

EXACT SCIENCES CORP  
Form 10-K  
March 09, 2012

Use these links to rapidly review the document

[TABLE OF CONTENTS](#)

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

[Table of Contents](#)

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

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

For the fiscal year ended: **December 31, 2011**

**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**

(State or other jurisdiction of  
incorporation or organization)

**02-0478229**

(IRS Employer  
Identification No.)

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

**53719**

(Zip Code)

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

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

**Common Stock, \$.01 Par Value**  
**Preferred Stock Purchase Rights**

**The NASDAQ Stock Market LLC**  
**The NASDAQ Stock Market LLC**

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

**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

## Edgar Filing: EXACT SCIENCES CORP - Form 10-K

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such report(s), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, as of the last business day of the Registrant's most recently completed second fiscal quarter was approximately \$446,504,260 (based on the closing price of the Registrant's Common Stock on June 30, 2011 of \$8.60 per share).

The number of shares outstanding of the Registrant's \$.01 par value Common Stock as of March 6, 2012 was 57,023,845.

### 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, 2011. Portions of such proxy statement are incorporated by reference into Part III of this Form 10-K.

---

Table of Contents

**EXACT SCIENCES CORPORATION  
ANNUAL REPORT ON FORM 10-K  
YEAR ENDED DECEMBER 31, 2011**

**TABLE OF CONTENTS**

	<b>Page No.</b>
<b><u>Part I</u></b>	
<u>Item 1. Business</u>	<u>1</u>
<u>Item 1A. Risk Factors</u>	<u>6</u>
<u>Item 1B. Unresolved Staff Comments</u>	<u>15</u>
<u>Item 2. Properties</u>	<u>15</u>
<u>Item 3. Legal Proceedings</u>	<u>15</u>
<u>Item 4. Mine Safety Disclosures</u>	<u>15</u>
<b><u>Part II</u></b>	
<u>Item 5. Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities</u>	<u>16</u>
<u>Item 6. Selected Financial Data</u>	<u>16</u>
<u>Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>18</u>
<u>Item 7A. Quantitative and Qualitative Disclosures about Market Risk</u>	<u>27</u>
<u>Item 8. Financial Statements and Supplementary Data</u>	<u>28</u>
<u>Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	<u>64</u>
<u>Item 9A. Controls and Procedures</u>	<u>64</u>
<u>Item 9B. Other Information</u>	<u>64</u>
<b><u>Part III</u></b>	
<u>Item 10. Directors, Executive Officers and Corporate Governance</u>	<u>65</u>
<u>Item 11. Executive Compensation</u>	<u>65</u>
<u>Item 12. Security and Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>65</u>
<u>Item 13. Certain Relationships and Related Transactions, and Director Independence</u>	<u>65</u>
<u>Item 14. Principal Accountant Fees and Services</u>	<u>65</u>
<b><u>Part IV</u></b>	
<u>Item 15. Exhibits and Financial Statement Schedules</u>	<u>65</u>
<u>SIGNATURES</u>	<u>66</u>

Table of Contents

**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, anticipated results of our pivotal clinical trial, expected license fee 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 focused on the early detection and prevention of colorectal cancer. We have exclusive intellectual property protecting our non-invasive, molecular screening technology for the detection of colorectal pre-cancer and cancer.

Our primary goal is to become the market leader for a patient-friendly 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:

develop and refine our non-invasive Cologuard® stool-based DNA (sDNA) colorectal pre-cancer and cancer screening test;

advance our product through U.S. Food and Drug Administration (FDA) clinical trials; and

commercialize an FDA-cleared/approved product that detects colorectal pre-cancer and cancer.

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

Our current focus is on seeking FDA clearance or approval for our Cologuard test. We also are in the process of developing our strategy for the ultimate commercialization of our Cologuard test. We believe obtaining FDA clearance or approval is important to building broad demand and successful commercialization for our sDNA colorectal cancer screening test. Product development efforts, product performance, throughput and cost are among the elements that will need to be addressed in the design and development of a commercial product based on our technology.

Table of Contents

Our Cologuard test is designed to detect pre-cancerous lesions or polyps, and each of the four stages of colorectal cancer. Pre-cancerous polyps are present in approximately 6 percent of average risk people 50 years of age and older who come in for routine colorectal cancer screening. We are designing 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 percent at a specificity of 90 percent. In preliminary validation studies our Cologuard 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 are in the process of developing our strategy for the ultimate commercialization of our Cologuard test.

Colorectal cancer is the second leading cause of cancer deaths in the United States and the leading cause of cancer deaths among nonsmokers. Patients who are diagnosed early in the progression of the disease with pre-cancerous lesions or polyps, or early-stage cancer are more likely to have a complete recovery and to be treated less expensively. Accordingly, the American Cancer Society (ACS) recommends that all people age 50 and older undergo regular colorectal cancer screening. Of the more than 80 million people in the United States for whom routine colorectal cancer screening is recommended, nearly 40 percent have not been screened according to current guidelines. We believe that this large population of unscreened and inadequately screened patients represents an opportunity to reduce colorectal cancer deaths and the health care costs associated with colorectal cancer.

Professional colorectal cancer screening guidelines in the United States, 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.

***Background***

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. However, it is the second leading cause of cancer death in the United States, killing almost 50,000 people each year.

There is a significant unmet clinical need related to the diagnosis of colorectal cancer. Approximately 40 percent of those who should be screened for colorectal cancer are not 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 can detect pre-cancers and cancers early, and is expected to be a powerful, preventive tool. By detecting pre-cancers and cancers early with our test, affected patients can be referred to colonoscopy, during which the polyp or lesions can be removed. The sDNA screening model has the potential to significantly reduce colorectal cancer deaths. The earlier the pre-cancer or cancer is detected, the greater the reduction in mortality.

Table of Contents

The competitive advantages of sDNA-based screening provide a significant market opportunity. Assuming a 30-percent test adoption rate and a three-year screening interval, we estimate the potential U.S. market for sDNA screening to be \$1.2 billion.

***Our Solution***

Our Cologuard test includes proprietary and patented methods that isolate and analyze the trace amounts of human DNA that are shed into stool every day from the exfoliation of cells that line the colon. When colorectal cancer or pre-cancer is present, a minute portion of the total isolated human DNA will often represent DNA shed from cancerous or pre-cancerous lesions. Once the human DNA in the sample is isolated, sDNA-based detection looks for specific mutations and other abnormalities in that DNA known to be associated with colorectal cancer. Our test will also detect blood in stool, utilizing an antibody-based Fecal Immunochemical Test (FIT). 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.

We believe that sDNA-based screening in the general population offers an opportunity to increase screening rates, decrease deaths and lower health care costs from colorectal cancer. We believe that our proprietary methods and technologies have the following advantages over other screening options that may lead to decreased mortality associated with colorectal cancer.

sDNA-based screening detects both pre-cancers and cancers.

sDNA-based screening is non-invasive and requires no bowel preparation or dietary restriction like other methods.

The sample for sDNA-based screening can be collected easily at home and shipped to the laboratory, where the testing would be conducted.

sDNA-based screening is affordable particularly relative to colonoscopy.

***Competition***

The competitive landscape is favorable to sDNA-based 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 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 66 percent detection rates for cancer and 27 percent detection rates for pre-cancers, and poor compliance. Blood-based DNA testing also is disadvantaged by its low sensitivity for cancer and its inability to reliably detect pre-cancer. Data from a validation study of one blood-based test was released in late 2011. It demonstrated only 68 percent sensitivity across all stages of cancer at 80 percent specificity, with little sensitivity for pre-cancer.

A number of companies are working to develop new blood-based tests for the detection of colorectal cancer. In addition, sDNA testing faces 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. We also are aware that some competitors are developing serum-based tests, or screening tests based on the detection of proteins or nucleic acids produced by colorectal cancer in the blood.

Table of Contents

***Reimbursement***

We are continuing to seek national coverage for sDNA colorectal cancer screening technologies from the Center for Medicare and Medicaid (CMS) and positive coverage decisions from major national and regional managed care organizations and insurance carriers, and self-insured employer groups.

