stock units and shares purchased under an employee stock purchase plan (ESPP) (if certain parameters are not met), are recognized in the financial statements based on their fair values. The 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.

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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 in Note 7 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 \$103.9 million and \$84.6 million valuation allowance at December 31, 2012 and 2011 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 \$19.3 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 is effective for annual reporting periods beginning on or after January 1, 2013, and interim periods within those annual periods. The adoption of this ASU is not expected to have a material impact on our financial statements.

Off-Balance Sheet Arrangements

As of December 31, 2012, 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, 2012 and December 31, 2011 were classified as available-for-sale. We place our cash equivalents and marketable securities with high-quality financial institutions, limit the amount of credit exposure to any one institution and have established investment guidelines relative to diversification and maturities designed to maintain safety and liquidity.

Based on a hypothetical ten percent adverse movement in interest rates, the potential losses in future earnings, fair value of risk-sensitive financial instruments, and cash flows are immaterial, although the actual effects may differ materially from the hypothetical analysis.

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Item 8. Financial Statements and Supplementary Data

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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders Exact Sciences Corporation Madison, Wisconsin

We have audited the accompanying balance sheets of Exact Sciences Corporation (the "Company") as of December 31, 2012 and 2011 and the related statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012. 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 financial statements referred to above present fairly, in all material respects, the financial position of Exact Sciences Corporation at December 31, 2012 and 2011, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, 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, 2012, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 1, 2013 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP Milwaukee, Wisconsin March 1, 2013

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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders Exact Sciences Corporation Madison, Wisconsin

We have audited Exact Sciences Corporation's (the "Company") internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control Integrated Framework* 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 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, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Exact Sciences Corporation as of December 31, 2012 and 2011, and the related statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012 and our report dated March 1, 2013 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP Milwaukee, Wisconsin March 1, 2013

EXACT SCIENCES CORPORATION

Balance Sheets

(Amounts in thousands, except share data)

	De	cember 31, 2012	De	cember 31, 2011
ASSETS				
Current Assets:				
Cash and cash equivalents	\$	13,345	\$	35,781
Marketable securities		94,776		57,580
Prepaid expenses and other current assets		593		1,034
Total current assets		108,714		94,395
Property and Equipment, at cost:				
Laboratory equipment		4,051		2,314
Office and computer equipment		824		729
Leasehold improvements		283		288
Furniture and fixtures		28		23
		5,186		3,354
Less Accumulated depreciation and amortization		(1,781)		(796)
· · · · · · · · · · · · · · · · · · ·		() /		(11 1)
		3,405		2,558
		3,403		2,330
	¢	112 110	ф	06.052
	\$	112,119	\$	96,953
A A A DAY AMARIA A A DA GARAGO CANANA A DADA CANANA A				
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current Liabilities:		0 < 70		
Accounts payable	\$	3,652	\$	765
Accrued expenses		3,327		3,069
Capital lease obligation, current portion		333		4.1.40
Deferred license fees, current portion		4,143		4,143
Total current liabilities		11,455		7,977
Long term debt		1,000		1,000
Long term accrued interest		63		42
Capital lease obligation, less current portion		711		
Deferred license fees, less current portion		295		4,439
Commitments and contingencies				
Stockholders' Equity:				
Preferred stock, \$0.01 par value				
Authorized 5,000,000 shares				
Issued and outstanding none at December 31, 2012 and 2011				
Common stock, \$0.01 par value				
Authorized 100,000,000 shares		620		=
Issued and outstanding 63,909,800 and 56,624,763 shares at December 31, 2012 and 2011, respectively		639		566
Additional paid-in capital		372,123		304,767
Other comprehensive income (loss)		78		(14)
Accumulated deficit		(274,245)		(221,824)
Total stockholders' equity		98,595		83,495
	\$	112,119	\$	96,953

EXACT SCIENCES CORPORATION

Statements of Operations

(Amounts in thousands, except per share data)

Year Ended December 31,

	Tear Enaca December 31,				•,	
		2012		2011		2010
Revenue:						
Product royalty fees	\$		\$	20	\$	26
License fees		4,144		4,143		5,318
		4,144		4,163		5,344
Cost of revenue:		ĺ		ĺ		,
Product royalty fees				24		24
Gross profit		4,144		4,139		5,320
Operating expenses:		.,		.,		0,020
Research and development		42,131		21,968		9,023
General and administrative		9,900		8,137		6,330
Sales and marketing		4,755		2,857		1,793
		,		,		,
		56,786		32,962		17,146
		50,700		32,702		17,110
Loss from operations		(52,642)		(28,823)		(11,826)
Investment income		262		169		46
Interest expense		(41)		(21)		(20)
Other income		(41)		(21)		244
other meone						211
Net loss	\$	(52,421)	\$	(20 675)	\$	(11 556)
Net ioss	Ф	(32,421)	Ф	(28,675)	Ф	(11,556)
		(0.00)			_	(0.00)
Net loss per share basic and diluted	\$	(0.88)	\$	(0.54)	\$	(0.29)
Weighted average common shares outstanding basic and diluted		59,481		52,512		40,455

EXACT SCIENCES CORPORATION

Statements of Comprehensive Loss

(Amounts in thousands)

	December 31,					
(In Thousands)		2012		2011		2010
Net loss	\$	(52,421)	\$	(28,675)	\$	(11,556)
Other comprehensive income (loss), net of tax:						
Unrealized gain (loss) on available-for-sale investments		92		(15)		2
Comprehensive loss	\$	(52,329)	\$	(28,690)	\$	(11,554)

EXACT SCIENCES CORPORATION

Statements of Stockholders' Equity

(Amounts in thousands, except share data)