A number of states have legislative mandates requiring that available colorectal cancer screening options offered by certain categories of insurers in these states must include all tests identified in the current ACS screening guidelines, which include sDNA screening. Additionally, in the second half of 2008, CIGNA, one of the nation's largest insurers, included sDNA screening among its nationwide covered benefits. While we view inclusion of sDNA screening for colorectal cancer in the state mandates and the positive coverage decision by CIGNA as important first steps in securing wide-spread coverage for sDNA screening for colorectal cancer from private insurance carriers, we believe that obtaining a positive national coverage decision from the CMS for our sDNA screening product will be a necessary element in achieving any material commercial success.

***Research and Development***

Research and development costs account for a substantial portion of our operating expenses. Our research and development expenses were \$22.0 million, \$9.0 million and \$4.2 million for the years ended December 31, 2011, 2010 and 2009, respectively.

***Government Regulation***

Certain of our activities are subject to regulatory oversight by the FDA under provisions of the Federal Food, Drug, and Cosmetic Act and regulations thereunder, including regulations governing the development, marketing, labeling, promotion, manufacturing and export of diagnostic products. Failure to comply with applicable requirements can lead to sanctions, including withdrawal of products from the market, recalls, refusal to authorize government contracts, product seizures, civil money penalties, injunctions and criminal prosecution.

***U.S. Food and Drug Administration***

The Food, Drug and Cosmetic Act requires that medical devices introduced to the U.S. market, unless otherwise exempted, be subject to either a premarket notification clearance, known as a 510(k), or a premarket approval (PMA). 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 510(k) or 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. 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 believe that the studies required in connection with any approval or clearance of our technology, regardless of whether the regulatory pathway is the 510(k) process or a PMA, will be material in cost and time-intensive. There can be no assurance that the FDA will ultimately approve any 510(k) request or approve any PMA submitted by us in a timely manner or at all.

Table of Contents

***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 Class I medical devices 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. Under 21 CFR Sec. 864.3250, specimen transport and storage containers generally have been exempt from the FDA's premarket notification requirement and much of the Quality System Regulation. However, there can be no assurance that the FDA will consider our products' collection containers to be exempt from the premarket notification requirement or the majority of the Quality System Regulation requirements. Moreover, we believe that if the collection kit becomes part of a cleared or approved device, the FDA will seek to include the container in the premarket clearance or approval requirement as part of the sDNA test system.

***Intellectual Property***

Our intellectual property portfolio positions us to be the leading player to develop and market tests for the detection of colorectal cancer from stool samples. We have intellectual property 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 plan to incorporate into our test kits. We have an extensive license to markers, digital PCR, and other technologies applicable to the detection of colorectal cancer from the Johns Hopkins University, and have additional licensed intellectual property from MDx Health (formerly Oncomethylome Sciences) 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, 2011, we owned 14 issued patents and 11 pending patent applications in the United States, and 47 issued patents and 4 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 42 patents issued and 16 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.

***Employees***

As of December 31, 2011, we had sixty-one full-time employees. None of our employees are represented by a labor union. We consider our relationship with our employees to be good.



Table of Contents

*Available Information*

We were incorporated in the State of Delaware on February 10, 1995. Our executive offices are located at 441 Charmany Drive, Madison, Wisconsin 53719. Our telephone number is 608-284-5700. Our Internet website address is *www.exactsciences.com*. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge through the investor relations page of our internet website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. Our Internet website and the information contained therein or connected thereto are not intended to be incorporated into this Annual Report on Form 10-K.

**Item 1A. Risk Factors**

We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. This discussion highlights some of the risks 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 since the commercial launch of PreGen-Plus in August 2003. From our date of inception on February 10, 1995 through December 31, 2011, we have accumulated a total deficit of approximately \$221.8 million. We expect that our losses will continue for at least the next several years and that we will be required to invest significant additional funds toward development and commercialization of our colorectal cancer screening technology. If our revenue does not grow significantly, we will not be profitable. We cannot be certain that the revenue from the sale of any products based on our technologies will be sufficient to make us profitable.

Our future revenues will depend on our ability to successfully commercialize an FDA-cleared/approved product for stool-based DNA 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 stool-based DNA screening reimbursement by Medicare and other third-party payors; and

our ability to commercialize 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 achieve necessary business objectives, and accordingly, we cannot assure you that we will ever successfully commercialize any stool-based DNA testing services or products utilizing our intellectual property. Our failure to do so would significantly impair our ability to generate revenues and achieve profitability.

Table of Contents

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

We believe obtaining FDA clearance or approval is critical to building broad demand for and successfully commercializing our Cologuard test. The FDA approval path for our Cologuard test is likely to 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 do not have sufficient capital to fully fund the commercial development of our Cologuard test and related FDA submission and commercialization efforts. If we are unable to obtain needed financing on acceptable terms, we may not be able to implement our business plan, which could have a material adverse effect on our business, financial condition and results of operations. If we raise additional funds through the sale of equity, convertible debt or other equity-linked securities, our stockholders' ownership will be diluted. In addition, these transactions may result in a decrease in the value of our outstanding stock. 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 in the United States. We will need to complete a successful clinical trial and obtain FDA clearance or approval before we can seek to commercialize this product.

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

FDA approval;

acceptance in the medical community;

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

sufficient coverage or reimbursement by third party payors;

our ability to successfully market Cologuard;

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

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

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

Table of Contents

***Although in our 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 are designing our Cologuard test with a goal of detecting both pre-cancers and cancers at certain target sensitivity rates. On October 28, 2010, we announced the results of a validation study involving a total of 1,178 stool samples. In this study, our Cologuard test was able to detect both pre-cancers and cancers at or above these target sensitivity rates. In November 2011, we further validated that we could meet these targets with an additional validation study involving a total of 355 stool samples. 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, the October 2010 study was a feasibility study and did not use a final product to test patient samples under real-life, clinical conditions (rather, for example, the study used frozen and stored samples). Further, the results achieved in future clinical trials and other studies may differ materially from our validation study results. To ensure successful completion of an FDA clinical trial for our Cologuard test, we expect to need to continue to refine the product. Additionally, we will need to develop FDA compliant manufacturing and quality control systems. There can be no assurance that we will be successful in these efforts or achieve our initial validation study results in future studies. Even if we do, FDA approval for our Cologuard test will take significant time and require significant research, development and clinical study expenditures and ultimately may not succeed.

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

The Food, Drug and Cosmetic Act requires that medical devices introduced to the U.S. market, unless otherwise exempted, be subject to either a premarket notification clearance (known as a 510(k)) or a premarket approval (known as a PMA). We currently expect to seek a PMA for our Cologuard test. PMA involves providing extensive data to the FDA to support an FDA finding that the device is safe and effective for its intended use. This process may also include the provision of additional data and updates to the FDA, the convening of expert panels, the inspection of manufacturing facilities and new or supplemented PMAs if the product is modified during the process. Even if granted, a 510(k) or PMA approval may place substantial restrictions on how our device is marketed or sold, and the FDA will continue to place considerable restrictions on our products, including, but not limited to, registering manufacturing facilities, listing the products with the FDA, complying with labeling and meeting reporting requirements. In 2012, we will devote significant time and resources on the pivotal FDA clinical trial for our Cologuard test. The trial design will be subject to ongoing discussions with the FDA and could change, potentially significantly. If for any reason this trial is not successful or is substantially delayed or for any other reason we are unable to successfully commercialize our Cologuard test, our business and prospects would likely be materially adversely impacted. There can be no assurance that FDA will ultimately approve any 510(k) request or 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

Table of Contents

Diagnosics 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 to demonstrate the performance of its blood-based screening test for colorectal cancer. 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 immunochemical FOBT and FIT. Our competitors may also be working on additional methods of detecting colorectal cancer that have not yet been announced. We may be unable to compete effectively against these competitors either because their test is superior or because they may have more expertise, experience, financial resources or stronger business relationships.

***If Medicare and other third-party payors, including managed care organizations, do not approve reimbursement for our Cologuard test, the commercial success of products utilizing our technologies would be compromised.***

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. There is significant uncertainty surrounding third-party reimbursement for the use of tests that incorporate new technology, such as our Cologuard test. 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 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.

***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 Hemocult II, Hemocult 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. 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

Table of Contents

procedures. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our studies may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our Cologuard test.

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

The development and commercialization of our Cologuard test relies upon strategic collaborations and licensing agreements with third parties. We currently have a collaborative arrangement with the Mayo Clinic. In addition, we have licensing agreements with Hologic, Johns Hopkins University, MDx Health (formerly Oncomethylome Sciences) and Case Western Reserve University. Such arrangements provide us with intellectual property crucial to our product development, including technology that we plan to incorporate into our test kits. 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. Discussion 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 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 products containing our colorectal cancer screening technology, which will involve the development of our commercial infrastructure and/or collaborative commercial arrangements and partnerships. We may be unable to attract, retain and manage the specialized workforce and collaborative manufacturing and distribution arrangements necessary to gain market acceptance and successfully commercialize our products and services. In addition, developing these functions is time consuming and expensive. In certain regions or markets, 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.

Table of Contents

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

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

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

its price;

the availability of alternative screening methods;

the willingness of physicians to prescribe our Cologuard test; and

sufficient third-party coverage or reimbursement.

Even if our Cologuard test is superior to other colorectal cancer screening options, adequate third-party reimbursement is obtained and medical practitioners choose to order tests using our technologies, 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 40 percent of these individuals are not screened according to current guidelines. Use of a sDNA 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.

***We may be subject to substantial costs and liability, or be prevented from using technologies incorporated in our Cologuard test, as a result of litigation or other proceedings relating to patent rights.***

Third parties may assert infringement or other intellectual property claims against our licensors, our licensees, our suppliers, our strategic partners or us. We pursue a patent strategy that we believe provides us with a competitive advantage in the non-invasive early detection of colorectal cancer and is designed to maximize our patent protection against third parties in the U.S. and, potentially, in certain foreign countries. We have filed patent applications that we believe cover the methods we have designed to help detect colorectal cancer and other cancers. In order to protect or enforce our patent rights, we may have to initiate actions against third parties. Any actions regarding patents could be costly and time-consuming and divert the attention of our management and key personnel from our business. Additionally, such actions could result in challenges to the validity or applicability of our patents. Because the U.S. Patent & Trademark Office maintains patent applications in secrecy until a patent application publishes or the patent is issued, we have no way of knowing if others may have filed patent applications covering technologies used by us or our partners. Additionally, there may be third-party patents, patent applications and other intellectual property relevant to our technologies that may block or compete with our technologies. Even if third-party claims are without merit, defending a lawsuit may result in substantial expense to us and may divert the attention of management and key personnel. In addition, we cannot provide assurance that we would prevail in any such suits or that the damages or other remedies, if any, awarded against us would not be substantial. Claims of intellectual property infringement may require that we, or our strategic partners, enter into royalty or license agreements with third parties that may not be available on acceptable terms, if at all. These claims may also result in injunctions against the further development and commercial sale of services or products containing our technologies, which would have a material adverse effect on our business, financial condition and results of operations.

Also, patents and patent applications owned by us may become the subject of interference proceedings in the U.S. Patent and Trademark Office to determine priority of invention, which could

Table of Contents

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.

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. 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.

***If we market our Cologuard test in a manner that violates healthcare fraud and abuse laws, or if we violate false claims laws or fail to comply with our reporting and payment obligations under the Medicaid rebate program or other governmental pricing programs, we may be subject to civil or criminal penalties or additional reimbursement requirements and sanctions, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.***

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. These laws include anti-kickback statutes and false claims statutes. Because of the breadth of these laws and the narrowness of the safe harbors,

Table of Contents

it is possible that some of our business activities in commercializing our Cologuard test could be subject to challenge under one or more of these laws.

***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, 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-cleared/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-cleared/approved product.

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

Our success depends in large part on our ability to attract and retain managerial personnel. If we were to lose any of our senior management team, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies. Competition for desirable personnel is intense, and there can be no assurance that we will be able to attract and retain the necessary staff. The failure to maintain management or to attract sales personnel as we move towards the commercialization of our Cologuard test could materially adversely affect our business, financial condition and results of operations.

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

We have established relationships with leading scientists at important research and academic institutions, such as the Mayo Clinic, Case Western Reserve University and Johns Hopkins University, that we believe are key to establishing tests using our technologies as a standard of care for colorectal cancer screening. If our collaborators determine that colorectal cancer screening tests using our technologies are not appropriate options for colorectal cancer screening, or inferior 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 products or services based on our technologies, or activities related to our research and clinical studies, could lead to the filing of product liability claims if someone were to allege 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.



Table of Contents

***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. 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.

Table of Contents

*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 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, 2011, we occupied approximately 24,000 square feet of space in our headquarters located in Madison, Wisconsin under a lease which expires in October 2014. These facilities are adequate to meet our space requirements with respect to the development of an FDA-cleared/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**

Table of Contents**PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**

Our common stock is currently listed on the NASDAQ Capital Market under the symbol "EXAS." The following table provides, for the periods indicated, the high and low sales prices per share as reported on the NASDAQ Capital Market.

	High	Low
<b>2011</b>		
First quarter	\$ 7.37	\$ 4.91
Second quarter	8.65	6.87
Third quarter	9.45	6.00
Fourth quarter	8.84	6.06
<b>2010</b>		
First quarter	\$ 5.25	\$ 3.36
Second quarter	5.00	3.85
Third quarter	7.40	3.15
Fourth quarter	9.24	5.32

As of March 6, 2012, there were 57,023,845 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, 2011, 2010 and 2009 and for the years then ended are derived from our financial statements, which have been audited by Grant Thornton LLP, an independent registered public accounting firm and which are included elsewhere in this Form 10-K. The selected historical balance sheet financial data as of December 31, 2008 and 2007 and statements of operations data for the years ended December 31, 2008 and 2007 are derived from our financial statements, which were audited by Ernst & Young LLP, not included elsewhere in this Form 10-K.

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

Edgar Filing: EXACT SCIENCES CORP - Form 10-K

Table of Contents

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,				
	2011	2010	2009	2008	2007
	(Amounts in thousands, except per share data)				
<b>Statements of Operations Data:</b>					
Revenue:					
Product royalty fees	\$ 20	\$ 26	\$ 25	\$ (2,234)	\$ (1,137)
License fees	4,143	5,318	4,733	1,351	2,857
Product				16	78
	4,163	5,344	4,758	(867)	1,798
Cost of revenue	24	24	20	1	49
Gross profit (loss)	4,139	5,320	4,738	(868)	1,749
Operating expenses:					
Research and development(1)	21,968	9,023	4,213	2,034	4,887
General and administrative(1)	8,137	6,330	9,549	6,469	7,541
Sales and marketing(1)	2,857	1,793	226		991
Restructuring(1)			(3)	602	1,177
	32,962	17,146	13,985	9,105	14,596
Loss from operations	(28,823)	(11,826)	(9,247)	(9,973)	(12,847)
Interest income	169	46	120	232	888
Interest expense	(21)	(20)	(1)		
Other income		244			
Net loss	\$ (28,675)	\$ (11,556)	\$ (9,128)	\$ (9,741)	\$ (11,959)
Net loss per share:					
Basic and diluted	\$ (0.54)	\$ (0.29)	\$ (0.28)	\$ (0.36)	\$ (0.44)
Weighted average common shares outstanding:					
Basic and diluted	52,512	40,455	32,791	27,212	26,945
<b>Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 35,781	\$ 78,752	\$ 21,924	\$ 4,937	\$ 4,486
Marketable securities	57,580	16,663	2,404		8,101
Total assets	96,953	96,515	25,770	5,898	14,595
Total long term debt	1,000	1,000	1,000		
Total liabilities	13,458	16,761	19,676	8,331	8,307
Stockholders' equity (deficit)	83,495	79,754	6,094	(2,433)	6,288

(1)

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

	2011	2010	2009	2008	2007
Research and development	\$ 1,685	\$ 1,067	\$ 319	\$ 89	\$ 541
General and administrative	1,622	1,132	2,308	918	1,889
Sales and marketing	657	50	4		202
Restructuring				3	174

Table of Contents

**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 is a molecular diagnostics company focused on the early detection and prevention of colorectal cancer. We have exclusive intellectual property protecting our non-invasive, molecular screening technology for the detection of colorectal pre-cancer and cancer.

Our primary goal is to become the market leader for a patient-friendly 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:

develop and refine our non-invasive Cologuard® stool-based DNA (sDNA) colorectal pre-cancer and cancer screening test;

advance our product through U.S. Food and Drug Administration (FDA) clinical trials; and

commercialize an FDA-cleared product that detects colorectal pre-cancer and cancer.