	Common Stock						Total	
	Number of Shares	\$0.01 Par Value	Additional Paid In Capital	Othe Compreh Incon (Loss	ensive ne	Accumulated Deficit		ockholders' (Deficit) Equity
Balance, January 1, 2010	35,523,140		_		(1)		\$	6,094
• •						,		
Issuance of common stock, net of issuance costs of \$5.6 million	15,700,000	157	82,170					82,327
Exercise of common stock options and warrants	528,937	5						466
Issuance of common stock to fund the Company's 2009 401(k)	,							
match	15,460	1	64					65
Compensation expense related to issuance of stock options and								
restricted stock awards	337,383	4	, ,					2,121
Purchase of employee stock purchase plan shares	58,709		128					128
Expense related to warrants (Note 4)			107					107
Net loss						(11,556)		(11,556)
Other comprehensive income					2			2
Balance, December 31, 2010	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)
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)
Other comprehensive income					92			92
Balance, December 31, 2012	63,909,800	\$ 639	\$ 372,123	\$	78	\$ (274,245)	\$	98,595

EXACT SCIENCES CORPORATION

Statements of Cash Flows

(Amounts in thousands, except share data)

	Year Ended December 31,					
		2012		2011		2010
Cash flows from operating activities:						
Net loss	\$	(52,421)	\$	(28,675)	\$	(11,556)
Adjustments to reconcile net loss to net cash used in operating activities:						
Depreciation and write-offs of fixed assets		985		411		230
Stock-based compensation		5,493		3,964		2,121
Amortization of deferred license fees		(4,144)		(4,143)		(5,318)
Warrant licensing expense		152		107		107
Restricted stock licensing expense		1,000				
Amortization of premium on short-term investments		532		360		37
Changes in assets and liabilities:						
Prepaid expenses and other current assets		441		(788)		238
Accounts payable		2,887		(263)		873
Accrued expenses		899		1,542		795
Accrued interest		21		21		20
Third party royalty obligation						(988)
Net cash used in operating activities		(44,155)		(27,464)		(13,441)
Cash flows from investing activities:		(1 1, 1 2 2)		(=1,101)		(,)
Purchases of marketable securities		(96,047)		(87,017)		(24,498)
Maturities of marketable securities		58,411		45,725		10,204
Purchases of property and equipment		(681)		(2,115)		(626)
Net cash used in investing activities		(38,317)		(43,407)		(14,920)
Cash flows from financing activities:		(= 0,= = 1)		(10,101)		(-1,,,_0)
Proceeds from Genzyme Collaboration, License and Purchase Agreement						1,896
Proceeds from sale of common stock, net of issuance costs		57,755		27,215		82,327
Proceeds from exercise of common stock options and stock purchase plan		2,388		685		466
Decrease in restricted cash		,				500
Payments on capital lease obligations		(107)				
Net cash provided by financing activities		60,036		27,900		85,189
Net increase (decrease) in cash and cash equivalents		(22,436)		(42,971)		56,828
Cash and cash equivalents, beginning of period		35,781		78,752		21,924
Cash and cash equivalents, end of period	\$	13,345	\$	35,781	\$	78,752
Supplemental disclosure of non-cash investing and financing activities:						
Unrealized gain (loss) on available-for-sale investments	\$	92	\$	(15)	\$	(2)
Issuance of 32,872, 27,872, and 15,460 shares of common stock to fund the Company's 401(k)						
matching contribution for 2011, 2010, and 2009, respectively	\$	274	\$	169	\$	65
Conversion of accrued expenses into 63,611, 51,857 and 58,709 shares of common stock in						
connection with the Company's ESPP for 2012, 2011 and 2010, respectively	\$	367	\$	291	\$	128
Laboratory equipment acquired with a capital lease	\$	1,151	\$		\$	

EXACT SCIENCES CORPORATION

Notes to 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

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, 2012 and 2011.

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, 2012 and December 31, 2011 the Company's investments were comprised of fixed income investments and all were deemed available-for-sale. The objectives of the Company's investment strategy are to provide liquidity and safety of principal while striving to achieve the highest rate of return consistent with these two objectives. The Company's investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer. Investments in 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 \$6,231, \$419, and \$13,149 for the years ended December 31, 2012, 2011, and 2010 respectively. Unrealized gains on investments recorded in other comprehensive income were \$77,808 and \$721 for the years ended

Notes to Financial Statements (Continued)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

December 31, 2012 and December 31, 2010. Unrealized losses on investments recorded in other comprehensive income were \$13,784 for the year ended December 31, 2011.

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

	A	mortized	December 3 Gains in accumulated Other omprehensive	Losses in Accumulated Other Comprehensive	Es	timated
(In thousands)		Cost	Income	Income	Fa	ir Value
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
Total available-for-sale securities	\$	94,698	\$ 78	\$	\$	94,776

Available-for-sale securities at December 31, 2011 consist of the following:

			December				
	A	mortized	Gains in Accumulated Other Comprehensive	Accu	sses in mulated Other orehensive	Es	timated
(In thousands)		Cost	Income	In	come	Fa	ir Value
U.S. government agency							
securities	\$	28,004	\$	\$	(10)	\$	27,994
Corporate bonds		19,124			(2)		19,122
Certificates of deposit		9,467			(2)		9,465
Commercial paper		999					999
Total available-for-sale securities	\$	57,594	\$	\$	(14)	\$	57,580

Property and Equipment

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

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

Depreciation expense for the years ended December 31, 2012, 2011, and 2010 was \$1.0 million, \$0.4 million, and \$0.2 million, respectively.

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

EXACT SCIENCES CORPORATION

Notes to Financial Statements (Continued)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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, 2012, 2011 and 2010 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 recorded an accrual of \$0.4 million at December 31, 2012 and 2011 for clinical trial costs related to site payments. We do not expect that actual amounts paid for these patient costs will materially differ from the amounts accrued.

Net Loss Per Share

Basic net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted average common shares outstanding during the period. Basic and diluted net loss per share is the same because all outstanding common stock equivalents have been excluded, as they are anti-dilutive as a result of the Company's losses.

The following potentially issuable common shares were not included in the computation of diluted net loss per share because they would have an anti-dilutive effect due to net losses for each period (amounts are in thousands):

	2012	2011	2010
Shares issuable upon exercise of stock options	6,182	6,454	6,217
Shares issuable upon exercise of outstanding warrants(1)	325	325	825
Shares issuable upon the release of restricted stock awards	814	401	264
Shares issuable upon exercise of restricted stock awards related to licensing agreement	73		
	7,394	7,180	7,306

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. At December 31, 2010 represents represents warrants to purchase 750,000 shares of common stock issued under a licensing agreement and warrants to purchase 75,000 shares of common stock issued under a consulting agreement.

Notes to Financial Statements (Continued)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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. On June 27, 2007, the Company entered into an amendment to its exclusive license agreement with LabCorp (the "Second Amendment") that, among other modifications to the terms of the license, extended the exclusive license period from August 2008 to December 2010, subject to carve-outs for certain named organizations. Accordingly, the Company amortized the remaining deferred revenue balance resulting from its license agreement with LabCorp at the time of the Second Amendment (\$4.7 million) on a straight-line basis over the remaining exclusive license period, which ended in December 2010.

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 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, 2012 and December 31, 2011. The Company recognized \$5.3 million in license fee revenue in connection with the amortization of the up-front payments from LabCorp and Genzyme during the year ended December 31, 2010.

EXACT SCIENCES CORPORATION

Notes to Financial Statements (Continued)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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, 2012 and no product royalty fees were recorded. Product royalty fees were \$20,000 and \$26,000 for the years ended December 31, 2011 and 2010, respectively.

Other Income

The Company recognizes other income as earned. Other income consists of income received related to activities not related to the Company's core business operations. The Company had no other income during the years ended December 31, 2012 and 2011. During 2010, the Company received notice that it had been awarded a total cash grant of \$244,479 under the Qualifying Therapeutic Discovery Project program administered under Section 48D of the Internal Revenue Code, all of which relates to qualifying expenses that have previously been incurred. The Company recognized the full amount of the grant as other income for the year ended December 31, 2010 as the Company has incurred all of the qualifying expenses and the amount had been received in full.

Advertising Costs

The Company expenses the costs of media advertising at the time the advertising takes place. The Company expensed approximately \$57,400, \$110,000 and \$68,100 of media advertising during the years ended December 31, 2012, 2011, and 2010, 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. This guidance was adopted in 2009 for non-financial assets and liabilities. 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 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, 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.

		Fair Value Measurement at December 31, 2012					
		Using:					
Description	r Value at ember 31, 2012		Quoted Prices in Active rkets for Identical Assets (Level 1)	O	ignificant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Cash equivalents(1)	\$ 8,405	\$	8,405	\$		\$	
Available-for-Sale							
Marketable securities							
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		
Total	\$ 103,181	\$	8,405	\$	94,776	\$	

⁽¹⁾ The \$8.4 million of cash equivalents above is included in the cash and cash equivalents balance of \$13.3 million at December 31, 2012.

EXACT SCIENCES CORPORATION

Notes to Financial Statements (Continued)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

The following table presents the Company's fair value measurements as of December 31, 2011 along with the level within the fair value hierarchy in which the fair value measurements in their entirety fall. Amounts in the table are in thousands.

			Fair Value Measurement at December 31, 2011						
			Using:						
D and dis	Decen	Value at	`	in Active sets for Identical Assets	Obse In	puts	Significant Unobservable Inputs		
Description		011	ф	(Level 1)	,	vel 2)	(Level 3)		
Cash equivalents(1)	\$	35,385	\$	35,385	3		\$		
Available-for-Sale									
Marketable securities									
U.S. government agency									
securities		27,994				27,994			
Certificates of deposit		9,465				9,465			
Corporate bonds		19,122				19,122			
Commercial paper		999				999			
Total	\$	92,965	\$	35,385	\$	57,580	\$		

(1) The \$35.4 million of cash equivalents above is included in the cash and cash equivalents balance of \$35.8 million at December 31, 2011.

As of December 31, 2012 and 2011 there were available for sale securities in a continuous unrealized loss position for less than twelve months where the total unrealized losses were \$4,800 and \$28,500 respectively. At December 31, 2012 and 2011 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, 2012 (in thousands):

	Cost	Fa	ir Value	
Due in one year or less	\$ 58,882	\$	58,922	
Due after one year through two years	35,816		35,854	
	\$ 94,698	\$	94,776	

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, 2012, 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 \$13.1 million. The Company has not experienced any losses in such accounts and management believes it is not exposed to any significant credit risk.

EXACT SCIENCES CORPORATION

Notes to Financial Statements (Continued)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Subsequent Events

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

Recent Accounting Pronouncements

In 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 is effective for annual reporting periods beginning on or after January 1, 2013, and interim periods within those annual periods. The adoption of this ASU is not expected to have a material impact on our financial statements.

Reclassifications

Certain prior year amounts have been reclassified to conform to the current year presentation in the financial statements and accompanying notes to the 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. As part of the transaction on January 27, 2009, the Company entered into an Assignment, Sublicense, Consent and Eighth Amendment to License Agreement (the "JHU Amendment") with Genzyme and Johns Hopkins University ("JHU") (collectively, with the licenses and assignment described herein, the "Genzyme Strategic Transaction"), whereby the Company assigned its rights under the license agreement between the Company and JHU dated March 25, 2003, as amended (the "JHU Agreement") to Genzyme. Pursuant to the JHU Amendment, Genzyme sublicensed to the Company the intellectual property subject to the JHU Agreement for colorectal cancer detection and stool-based disease detection, including the BEAMing technology for the detection of colorectal cancer. Under the JHU Amendment, the Company and Genzyme will share in the royalty and annual payment obligations to JHU.