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

Our current focus is on seeking U.S. Food and Drug Administration clearance or approval for our Cologuard test. We also are in the process of developing our strategy for the ultimate commercialization of our Cologuard test. We believe obtaining FDA clearance or approval is critical to building broad demand and successful commercialization for our sDNA colorectal cancer screening technologies. Product performance, throughput and cost are among the elements that will need to be addressed in the design and development of a commercial product based on our technology.

Our Cologuard test is designed to detect pre-cancerous lesions or polyps, and each of the four stages of colorectal cancer. Pre-cancerous polyps are present in approximately 6 percent of average risk people 50 years of age and older who come in for routine colorectal cancer screening.

We are designing 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 percent at a specificity of 90 percent. In preliminary validation studies our Cologuard 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 are in the process of developing our strategy for the ultimate commercialization of our Cologuard test.

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. However, it is the second-leading cause of cancer death in the United States, killing almost 50,000 people each year.

There is a significant unmet clinical need related to the diagnosis of colorectal cancer. Approximately 40 percent of those who should be screened for colorectal cancer are not 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.

Table of Contents

Our Cologuard test can detect pre-cancers and cancers early, and is expected to be a powerful, preventive tool. By detecting pre-cancers and cancers early with our test, affected patients can be referred to colonoscopy, during which the polyp or lesion 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.

The benefits of sDNA-based screening are clear. It detects both pre-cancers and cancers. sDNA-based screening is non-invasive and requires no bowel preparation or dietary restriction like other methods. The sample for sDNA-based screening can be collected easily at home and mailed to the appropriate laboratory, where the testing would be conducted. sDNA-based screening also is affordable, particularly relative to colonoscopy.

The competitive landscape is favorable to sDNA-based 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 and expensive. A 2010 study showed 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 66 percent detection rates for cancer and 27 percent detection rates for pre-cancers, and poor compliance. Blood-based DNA testing also is disadvantaged by its low sensitivity for cancer and its inability to reliably detect pre-cancer. Data from a validation study of one blood-based test was released in late 2011. It demonstrated only 68 percent sensitivity across all stages of cancer at 80 percent specificity, with little sensitivity for pre-cancer.

The competitive advantages of sDNA-based screening provide a significant market opportunity. Assuming a 30-percent test adoption rate and a three-year screening interval, we estimate the potential U.S. market for sDNA screening to be \$1.2 billion.

Our intellectual property portfolio positions us to be the leading player to develop and market tests for the detection of colorectal cancer from stool samples. Our portfolio of issued and pending patents broadly protects our position from competitors and yields freedom to operate in this market. We have continued to invest in our intellectual property filings. We have intellectual property 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 plan to incorporate into our Cologuard test. We have an extensive license to markers, digital PCR, and other technologies applicable to the detection of colorectal cancer from Johns Hopkins University, and have additional licensed intellectual property from MDx Health (formerly Oncomethylome Sciences) and Case Western Reserve University.

We have generated limited operating revenues since inception and, as of December 31, 2011, we had an accumulated deficit of approximately \$221.8 million. We expect to continue to incur losses for the next several years, and it is possible we may never achieve profitability.

***2012 Priorities***

In 2012 we will devote significant time and resources on the FDA clinical trial for our Cologuard test and preparing our FDA submissions. Currently we expect approximately 10,000 patients to be enrolled in the trial. Our goal is to complete the clinical trial and submit the PMA to the FDA for the manufacturing and analytical modules by the end of 2012. If for any reason this trial is not successful or is substantially delayed, if the FDA does not approve our PMA or such approval is substantially delayed or for any other reason we are unable to successfully commercialize our Cologuard test, our business and prospects would likely be materially adversely impacted.

Table of Contents

With the goal of expediting receipt of a favorable coverage decision, we are working with the Center for Medicare and Medicaid (CMS) to coordinate our clinical trial with the CMS coverage review process for our Cologuard test.

We also plan to focus on manufacturing preparations and developing the market for our Cologuard test during 2012. This includes working to develop an FDA compliant quality management system and the capability to manufacture and ship reagents to customers as well as completing a healthcare/cost effectiveness study, publishing scientific papers regarding our sDNA colorectal cancer screening technologies and continuing our outreach to physicians, third-party payors and advocates.

***Financial Overview***

***Revenue***

Our revenue is comprised of the amortization of up-front license fees for the licensing of certain patent rights to LabCorp and Genzyme and product royalty fees on tests sold by LabCorp utilizing our technology. We expect that product royalty fees and license fees for the full year 2012 will be consistent with amounts recorded in 2011.

***Our Cost Structure***

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

**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, 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.

Table of Contents

In connection with our January 2009 strategic transaction with Genzyme Corporation, Genzyme agreed to pay us a total of \$18.5 million, of which \$16.65 million was paid on January 27, 2009 and \$1.85 million was subject to a holdback by Genzyme to satisfy certain potential indemnification obligations in exchange for the assignment and licensing of certain intellectual property to Genzyme. Our on-going performance obligations to Genzyme under the Collaboration, License and Purchase Agreement (the "CLP Agreement"), as described below, including our obligation to deliver certain intellectual property improvements to Genzyme, if improvements are made during the initial five-year collaboration period, were deemed to be undelivered elements of the CLP Agreement on the date of closing. Accordingly, we deferred the initial \$16.65 million in cash received at closing and are amortizing that up-front payment on a straight line basis into revenue over the initial five-year collaboration period ending in January 2014. We received the first holdback amount of \$962,000, which included accrued interest, due from Genzyme during the first quarter of 2010 and the second holdback amount of \$934,250, which included accrued interest, due from Genzyme during the third quarter of 2010. The amounts were deferred and are being amortized on a straight-line basis into revenue over the remaining term of the collaboration at the time of receipt.

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

In total, we recognized approximately \$4.1 million in license fee revenue in connection with the amortization of the up-front payments and holdback amounts from Genzyme during the year ended December 31, 2011.

***Stock-Based Compensation.***

In accordance with GAAP, 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 remaining term.



Table of Contents

**Forfeitures** The Company records stock-based compensation expense only for those awards that are expected to vest. Awards granted in 2011 and 2010 are all expected to vest and no forfeiture rate was utilized.

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.

**Third-Party Royalty Obligation**

Pursuant to the terms of the agreement the Company has with LabCorp, we agreed to reimburse LabCorp \$3.5 million for certain third party royalty payments. Based on anticipated sales of ColoSure, as of December 31, 2009, we accrued a total of \$988,000 related to the total potential remaining liability of \$1.0 million. As of December 31, 2010 we had paid \$3.5 million in payments to LabCorp, to fully satisfy this liability. We recorded charges of \$5,000 and \$13,000 during the years ended December 31, 2010 and 2009, respectively, in connection with this third-party royalty obligation. These charges were recorded under the caption "Product royalty fees" in our statements of operations.

**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 \$84.6 million and \$74.6 million valuation allowance at December 31, 2011 and 2010 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 \$10.0 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 May 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2011-04, "*Fair Value Measurements (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in US GAAP and IFRS*," ("*ASU 2011-04*"). These amendments, effective for the interim and annual periods beginning on or after December 15, 2011, result in common definition of fair value and common requirements for measurement of and disclosure requirements between US GAAP and IFRS. ASU 2011-04 clarifies or changes certain fair value measurement principles and enhances the disclosure requirements particularly for Level 3 fair value measurements. The adoption of ASU 2011-04 is not expected to have a material impact on the Company's financial condition or results of operation.

In June 2011, the FASB issued ASU No. 2011-05, "*Comprehensive Income (ASC Topic 220): Presentation of Comprehensive Income*," ("*ASU 2011-05*") which amends current comprehensive income guidance. This guidance is effective retrospectively for the interim and annual periods beginning on or after December 15, 2011, and requires presentation of total comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity. The pronouncement does not change the current option for presenting components of other comprehensive income, gross, or net of the effect of income taxes, provided that such tax effects are presented in the statement in which other comprehensive income is presented or disclosed in the notes to the financial statements. Additionally, the pronouncement does

Table of Contents

not affect the calculation or reporting of earnings per share. The pronouncement also does not change the items which must be reported in other comprehensive income, how such items are measured, or when such items must be reclassified to net income. The Company will adopt this guidance in the first quarter of 2012. The adoption of ASU 2011-05 is not expected to have a material impact on the Company's financial condition or results of operation.

In December 2011, the FASB issued ASU 2011-12, "Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05" (ASU 2011-12), which deferred the requirement to present on the face of the financial statements reclassification adjustments for items that are reclassified from other comprehensive income to net income while the FASB further deliberates this aspect of the proposal. The amendments contained in ASU 2011-05 do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The amendments also do not affect how earnings per share is calculated or presented. ASU 2011-05, as amended by ASU 2011-12, is effective for us on January 1, 2012.

**Results of Operations**

***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.

**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 was primarily the result of increased research and development activities in support of our efforts to develop and seek FDA clearance or approval for our Cologuard test. The increase in research and development expenses included increases of \$5.2 million in professional fees, \$2.7 million in trial related expenses, \$2.6 million in personnel related expenses, \$1.1 million in lab related expenses, \$0.7 million in non-cash stock-based compensation expenses, \$0.6 million in other research and development expenses, and \$0.4 million in license and royalty fees. These increases in expenses were partially offset by a decrease in research collaborations of \$0.3 million.

**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. This increase in general and administrative expenses includes increases of \$0.7 million in legal and professional fees, \$0.6 million in non-cash stock-based compensation expenses, \$0.3 million in other general and administrative costs, and \$0.2 million in personnel related expenses.

Table of Contents

**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. This increase in sales and marketing expenses includes increases of \$0.9 million in personnel related expenses, \$0.6 million in non-cash stocked based compensation expenses, and \$0.2 million in other sales and marketing expenses. These increases were partially offset by a decrease in professional fees of \$0.6 million.

**Interest income.** Interest 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 balance during the year ended December 31, 2011 as compared to the same period of 2010.

**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 grant for the Qualifying Therapeutic Discovery Project issued by the federal government in 2010 which was not available in 2011.

**Comparison of the years ended December 31, 2010 and 2009**

**Revenue.** Total revenue increased to \$5.3 million for the year ended December 31, 2010 from \$4.8 million for the year ended December 31, 2009. The increase in total revenue for the year ended December 31, 2010 when compared to the same period of 2009 was primarily the result of the receipt in 2010 of the Genzyme holdback amounts of \$1.9 million which are being amortized on a straight-line basis into revenue over the collaboration period.

**Research and development expenses.** Research and development expenses increased to \$9.0 million for the year ended December 31, 2010 from \$4.2 million for the year ended December 31, 2009. The increase was primarily the result of increased research and development activities in support of our efforts to develop and seek FDA clearance or approval for our Cologuard test. The increase in research and development expenses included increases of \$2.0 million in personnel related expenses, \$1.3 million in lab related expenses, \$1.0 million in research collaborations, \$1.0 million in professional fees, \$0.6 million in non-cash stock-based compensation expenses, and \$0.5 million in other research and development expenses. These increases in expenses were partially offset by a decrease in license and royalty fees of \$1.6 million due primarily to \$1.8 million of non-cash stock-based expenses recognized in 2009 related to common stock warrants issued by us in June 2009 to the Mayo Clinic Foundation pursuant to our license agreement with the Mayo Clinic Foundation.

**General and administrative expenses.** General and administrative expenses decreased to \$6.3 million for the year ended December 31, 2010, compared to \$9.5 million for the year ended December 31, 2009. This decrease was primarily the result of \$1.9 million in transaction costs related to the Genzyme strategic transaction in January 2009, including \$1.1 million in legal, audit, and investment banking fees as well as approximately \$0.8 million in retention bonus payments made to employees pursuant to board-approved retention agreements. Also contributing to this overall decrease was a reduction in non-cash stock-based compensation expense of \$1.3 million in 2010 compared to 2009, as well as a decrease of \$0.4 million in personnel related costs. These decreases in general and administrative expenses for the year ended December 31, 2010 were partially offset by increases of \$0.4 million in other general and administrative costs.

Table of Contents

**Sales and marketing expenses.** Sales and marketing expenses increased to \$1.8 million for the year ended December 31, 2010 from \$0.2 million for the year ended December 31, 2009 as a result of increased sales and marketing efforts and activities in support of our efforts to develop and commercialize our Cologuard test.

**Interest income.** Interest income decreased to \$46,000 for the year ended December 31, 2010 from \$120,000 for the year ended December 31, 2009. This decrease was due to less favorable interest rates for cash, cash equivalents and marketable securities balances held during the year ended December 31, 2010 as compared to the same period of 2009.

**Interest expense.** Interest expense increased to \$20,000 for the year ended December 31, 2010 from \$1,000 for the year ended December 31, 2009. This increase was due to one month of interest expense recognized at December 31, 2009 compared to a full year of interest expense recognized at December 31, 2010 from our loan from the Wisconsin Department of Commerce.

**Other income.** Other income increased to \$244,000 for the year ended December 31, 2010 from none for the year ended December 31, 2009. This increase was due to the receipt of a grant for the Qualifying Therapeutic Discovery Project issued by the federal government in 2010 which was not available in 2009.

***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, 2011, we had approximately \$35.8 million in unrestricted cash and cash equivalents and approximately \$57.6 million in marketable securities.

All of our investments in marketable securities are comprised of fixed income investments and all are deemed available-for-sale. The objectives of this portfolio are to provide liquidity and safety of principal while striving to 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 \$27.8 million, \$13.5 million, and \$12.6 million for the years ended December 31, 2011, 2010 and 2009, respectively. The principal use of cash in operating activities for each of the years ended December 31, 2011, 2010 and 2009 was to fund our net loss. The increase in net cash used in operating activities for the year ended December 31, 2011 as compared to the year ended December 31, 2010 was primarily due to increased research and development activities. The increase for the year ended December 31, 2010 as compared to the year ended December 31, 2009, 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 \$43.0 million, \$14.9 million, and \$2.9 million for the years ended December 31, 2011, 2010, and, 2009, respectively. The increase in cash used in investing activities for the year ended December 31, 2011 when compared to the same period in 2010 was the result of increased purchases of marketable securities. Excluding the impact of purchases and maturities of marketable securities, net cash used in investing activities was \$2.1 million for the year ended December 31, 2011, compared to net cash used in investing activities of \$0.6 million for the year ended December 31, 2010 which was primarily the result of an increase in purchases of property and equipment. Net cash used in investing activities for the year ended December 31, 2009 was primarily the result of purchases of property and equipment.

## Edgar Filing: EXACT SCIENCES CORP - Form 10-K

### Table of Contents

Net cash provided by financing activities was \$27.9 million, \$85.2 million and \$32.5 million for the years ended December 31, 2011, 2010 and 2009, respectively. The decrease in cash provided by 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 the 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, net cash provided by financing activities was \$0.7 million for the year ended December 31, 2011, compared to net cash provided by financing activities of \$2.9 million for the year ended December 31, 2010. This decrease in 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. The increase in cash provided by financing activities for the year ended December 31, 2010 when compared to the same period in 2009 was primarily the result of an increase in the proceeds from the sale of common stock from \$8.1 million in 2009 to \$82.3 million in 2010.

We expect that cash and cash equivalents on hand at December 31, 2011, 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, we expect that we will need to raise additional capital to fully fund our current strategic plan, the primary goal of which is developing and commercializing an FDA-cleared/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 you that our business will ever generate sufficient cash flow from operations to become profitable.

The table below reflects our estimated fixed obligations and commitments as of December 31, 2011:

Description	Total	Less Than One Year	Payments Due by Period		More Than 5 Years
			1 - 3 Years	3 - 5 Years	
			(in Thousands)		
Long-term debt obligations(1)	\$ 1,158	\$	\$ 39	\$ 463	\$ 656
Obligations under license and collaborative agreements(2)	3,969	281	592	552	2,544
Operating lease obligations	1,127	389	738		
<b>Total</b>	<b>\$ 6,254</b>	<b>\$ 670</b>	<b>\$ 1,369</b>	<b>\$ 1,015</b>	<b>\$ 3,200</b>

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

(2) 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 8 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.

Table of Contents

*Net Operating Loss Carryforwards*

At December 31, 2011, the Company had federal net operating loss and state net operating loss carryforward of approximately \$194.4 million and \$170.1 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 \$3.3 million, respectively which may be used to offset future income tax liability. The federal and state carryforwards expire beginning 2015 through 2031 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.

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.

*Off-Balance Sheet Arrangements*

As of December 31, 2011, 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 and, as of December 31, 2011 and December 31, 2010 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.