EXACT SCIENCES CORPORATION

Notes to Financial Statements (Continued)

(3) GENZYME STRATEGIC TRANSACTION (Continued)

Also as part of the Genzyme Strategic Transaction, the Company entered into an Amended and Restated License Agreement (the "Restated License") with Genzyme on January 27, 2009, which amended and restated the License Agreement between the parties dated March 25, 1999, effective as of January 27, 2009. Pursuant to the Restated License, Genzyme granted to the Company a non-exclusive license to use technology related to the use of certain genes, specifically APC and p53, and methodologies related thereto. In exchange for the license, which continues until the expiration of the last to expire licensed patent, the Company agreed to pay Genzyme royalties based on net revenues received from performing tests that incorporate the licensed technology and sales of reagents and diagnostic test kits that incorporate the licensed technology, as well as certain minimum royalties, milestone payments and maintenance fees.

Pursuant to the Genzyme Strategic Transaction, Genzyme agreed to pay an aggregate of \$18.5 million to the Company, of which \$16.65 million was paid at closing and \$1.85 million (the "Holdback Amount") was subject to a holdback by Genzyme to satisfy certain potential indemnification obligations of the Company. Genzyme also agreed to pay a double-digit royalty to the Company on income received by Genzyme as a result of any licenses or sublicenses to third parties of the Transferred Intellectual Property or the Retained Intellectual Property in any field other than the Genzyme Core Field or the Company Field.

The Company's on-going performance obligations to Genzyme under the CLP, including the obligation to deliver certain intellectual property improvements to Genzyme, if improvements are made during the initial five year collaboration period, were deemed to be undelivered elements of the CLP Agreement on the date of closing. Accordingly, the Company deferred the initial \$16.65 million in cash received at closing and is amortizing that up-front payment on a straight line basis into the License Fee Revenue line item in its statements of operations over the initial five year collaboration period. The Company received the first holdback amount of \$962,000, which included accrued interest, due from Genzyme during the first quarter of 2010. The Company received the second holdback amount of \$934,250 which included accrued interest due, from Genzyme during the third quarter of 2010. The amounts were deferred and 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, \$4.1 million, and \$4.0 million in license fee revenue in connection with the amortization of the up-front payments and holdback amounts from Genzyme during the years ended December 31, 2012, 2011, and 2010, respectively.

EXACT SCIENCES CORPORATION

Notes to Financial Statements (Continued)

(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 licenses 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 also is 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 agreement. In addition to the license to intellectual property owned by MAYO, the Company will receive product development and research and development efforts from MAYO personnel. The Company determined that the payments made for intellectual property should not be capitalized as the future economic benefit derived from the transactions is uncertain. The Company is also liable to make royalty payments to MAYO on potential future net sales of any products developed from the licensed technology.

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. The total value of the warrants was calculated to be \$2.1 million and a non-cash charge of \$1.7 million was recognized as research and development expense in the second quarter of 2009 and the remaining \$0.4 million non-cash charge is being recognized straight-line over the four year vesting 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.

Notes to Financial Statements (Continued)

(4) MAYO LICENSE AGREEMENT (Continued)

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 was fully exercised.

As of December 31, 2012 the warrant grant to purchase 250,000 shares remained outstanding and unexercised.

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 \$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 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 FDA trial 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 \$1.2 million and has made payments of \$1.1 million for the year ended December 31, 2012. The Company has recorded an estimated liability in the amount of \$127,000 for research and development efforts as of December 31, 2012. The Company incurred charges of \$1.4 million and made payments of \$1.4 million for the year ended December 31, 2011. The Company recorded an estimated liability in the amount of \$53,000 for research and development efforts at December 31, 2011.

Amendments May 2012

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 licensing expense during the twelve months ended December 31, 2012 in connection with the restricted stock grant due to the uncertainty in the license providing a future benefit.

Notes to Financial Statements (Continued)

(4) MAYO LICENSE AGREEMENT (Continued)

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 the 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 these milestones will be met; therefore, the milestone payments have not been recorded as a liability. The Company evaluates the status of the milestone payments at each reporting date to determine if a liability should be recorded for the milestone payment.

(5) ISSUANCES OF COMMON STOCK

On April 19, 2010, the Company completed an underwritten public offering of 4.2 million shares of common stock at a price of \$4.50 per share to the public. The Company received approximately \$17.6 million of net proceeds from the offering, after deducting \$1.3 million for the underwriting discount and other stock issuance costs paid by the Company. The Company expects to use the net proceeds from the offering for general corporate and working capital purposes, including the funding of strategic initiatives that the Company may undertake from time to time, for product development and the furtherance of the Company's efforts to obtain FDA clearance in its sDNA colorectal cancer screening product.

On November 10, 2010, the Company completed an underwritten public offering of 11.5 million shares of common stock at a price of \$6.00 per share to the public. The Company received approximately \$64.7 million of net proceeds from the offering, after deducting \$4.3 million for the underwriting discount and other stock issuance costs paid by the Company.

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.

(6) STOCK-BASED COMPENSATION

Stock-Based Compensation Plans

The Company maintains the 2010 Omnibus Long-Term Incentive Plan, the 2010 Employee Stock Purchase Plan, the 2000 Stock Option and Incentive Plan and the 2000 Employee Stock Purchase 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

Notes to Financial Statements (Continued)

(6) STOCK-BASED COMPENSATION (Continued)

expire ten years from the date of grant. Grants made from the 2000 Option Plan generally vest over a period of three to four years.