Table of Contents

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

**EXACT SCIENCES CORPORATION  
Index to Financial Statements**

	<b>Page</b>
<u>Reports of Independent Registered Public Accounting Firm</u>	<u>29</u>
<u>Balance Sheets as of December 31, 2011 and 2010</u>	<u>31</u>
<u>Statements of Operations for the Years Ended December 31, 2011, 2010 and 2009</u>	<u>32</u>
<u>Statements of Stockholders' (Deficit) Equity for the Years Ended December 31, 2011, 2010 and 2009</u>	<u>33</u>
<u>Statements of Cash Flows for the Years Ended December 31, 2011, 2010 and 2009</u>	<u>34</u>
<u>Notes to Financial Statements</u>	<u>35</u>

Table of Contents

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders  
Exact Sciences Corporation

We have audited the accompanying balance sheets of Exact Sciences Corporation (a Delaware Corporation) (the Company) as of December 31, 2011 and 2010, and the related statements of operations, stockholders' (deficit) equity, and cash flows for each of the three years in the period ended December 31, 2011. 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. An audit also includes 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 the Company as of December 31, 2011 and 2010, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, 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), the Company's internal control over financial reporting as of December 31, 2011, 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 9, 2012 expressed an unqualified opinion.

/s/ Grant Thornton LLP

Chicago, Illinois  
March 9, 2012



Table of Contents

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders  
Exact Sciences Corporation

We have audited Exact Sciences Corporation's (a Delaware Corporation) (the Company) internal control over financial reporting as of December 31, 2011, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying 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, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and 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, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on criteria established in *Internal Control Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of the Company as of December 31, 2011 and 2010 and the related statements of operations, stockholders' (deficit) equity, and cash flows for each of the three years in the period ended December 31, 2011 and our report dated March 9, 2012 expressed an unqualified opinion.

/s/ Grant Thornton LLP

Chicago, Illinois  
March 9, 2012

Table of Contents

## EXACT SCIENCES CORPORATION

## Balance Sheets

(Amounts in thousands, except share data)

	December 31, 2011	December 31, 2010
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 35,781	\$ 78,752
Marketable securities	57,580	16,663
Prepaid expenses and other current assets	1,034	246
Total current assets	94,395	95,661
Property and Equipment, at cost:		
Laboratory equipment	2,314	943
Office and computer equipment	729	188
Leasehold improvements	288	89
Furniture and fixtures	23	20
	3,354	1,240
Less Accumulated depreciation and amortization	(796)	(386)
	2,558	854
	\$ 96,953	\$ 96,515
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 765	\$ 1,028
Accrued expenses	3,069	1,987
Deferred license fees, current portion	4,143	4,143
Total current liabilities	7,977	7,158
Long term debt	1,000	1,000
Long term accrued interest	42	21
Deferred license fees, less current portion	4,439	8,582
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, \$0.01 par value		
Authorized 5,000,000 shares		
Issued and outstanding none at December 31, 2011 and 2010		
Common stock, \$0.01 par value		
Authorized 100,000,000 shares		
Issued and outstanding 56,624,763 and 52,163,629 shares at December 31, 2011 and 2010, respectively	566	522
Additional paid-in capital	304,767	272,380
Other comprehensive loss (income)	(14)	1
Accumulated deficit	(221,824)	(193,149)
Total stockholders' equity	83,495	79,754
	\$ 96,953	\$ 96,515

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

Table of Contents**EXACT SCIENCES CORPORATION****Statements of Operations****(Amounts in thousands, except per share data)**

	Year Ended December 31,		
	2011	2010	2009
<b>Revenue:</b>			
Product royalty fees	\$ 20	\$ 26	\$ 25
License fees	4,143	5,318	4,733
	4,163	5,344	4,758
<b>Cost of revenue:</b>			
Product royalty fees	24	24	20
Gross profit	4,139	5,320	4,738
<b>Operating expenses:</b>			
Research and development	21,968	9,023	4,213
General and administrative	8,137	6,330	9,549
Sales and marketing	2,857	1,793	226
Restructuring			(3)
	32,962	17,146	13,985
Loss from operations	(28,823)	(11,826)	(9,247)
Interest income	169	46	120
Interest expense	(21)	(20)	(1)
Other income		244	
Net loss	\$ (28,675)	\$ (11,556)	\$ (9,128)
Net loss per share basic and diluted	\$ (0.54)	\$ (0.29)	\$ (0.28)
<b>Weighted average common shares</b>			
outstanding basic and diluted	52,512	40,455	32,791

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

Table of Contents**EXACT SCIENCES CORPORATION****Statements of Stockholders' (Deficit) Equity****(Amounts in thousands, except share data)**

	Common Stock			Treasury Stock		Other Comprehensive Income	Accumulated Deficit	Total Stockholders' (Deficit) Equity	Other Comprehensive (Loss) Income
	Number of Shares	\$0.01 Par Value	Additional Paid In Capital	Number of Shares	Value				
Balance, January 1, 2009	27,522,931	\$ 275	\$ 169,854	85,550	\$ (97)	\$	\$ (172,465)	\$ (2,433)	
Issuance of common stock related to the Genzyme Transaction (Note 3)	3,000,000	30	4,440					4,470	\$
Issuance of common stock in private placement	4,315,792	43	8,019					8,062	
Exercise of common stock options	380,355	4	728					732	
Issuance of common stock to fund the Company's 2008 401(k) match	24,430		32					32	
Compensation expense related to issuance of stock options and restricted stock awards	365,182	4	1,422					1,426	
Compensation expense related to stock option modifications (Note 7)			1,155					1,155	
Expense related to warrants (Note 4)			1,779					1,779	
Treasury share retirement	(85,550)	(1)	(96)	(85,550)	97				
Net loss							(9,128)	(9,128)	(9,128)
Other comprehensive loss						(1)		(1)	(1)
Comprehensive loss									\$ (9,129)
Balance, December 31, 2009	35,523,140	\$ 355	\$ 187,333		\$	\$ (1)	\$ (181,593)	\$ 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	461					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	396,092	4	2,245					2,249	
Expense related to warrants (Note 4)			107					107	
Net loss							(11,556)	(11,556)	(11,556)
Other comprehensive income						2		2	2
Comprehensive loss									\$ (11,554)
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	130,922	1	4,254					4,255	
Expense related to warrants (Note 4)			107					107	

Edgar Filing: EXACT SCIENCES CORP - Form 10-K

Net loss					(28,675)	(28,675)	(28,675)
Other comprehensive loss				(15)		(15)	(15)
Comprehensive income							\$ (28,690)
Balance, December 31, 2011	56,624,763	\$ 566	\$ 304,767		\$ (14)	\$ (221,824)	\$ 83,495

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

Table of Contents**EXACT SCIENCES CORPORATION****Statements of Cash Flows****(Amounts in thousands, except share data)**

	Year Ended December 31,		
	2011	2010	2009
<b>Cash flows from operating activities:</b>			
Net loss	\$ (28,675)	\$ (11,556)	\$ (9,128)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>			
Depreciation and write-offs of fixed assets	411	230	80
Write-offs of patents			95
Stock-based compensation	4,255	2,249	2,631
Amortization of deferred license fees	(4,143)	(5,318)	(4,733)
Warrant licensing expense	107	107	1,779
<b>Changes in assets and liabilities:</b>			
Prepaid expenses and other current assets	(788)	238	(294)
Accounts payable	(263)	873	(528)
Accrued expenses	1,251	667	(81)
Accrued interest	21	20	1
Third party royalty obligation		(988)	(2,462)
<b>Net cash used in operating activities</b>	<b>(27,824)</b>	<b>(13,478)</b>	<b>(12,640)</b>
<b>Cash flows from investing activities:</b>			
Purchases of marketable securities	(87,017)	(24,498)	(18,879)
Maturities of marketable securities	46,085	10,241	16,474
Purchases of property and equipment	(2,115)	(626)	(462)
<b>Net cash used in investing activities</b>	<b>(43,047)</b>	<b>(14,883)</b>	<b>(2,867)</b>
<b>Cash flows from financing activities:</b>			
Proceeds from Genzyme Collaboration, License and Purchase Agreement		1,896	16,650
Proceeds from sale of common stock to Genzyme			6,000
Proceeds from sale of common stock, net of issuance costs	27,215	82,327	8,062
Proceeds from exercise of common stock options and stock purchase plan	685	466	732
Decrease in restricted cash		500	100
Payment for repurchase of stock options			(50)
Proceeds from long term debt			1,000
<b>Net cash provided by financing activities</b>	<b>27,900</b>	<b>85,189</b>	<b>32,494</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>(42,971)</b>	<b>56,828</b>	<b>16,987</b>
<b>Cash and cash equivalents, beginning of period</b>	<b>78,752</b>	<b>21,924</b>	<b>4,937</b>
<b>Cash and cash equivalents, end of period</b>	<b>\$ 35,781</b>	<b>\$ 78,752</b>	<b>\$ 21,924</b>
<b>Supplemental disclosure of non-cash investing and financing activities:</b>			
Unrealized gain (loss) on available-for-sale investments	\$ (15)	\$ (2)	\$ 1
Retirement of 85,550 treasury shares of common stock	\$	\$	\$ 97
Issuance of 27,872, 15,460, and 24,430 shares of common stock to fund the Company's 401(k) matching contribution for 2010, 2009, and 2008, respectively	\$ 169	\$ 65	\$ 32

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



Table of Contents

**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 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, 2011 and 2010.

**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 interest 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 interest income.

At December 31, 2011 and December 31, 2010 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. All of the Company's investments are considered current. Realized gains were \$419, \$13,149, and \$6,380 during the years ended December 31, 2011, 2010, and 2009 respectively. Unrealized losses on investments recorded in other comprehensive income were \$13,784 during the year ended December 31, 2011. Unrealized gains on investments recorded in other comprehensive income were \$721 during the year ended December 31, 2010.

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Financial Statements (Continued)****(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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

(In thousands)	Amortized Cost	December 31, 2011		Estimated Fair Value
		Gains in Accumulated Other Comprehensive Income	Losses in Accumulated Other Comprehensive Income	
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
<b>Total available-for-sale securities</b>	<b>\$ 57,594</b>	<b>\$</b>	<b>\$ (14)</b>	<b>\$ 57,580</b>

Available-for-sale securities at December 31, 2010 consist of the following:

(In thousands)	Amortized Cost	December 31, 2010		Estimated Fair Value
		Gains in Accumulated Other Comprehensive Income	Losses in Accumulated Other Comprehensive Income	
Certificates of deposit	\$ 6,662	\$ 1	\$	\$ 6,663
Mutual funds	10,000			10,000
<b>Total available-for-sale securities</b>	<b>\$ 16,662</b>	<b>\$ 1</b>	<b>\$</b>	<b>\$ 16,663</b>

**Property and Equipment**

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

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, 2011, 2010, and 2009 was \$0.4 million, \$0.2 million, and \$0.1 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 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

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Financial Statements (Continued)****(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

patent costs incurred during the year ended December 31, 2011 and 2010 should be expensed and not capitalized as the future economic benefit derived from the transactions cannot be determined.

**Net Loss Per Share**

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

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

(In thousands)	2011	2010	2009
Shares issuable upon exercise of stock options	6,454	6,217	5,912
Shares issuable upon exercise of outstanding warrants(1)	325	825	1,250
Shares issuable upon the release of restricted stock awards	401	264	40
	7,180	7,306	7,202

(1)

At 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 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. At December 31, 2009, represents warrants to purchase 1,250,000 shares of common stock issued under a licensing agreement.

**Accounting for Stock-Based Compensation**

In accordance with Generally Accepted Accounting Principles (GAAP), the Company requires all share-based payments to employees, including grants of employee stock options, restricted stock, restricted stock units and shares purchased under an employee stock purchase plan (if certain parameters are not met), to be recognized in the financial statements based on their fair values.

**Revenue Recognition**

**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

Table of Contents

**EXACT SCIENCES CORPORATION**

**Notes to Financial Statements (Continued)**

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

\$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 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 year ended 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.

**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 PreGen-Plus, a non-invasive stool-based DNA colorectal cancer screening service for the average-risk population based on the Company's Version 1 technology, from August 2003 through June 2008. In June 2008, LabCorp stopped offering PreGen-Plus. On July 14, 2008, LabCorp began to commercially offer ColoSure, its next generation non-invasive, stool-based DNA testing service for the detection of colorectal cancer in the average-risk population, which is based on certain of the Company's intellectual property. The Company is entitled to the same royalty and milestone structure on any sales of ColoSure as it was entitled to on sales of PreGen-Plus.

Prior to the effective date of the Second Amendment, the Company's product royalty fees were based on a specified contractual percentage of LabCorp's cash receipts from performing PreGen-Plus tests. Accordingly, the Company recorded product royalty fees based on this specified percentage of LabCorp's cash receipts, as reported to the Company each month by LabCorp. Subsequent to the effective date of the Second Amendment, the Company's product royalty fees are based on a specified contractual percentage of LabCorp's net revenues from sales of PreGen-Plus through June 1, 2008, when LabCorp stopped offering PreGen-Plus, and from sales of ColoSure from and after July 2008. Accordingly, subsequent to the effective date of the Second Amendment, 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

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Financial Statements (Continued)****(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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.

Additionally, pursuant to the Second Amendment, the Company is potentially obligated to reimburse LabCorp for certain third-party royalty payments, as described in Note 5 below. To the extent the Company incurs liabilities in connection with this provision of the Second Amendment, the accretion of such liabilities will be recorded as a reduction in the product royalty fee line item in the Company's statements of operations.

**Other Income**

The Company recognizes other income as earned. Other income consists of income received related to activities other than normal business operations resulting from activities that are not consistent with the Company's central operations. The Company did not recognize any other income during the year ended December 31, 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 has been received in full. The Company did not recognize any other income during the year ended December 31, 2009.

**Advertising Costs**

The Company expenses the costs of media advertising at the time the advertising takes place. The Company expensed approximately \$110,000, \$68,100 and \$9,800 of media advertising during the years ended December 31, 2011, 2010, and 2009, respectively.

**Comprehensive Loss**

Comprehensive loss consists of net loss and the change in unrealized gains and losses on marketable securities. Comprehensive loss for the years ended December 31, 2011, 2010, and 2009 was as follows:

(In Thousands)	December 31,		
	2011	2010	2009
Net loss	\$ (28,675)	\$ (11,556)	\$ (9,128)
Unrealized gain (loss) on marketable securities	\$ (15)	\$ 2	\$ (1)
Comprehensive loss	\$ (28,690)	\$ (11,554)	\$ (9,129)

**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

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Financial Statements (Continued)****(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

minimizes the use of unobservable inputs. Observable inputs are inputs that reflect the assumptions that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances.

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

- Level 1** Quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access as of the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis.
- Level 2** Pricing inputs other than quoted prices in active markets included in Level 1, which are either directly or indirectly observable as of the reporting date. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.
- Level 3** Unobservable inputs that reflect the Company's assumptions about the assumptions that market participants would use in pricing the asset or liability. Unobservable inputs shall be used to measure fair value to the extent that observable inputs are not available.

Fixed-income securities and mutual funds are valued using a third party pricing agency. The valuation is based on observable inputs including pricing for similar assets and other observable market factors. There has been no material change from period to period.

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.

Description	Fair Value Measurement at December 31, 2011 Using:			
	Fair Value at December 31, 2011	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 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	
<b>Total</b>	<b>\$ 57,580</b>	<b>\$</b>	<b>\$ 57,580</b>	<b>\$</b>

Table of Contents**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, 2010 along with the level within the fair value hierarchy in which the fair value measurements in their entirety fall. Amounts in the table are in thousands.

Description	Fair Value at December 31, 2010	Fair Value Measurement at December 31, 2010 Using:		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-Sale				
Marketable securities				
Certificates of deposit	\$ 6,663	\$	\$ 6,663	\$
Mutual funds	10,000	10,000		
<b>Total</b>	<b>\$ 16,663</b>	<b>\$ 10,000</b>	<b>\$ 6,663</b>	<b>\$</b>

**Concentration of Credit Risk**

In accordance with GAAP, the Company is required to disclose any significant off-balance-sheet risk and credit risk concentration. The Company has no significant off-balance-sheet risk, such as foreign exchange contracts or other hedging arrangements. Financial instruments that subject the Company to credit risk consist of cash, cash equivalents and marketable securities. As of December 31, 2011, 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 \$35.5 million. The Company has not experienced any losses in such accounts and management believes it is not exposed to any significant credit risk.