The 2000 Option Plan was administered by the compensation committee of the Company's board of directors, which selected the individuals to whom equity-based awards would be granted and determined the option exercise price and other terms of each award, subject to the provisions of the 2000 Option Plan. The 2000 Option Plan provides that upon an acquisition of the Company, the vesting of 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, 2012, options to purchase 4,889,933 shares and 54,000 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, 2012, options to purchase 1,292,063 shares were outstanding under the 2010 Stock Plan, and 759,955 shares of restricted stock and restricted stock units were outstanding. At December 31, 2012, there were 1,489,918 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, 2012, there were 184,532 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

Notes to Financial Statements (Continued)

(6) STOCK-BASED COMPENSATION (Continued)

fair market value, as defined under the 2010 Purchase Plan and no employee can purchase more than \$25,000 of Company common stock under the 2010 Purchase Plan in any calendar year. Rights granted under the 2010 Purchase Plan terminate upon an employee's voluntary withdrawal from the 2010 Purchase Plan at any time or upon termination of employment. At December 31, 2012, there were 115,468 cumulative shares issued under the 2010 Purchase Plan, and 63,611 shares were issued in the year ended December 31, 2012, as follows:

	Number of	Weig	hted Average
Offering period ended	Shares	Pric	ce per Share
April 30, 2012	34,336	\$	5.67
October 31, 2012	29,275	\$	5.89

Stock-Based Compensation Expense

The Company recorded approximately \$5.5 million in stock-based compensation expense during the year ended December 31, 2012, in connection with the amortization of restricted stock and restricted stock unit awards, stock purchase rights granted under the Company's employee stock purchase plans and stock options granted to employees and non-employee directors. The Company recorded \$4.0 million in stock-based compensation expense during the year ended December 31, 2011 in connection with the amortization of restricted stock and restricted stock unit awards, stock purchase rights granted under the Company's employee stock purchase plans and stock options granted to employees and non-employee directors. The Company recorded approximately \$2.1 million in stock-based compensation expense during the year ended December 31, 2010 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, 2012, 2011, and 2010 are as follows, and amounts included in the table are in thousands:

	December 31,					
		2012		2011		2010
Research and development	\$	2,396	\$	1,685	\$	1,087
General and administrative		2,579		1,622		993
Sales and marketing		518		657		41

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 will have 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.

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

Notes to Financial Statements (Continued)

(6) STOCK-BASED COMPENSATION (Continued)

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 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 Company's forfeiture rate used in 2012 is 1.4%.

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,			
	2012	2011	2010	
Option Plan Shares				
Risk-free interest rates	0.81% - 1.00%	0.88% - 2.3%	1.17% - 2.69%	
Expected term (in years)	6	6	6	
Expected volatility	85% - 92%	92%	91% - 92%	
Dividend yield	0%	0%	0%	
Weighted average fair value per share of options granted during the period	\$6.90	\$4.78	\$3.07	
ESPP Shares				
Risk-free interest rates	0.18% - 0.30%	0.13% - 0.61%	0.16% - 0.38%	
Expected term (in years)	0.5 - 2	0.5 - 2	0.5 - 2	
Expected volatility	34.0% - 54.9%	48% - 63%	53% - 127%	
Dividend yield	0%	0%	0%	
Weighted average fair value per share of stock purchase rights granted during the				
period	\$2.84	\$2.83	\$2.03	
51				

EXACT SCIENCES CORPORATION

Notes to 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 2012, 2011 and 2010 is as follows:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Iı	ggregate ntrinsic 'alue(1)
(Aggregate intrinsic value in thousands)	Shares	Trice	Term (Tears)	·	aruc(1)
(1-88) egane in mote value in mousands)					
Outstanding, January 1, 2010	5,912,019	\$ 1.76			
Granted	518,566	4.09			
Exercised	(213,386)	2.19			
Outstanding, December 31, 2010	6,217,199	1.93			
Granted	814,424	6.26			
Exercised	(325,477)	2.11			
Forfeited	(252,502)	7.15			
Outstanding, December 31, 2011	6,453,644	2.27			
Granted	499,198	9.18			
Exercised	(691,471)	3.45			
Forfeited	(79,375)	7.60			
Outstanding, December 31, 2012	6,181,996	\$ 2.62	6.6	\$	49,439
Exercisable, December 31, 2012	4,730,475	\$ 1.72	6.2	\$	42,154
*					•
Vested and expected to vest, December 31, 2012	6,175,107	\$ 2.66	6.6	\$	49,430
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The aggregate intrinsic value of options outstanding at December 31, 2012 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 6,100,211 options that had exercise prices that were lower than the \$10.59 market price of our common stock at December 31, 2012. The aggregate intrinsic value of options exercisable at December 31, 2012 is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for the 4,655,475 options that had exercise prices that were lower than the \$10.59 market price of our common stock at December 31, 2012. The total intrinsic value of options exercised during the years ended December 31, 2012, 2011 and 2010 was \$4.5 million, \$1.9 million, \$0.4 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, 2012. The exercise price of the warrant is \$0.01.

Notes to 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, 2012, 2011 and 2010 is as follows:

		Weighted Average
	Restricted Shares	Grant Date Fair Value
Outstanding, January 1, 2010	40,000	\$ 1.72
Granted	326,197	5.73
Released	(102,567)	2.94
Outstanding, December 31, 2010	263,630	6.20
<u> </u>		
Granted	335,716	6.06
Released	(192,856)	5.89
Forfeited	(5,000)	5.61
Outstanding, December 31, 2011	401,490	6.24
<u> </u>		
Granted	602,268	9.47
Released	(185,116)	5.67
Forfeited	(4,687)	7.69
Outstanding, December 31, 2012	813,955	\$ 8.51

As of December 31, 2012, there was approximately \$9.8 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under all equity compensation plans. Total unrecognized compensation cost will be adjusted for future changes in forfeitures. The Company expects to recognize that cost over a weighted average period of 2.4 years.

The Company received approximately \$2.4 million, \$0.7 million and \$0.5 million from stock option exercises during the years ended December 31, 2012, 2011 and 2010, respectively. During the years ended December 31, 2012 and 2011, 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 \$0.4 million and \$0.3 million, respectively. During the year ended December 31, 2010, 58,709 shares of common stock were issued under the Company's 2000 Purchase Plan resulting in proceeds to the Company of \$0.1 million.

Notes to 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, 2012:

		Outstanding Weighted	Exercisable				
Exercise Price	Number of Options	Average Remaining Contractual Life (Years)	Ay Ex	eighted verage xercise Price	Number of Options	Ay Ex	eighted verage xercise Price
\$ - \$1.00	3,780,000	6.2	\$	0.83	3,545,625	\$	0.83
\$1.01 - \$2.00	98,500	6.3	\$	1.41	27,250	\$	1.39
\$2.01 - \$3.00	786,250	6.3	\$	2.80	629,999	\$	2.79
\$3.01 - \$4.00	124,566	7.5	\$	3.51	94,896	\$	3.48
\$4.01 - \$5.00	341,183	6.7	\$	4.27	193,433	\$	4.36
\$5.01 - \$7.00	269,625	8.2	\$	5.85	56,438	\$	5.98
\$7.01 - \$9.00	205,174	7.8	\$	8.15	97,834	\$	8.21
\$9.01 - \$14.00	576,698	7.9	\$	9.72	85,000	\$	12.79
	6,181,996	6.6	\$	2.62	4,730,475	\$	1.72

During the first quarter of 2012, the Company granted a total of 262,500 restricted stock units to certain executives that will vest 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 are most likely to vest based on the probability of what performance conditions will be met. The expense for the fair value of the awards that are expected to vest, is being recognized ratably over the vesting period.

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, 2012, as follows:

Shares reserved for issuance	
2010 Option Plan	1,489,918
2010 Purchase Plan	184,532
	1.674.450

(7) COMMITMENTS AND CONTINGENCIES

Operating Leases

During November 2009, the Company entered into a five year lease for a 17,500 square feet 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.

EXACT SCIENCES CORPORATION

Notes to Financial Statements (Continued)

(7) COMMITMENTS AND CONTINGENCIES (Continued)

Future minimum payments under operating leases as of December 31, 2012 are as follows. Amounts included in the table are in thousands.

Year Ending December 31,	
2013	\$ 527
2014	449
2015	
2016	
2017	
Thereafter	
Total lease obligations	\$ 976

Rent expense included in the accompanying statements of operations was approximately \$0.4 million, \$0.3 million, and \$0.2 million for the years ended December 31, 2012, 2011 and 2010, respectively.

During the fourth quarter of 2009, the Company entered into a sublease agreement (the "2009 Sublease Agreement") with an unrelated party (Sublessee) 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, Sublessee has no rights to renew or extend the 2009 Sublease Agreement. The Company received \$66,800, \$78,500 and \$76,600 in sublease payments in 2012, 2011, and 2010, respectively. The 2009 Sublease Agreement expired on November 1, 2012.

Licensing and Research 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.

JHU

On March 24, 2003, the Company entered into a license agreement, subsequently amended on November 17, 2004, May 11, 2006, March 19, 2007, October 17, 2008, October 30, 2008, and again on January 27, 2009 with JHU for an exclusive long-term license to certain patents for use in colorectal cancer detection in stool relating to the digital-PCR technology developed by Dr. Bert Vogelstein's laboratory at the Johns Hopkins Kimmel Cancer Center. Pursuant to the terms of this license agreement, and subsequent to the closing of the Genzyme strategic transaction (See Note 3), the Company has agreed to pay JHU a license fee based on a percentage of the Company's net revenues, including an annual minimum license fee of approximately \$0.1 million, over the life of the licensed patents, or 2023.

EXACT SCIENCES CORPORATION

Notes to Financial Statements (Continued)

(7) COMMITMENTS AND CONTINGENCIES (Continued)

Mayo

On June 11, 2009 the Company entered into a patent licensing agreement with MAYO primarily for the rights to certain patented intellectual property owned by Mayo. The Company has agreed to pay Mayo a royalty fee based on a percentage of the Company's net sales of licensed products. 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 Company is required to make a \$500,000 payment to MAYO 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 \$500,000 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.

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 and improvements. On December 14, 2012 the Company and Hologic entered into an amendment to this license agreement pursuant to which Hologic granted the Company a non-exclusive worldwide license within the field of any disease or condition within, related to or affecting the gastrointestinal tract and/or appended mucosal surfaces with regard to certain Hologic patents and improvements. 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 royalty fee based on a percentage of the Company's net sales of the licensed products, and required 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.

The Company has recorded research and development expense associated with license agreements of \$1.4 million, \$0.8 million, and \$0.4 million, respectively, for the years ended December 31, 2012,

Notes to Financial Statements (Continued)

(7) COMMITMENTS AND CONTINGENCIES (Continued)

2011 and 2010. Future minimum payments due under the Company's technology licenses as of December 31, 2012 are as follows. Amounts included in the table are in thousands.

Year ending December 31,	
2013	\$ 496
2014	296
2015	296
2016	256
2017	256
Thereafter	2,288

\$ 3,888

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. The Company has recorded research and development expense associated with clinical research agreements of approximately \$1.2 million, \$1.0 million, and \$1.3 million, respectively, for the years ended December 31, 2012, 2011 and 2010. As of December 31, 2012, 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 \$1,151,000 and is included in the balance sheet as laboratory equipment at December 31, 2012. 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, 2012 was approximately \$128,000. 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.

The future minimum lease payments required under the capital lease and the present value of the net minimum lease payments as of December 31, 2012 are as follows (in thousands):

Year Ending December 31,		
2013	\$	381
2014		381
2015		368
Total lease obligations	\$	1,130
Less imputed interest		(86)
Present value of minimum lease payments		1,044
•		
Less current maturities of capital lease obligations		(333)
2000 current materiales of cupital lease configurions		(333)
Long term capital lease obligations	\$	711
Long term capital lease obligations	Ψ	/11
	57	

EXACT SCIENCES CORPORATION

Notes to Financial Statements (Continued)

(8) RELATED PARTY TRANSACTIONS

In 2012, the Company entered into a one year consulting agreement with a non-employee director under which the director will 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 vests over one year, and will make cash payments totaling \$60,000 over the one year term of the agreement.

(9) ACCRUED EXPENSES

Accrued expenses at December 31, 2012 and 2011 consisted of the following. Amounts included in the table are in thousands.

	December 31,			
		2012		2011
Compensation	\$	1,985	\$	2,041
Research and trial related expenses		576		440
Licenses		373		338
Professional fees		351		182
Occupancy costs		23		31
Other		19		37
	\$	3,327	\$	3,069

(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. The difference between the fair value of this loan at December 31, 2012 and the carrying value at this date is not significant. That determination is a Level 3 fair value measurement and the Company considered the expected repayment terms and current interest rates. Based on the Company's

Notes to Financial Statements (Continued)

(10) LONG TERM DEBT (Continued)

estimation of the loan obligation, the table below represents the future principal obligations as of December 31, 2012:

Year ending December 31,	
2013	\$
2014	
2015	145
2016	217
2017	221
Thereafter	417

\$ 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, 2012, 2011 and 2010 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 \$0.4 million, \$0.3 million, and \$0.2 million, respectively, in the statements of operations for the years ended December 31, 2012, 2011 and 2010 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, 2012, the Company had federal net operating loss and state net operating loss carryforward of approximately \$250.7 million and \$158.7 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 \$4.2 million and \$9.0 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.

Notes to Financial Statements (Continued)

(12) INCOME TAXES (Continued)

As of December 31, 2012 and 2011, the Company had \$14.2 million and \$10.6 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,			
		2012		2011
Deferred tax assets:				
Operating loss carryforwards	\$	88,532	\$	71,471
Tax credit carryforwards		10,184		7,511
Deferred revenue		1,758		3,399
Other temporary differences		3,445		2,257
Tax assets before valuation allowance		103,919		84,638
Less Valuation allowance		(103,919)		(84,638)
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 \$103.9 million and \$84.6 million valuation allowance at December 31, 2012 and 2011 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 \$19.3 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.

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

	December 31,		
	2012	2011	2010
U.S. Federal statutory rate	34.0%	34.0%	34.0%
State taxes	1.7	5.6	5.6
Research and development tax credit	5.1	1.7	2.6
Stock-based compensation expense	(0.6)	(2.4)	(1.9)
Other adjustments	(0.1)	0.1	(0.1)
Valuation allowance	(40.1)	(39.0)	(40.1)
Effective tax rate	0.0%	0.0%	0.1%

The Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority. The amount of unrecognized tax benefits as of

EXACT SCIENCES CORPORATION

Notes to Financial Statements (Continued)

(12) INCOME TAXES (Continued)

January 1, 2010 was none. There have been no changes in unrecognized tax benefits since January 1, 2010, 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, 2012.

As of December 31, 2012, 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 2012, and to state income tax examinations for the tax years 1995 through 2012. Interest and penalties are recorded as income tax expense in the period incurred. 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, 2012, 2011 and 2010.

(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, 2012. In the opinion of management, this information has been prepared on the same basis as the audited financial statements and all necessary adjustments, consisting only of normal recurring adjustments, have been included in the amounts stated below to present fairly

EXACT SCIENCES CORPORATION

Notes to Financial Statements (Continued)

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

the unaudited quarterly results of operations. The quarterly data should be read in conjunction with our financial statements.

	Quarter Ended							
	M	arch 31,	J	June 30,	Se	eptember 30,	D	ecember 31,
		(Am	oun	ts in thousai	ıds,	ids, except per share		ta)
2012		Ì						
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
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
		,		,		,		,
2011								
Revenue	\$	1,040	\$	1,042	\$	1,039	\$	1,042
Cost of revenue		6		6		6		6
Gross profit		1,034		1,036		1,033		1,036
Research and development		2,989		5,197		6,110		7,672
General and administrative		2,150		1,830		1,951		2,206
Sales and marketing		297		651		815		1,094
Loss from operations		(4,402)		(6,642)		(7,843)		(9,936)
Investment income		34		22		75		38
Interest expense		(5)		(5)		(5)		(6)
Net loss	\$	(4,373)	\$	(6,625)	\$	(7,773)	\$	(9,904)
Net loss per share basic and diluted	\$	(0.08)	\$	(0.13)	\$	(0.15)	\$	(0.18)
Weighted average common shares outstanding basic and diluted		51,930		52,010		52,443		53,647
		21,750		22,010		22,113		23,017
	62	,						
	0.	<u>-</u>						

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Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

There have been no disagreements with accountants on accounting or financial disclosure matters.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934 (the "Exchange Act"), our management, including our principal executive officer and principal financial officer, conducted an evaluation as of the end of the period covered by this report, of the effectiveness of our disclosure controls and procedures as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934. Based on that evaluation, our principal executive officer and principal financial officer have concluded that these disclosure controls and procedures were effective as of December 31, 2012 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, 2012, 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, 2012. 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, 2012, 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, 2012, 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 2013 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 2013 Annual Meeting of Stockholders: "Compensation and Other Information Concerning Directors and Officers," "The Board of Directors and Its Committees," and "Report of 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 2013 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 2013 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 2013 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 "Financial Statements and Supplementary Data" at Item 8 and incorporated herein by reference).
 - (2)
 Financial Statement Schedules (Schedules to the Financial Statements have been omitted because the information required to be set forth therein is not applicable or is shown in the accompanying Financial Statements or notes thereto).
 - (3) Exhibits (The exhibits required to be filed as a part of this Report are listed in the Exhibit Index).

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SIGNATURES

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

		EXACT SCIENCES CORPORATION	
Date: March 1, 2013	Ву:	/s/ KEVIN T. CONROY	
		Kevin T. Conroy President & Chief Executive Officer	

POWER OF ATTORNEY AND SIGNATURES

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

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

Name	Title	Date	
/s/ KEVIN T. CONROY	President and Chief Executive Officer	March 1, 2013	
Kevin T. Conroy	(Principal Executive Officer)		
/s/ MANEESH K. ARORA	Chief Operating Officer, Chief Financial Officer and Secretary (Principal Financial Officer and Principal	March 1, 2013	
Maneesh K. Arora	Accounting Officer)	•	
/s/ JAMES CONNELLY	Chairman of the Board	March 1, 2013	
James Connelly		1, 2013	
/s/ SALLY W. CRAWFORD	LLY W. CRAWFORD Director		
Sally W. Crawford	Bilector	March 1, 2013	
/s/ DANIEL J. LEVANGIE	/s/ DANIEL J. LEVANGIE Director		
Daniel J. Levangie 65		March 1, 2013	

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Name	Title	Date
/s/ KATHERINE NAPIER	Dinastan	Mk 1 2012
Katherine Napier	Director	March 1, 2013
/s/ LIONEL STERLING	Director	March 1, 2013
Lionel Sterling	Director	Match 1, 2013
/s/ DAVID THOMPSON	Director	March 1, 2013
David Thompson	66	Walcii 1, 2015

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Exhibit Index to Annual Report on Form 10-K

Exhibit Number 3.1	Description 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)
4.2	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)
4.3	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 Incentive Stock Option Agreement (previously filed as Exhibit 10.14 to our Annual Report on Form 10-K filed for the period ended December 31, 2008, which is incorporated herein by reference)
10.3*	2000 Stock Option and Incentive Plan Form of Nonstatutory (Non-Qualified) Stock Option Agreement (previously filed as Exhibit 10.1 to our Report on Form 10-Q for the period ended September 30, 2004, which is incorporated herein by reference)
10.4*	2000 Employee Stock Purchase Plan (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)
10.5*	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)
10.6**	License Agreement between the Registrant and Case Western Reserve University, dated as of July 18, 2005, as amended (previously filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the period ended June 30, 2008, which is incorporated herein by reference)
10.7**	Amended and Restated License Agreement between The Johns Hopkins University and the Registrant, dated as of March 25, 2003, as amended (previously filed as Exhibit 10.1 to our Quarterly Report on Form 10-Qfor the period ended September 30, 2008, which is incorporated herein by reference)

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Exhibit Number 10.8**	Description Seventh Amendment to License Agreement between the Registrant and The Johns Hopkins University, dated as of December 15, 2008 (previously filed as Exhibit 10.33 to our Annual Report on Form 10-K filed for the period ended December 31, 2008, which is incorporated herein by reference)
10.9**	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)
10.10**	Assignment, Sublicense, Consent and Eighth Amendment to License Agreement among the Registrant, Genzyme Corporation and The Johns Hopkins University, dated January 27, 2009 (previously filed as Exhibit 10.2 to our Report on Form 8-K filed on January 28, 2009, which is incorporated herein by reference)
10.11**	Amended and Restated License Agreement between Genzyme Corporation and the Registrant, dated January 27, 2009 (previously filed as Exhibit 10.3 to our Report on Form 8-K filed on January 28, 2009, which is incorporated herein by reference)
10.12	Common Stock Subscription Agreement between the Registrant and Genzyme Corporation, dated January 27, 2009 (previously filed as Exhibit 10.4 to our Report on Form 8-K filed on January 28, 2009, which is incorporated herein by reference)
10.13*	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)
10.14*	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)
10.15*	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)
10.16**	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)
10.17	Form of Securities Purchase Agreement, dated June 11, 2009 (previously filed as Exhibit 10 to our Report on Form 8-K filed on June 12, 2009, which is incorporated herein by reference)
10.18**	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)
10.19	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)
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Exhibit Number	Description
10.20	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)
10.21*	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)
10.22*	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)
10.23*	Amended and Restated Employment Agreement by and between Barry Berger, M.D. and the Registrant, dated as of October 28, 2010 (previously filed as Exhibit 10.32 our Annual Report on Form 10-K filed for the period ended December 31, 2010, which is incorporated herein by reference)
10.24*	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)
10.25*	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)
10.26*	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)
10.27*	Exact Sciences Corporation Non-Employee Director Compensation Policy dated as of July 28, 2011 (previously filed as Exhibit 10 our Quarterly Report on Form 10-Q filed for the period ended September 30, 2011, which is incorporated herein by reference)
10.28*	Employment Agreement by and between John M. Krayacich and the Company, dated as of March 15, 2011 (previously filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q filed for the period ended March 31, 2011, which is incorporated herein by reference)
10.29*	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)
10.30	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)
10.31*	Consulting Agreement dated August 27, 2012 between the Registrant and James P. Connelly (previously filed as Exhibit 10.1 to our Report on Form 10-Q for the period ended September 30, 2012, which is incorporated herein by reference)
10.32**+	Amendment to Technology License Agreement by and between Hologic, Inc., Third Wave Technologies, Inc., and the Registrant, dated as of December 7, 2012

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Exhibit Number 1	Description Letter from Grant Thornton LLP to the Securities and Exchange Commission dated April 30, 2012, regarding change in certifying accountant (previously filed as Exhibit 16 to our Report on Form 8-K filed on April 30, 2012, which is incorporated herein by reference)
23.	+ Consent of BDO USA, LLP
24.	Power of Attorney (included on signature page)
31.	+ Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934
31.	+ 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
10	+ Interactive Data File
**	Indicates a management contract or any compensatory plan, contract or arrangement. Confidential Treatment requested for certain portions of this Agreement. Filed herewith.

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