**Subsequent Events**

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

**Recent Accounting Pronouncements**

In May 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2011-04, "Fair Value Measurements (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in US GAAP and IFRS," ("ASU 2011-04"). These amendments, effective for the interim and annual periods beginning on or after December 15, 2011, result in common definition of fair value and common requirements for measurement of and disclosure requirements between US GAAP and IFRS. ASU 2011-04 clarifies or changes certain fair value measurement principles and enhances the disclosure requirements particularly for Level 3 fair value measurements. The adoption of ASU 2011-04 is not expected to have a material impact on the Company's financial condition or results of operation.



Table of Contents

**EXACT SCIENCES CORPORATION**

**Notes to Financial Statements (Continued)**

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

In June 2011, the FASB issued ASU No. 2011-05, "*Comprehensive Income (ASC Topic 220): Presentation of Comprehensive Income*," ("ASU 2011-05") which amends current comprehensive income guidance. This guidance is effective retrospectively for the interim and annual periods beginning on or after December 15, 2011, and requires presentation of total comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity. The pronouncement does not change the current option for presenting components of other comprehensive income, gross, or net of the effect of income taxes, provided that such tax effects are presented in the statement in which other comprehensive income is presented or disclosed in the notes to the financial statements. Additionally, the pronouncement does not affect the calculation or reporting of earnings per share. The pronouncement also does not change the items which must be reported in other comprehensive income, how such items are measured, or when such items must be reclassified to net income. The Company will adopt this guidance in the first quarter of 2012. The adoption of ASU 2011-05 is not expected to have a material impact on the Company's financial condition or results of operation.

In December 2011, the FASB issued ASU 2011-12, "Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05" (ASU 2011-12), which deferred the requirement to present on the face of the financial statements reclassification adjustments for items that are reclassified from other comprehensive income to net income while the FASB further deliberates this aspect of the proposal. The amendments contained in ASU 2011-05 do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The amendments also do not affect how earnings per share is calculated or presented. ASU 2011-05, as amended by ASU 2011-12, is effective for us on January 1, 2012.

**Reclassifications**

Certain prior year amounts have been reclassified to conform to the current year presentation in the footnotes.

**(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

Table of Contents

**EXACT SCIENCES CORPORATION**

**Notes to Financial Statements (Continued)**

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

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.

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.

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

Table of Contents

**EXACT SCIENCES CORPORATION**

**Notes to Financial Statements (Continued)**

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

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 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, 2011 and 2010, respectively.

**(4) MAYO LICENSING 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 based on 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

Table of Contents

**EXACT SCIENCES CORPORATION**

**Notes to Financial Statements (Continued)**

**(4) MAYO LICENSING AGREEMENT (Continued)**

of 200,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its rights with respects to 86,596 shares leaving it with a net amount of 113,404 shares.

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

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

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

**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 MAYO 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 cancer screening 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 cancer screening test, therefore the \$500,000 milestone payment has not been recorded as a liability. The Company periodically evaluates the status of the FDA trial. In addition, the Company is paying MAYO for research and development efforts. Through December 31, 2011, as part of the Company's research collaboration with MAYO, the Company has incurred charges of \$1.4 million and has made payments of \$1.4 million. The Company has recorded an estimated liability in the amount of \$53,000 for research and development efforts as of December 31, 2011.

**(5) LABCORP STRATEGIC ALLIANCE AGREEMENT**

On June 26, 2002, the Company entered into a license agreement (subsequently amended on January 19, 2004, June 27, 2007, August 31, 2007, and March 17, 2008) with LabCorp for an exclusive, strategic alliance between the parties to commercialize LabCorp's proprietary, non-invasive DNA-based technologies for the early detection of colorectal cancer in the average-risk population. Pursuant to the

Table of Contents

**EXACT SCIENCES CORPORATION**

**Notes to Financial Statements (Continued)**

**(5) LABCORP STRATEGIC ALLIANCE AGREEMENT (Continued)**

amended agreement, the Company exclusively licensed to LabCorp all U.S. and Canadian patents and patent applications owned by the Company relating to its stool-based colorectal cancer screening technology initially through August 2008, followed by a non-exclusive license for the life of the patents. In return for the license, LabCorp agreed to pay the Company certain up-front, milestone and performance-based payments, and a per-test royalty fee. LabCorp made an initial payment of \$15 million upon the signing of the agreement, and a second payment of \$15 million was made in August 2003 upon the commercial launch of PreGen-Plus. In addition to certain royalty fees, under the amended license agreement, the Company may also be eligible for certain milestone payments from LabCorp as described below.

In conjunction with the strategic alliance, in June 2002, the Company issued to LabCorp a warrant (the "LabCorp Warrant") to purchase 1,000,000 shares of its common stock, exercisable over a three-year period at an exercise price of \$16.09 per share. The Company assigned a value to the warrant of \$6.6 million under the Black-Scholes option-pricing model which has been recorded as a reduction in the initial up-front deferred license fee of \$15 million. The Company is amortizing the first two payments totaling \$30 million, net of the \$6.6 million value of the warrant, as license fee revenue over the exclusive license period described below.

At the time of issuance, the LabCorp Warrant had an expiration date of June 26, 2005. On June 24, 2005, the Company entered into an amendment to the LabCorp Warrant to extend the expiration date of the LabCorp Warrant to August 13, 2008, which was the expiration date of the exclusive period at the time of the extension. All other terms of the LabCorp Warrant were unaffected. The Company assigned a value to the LabCorp Warrant extension of \$0.6 million using the Black-Scholes option pricing model. The Company recorded the cost of the LabCorp Warrant extension as a one-time, non-cash reduction in license fee revenue of \$0.6 million in the quarter ended June 30, 2005. The LabCorp Warrant expired unexercised on August 13, 2008.

**Second Amendment to LabCorp License Agreement** On June 27, 2007, the Company entered into the Second Amendment with LabCorp. The Second Amendment modified LabCorp's exclusive rights to the Company's DNA technology for colorectal cancer screening to permit the Company to license its technology to select third-party organizations and commercial service laboratories, subject to LabCorp's preferential pricing terms, and to extend LabCorp's modified exclusive period under the Second Amendment until December 31, 2010. Additionally, the Second Amendment clarifies the rights and obligations with respect to the Company's second-generation stool-based DNA screening technology for colorectal cancer screening ("Version 2").

The Second Amendment also revised the milestone and royalty obligations of LabCorp. The milestones were revised to eliminate milestone payments aggregating \$15 million based upon stool-based colorectal cancer screening being included as standard of care and certain policy-level reimbursement approvals. As revised under the Second Amendment, the Company may be eligible for up to an aggregate of \$40 million in milestone payments, all of which relate to the achievement of significant sales thresholds. Royalties due to the Company under the Second Amendment are equal to 15% of LabCorp's net revenues from tests performed using the Company's DNA technology licensed under the Second Amendment, and could increase to 17% if LabCorp achieves a significant annual ColoSure net revenue threshold. LabCorp also retains certain pricing protections over third-party organizations and commercial service laboratories to whom the Company may license its DNA technology for colorectal cancer screening.

Table of Contents

**EXACT SCIENCES CORPORATION**

**Notes to Financial Statements (Continued)**

**(5) LABCORP STRATEGIC ALLIANCE AGREEMENT (Continued)**

The Second Amendment also eliminated an approximate \$3.0 million contingent liability of the Company to LabCorp resulting from a historical third-party royalty obligation of LabCorp.

Pursuant to the terms of the Second Amendment, the Company became obligated to reimburse LabCorp for certain third-party royalty payments if LabCorp's third-party royalty rate is greater than a specified royalty rate during the measuring period. The Company's obligation to pay LabCorp pursuant to this provision of the Second Amendment was based on LabCorp's sales volumes of colorectal cancer screening tests using the Company's technology during three separate measurement periods. The Company did not record any charges in connection with this third-party royalty obligation during the year ended December 31, 2011. The Company recorded charges of \$5,000, and \$13,000 during the years ended December 31, 2010 and 2009 respectively, in connection with this third-party royalty obligation. These charges were recorded under the caption "Product royalty fees" in the Company's statements of operations. During 2009, the Company made payments of \$2.5 million to LabCorp. During 2010, the Company made a final payment of \$1.0 million to LabCorp to fully satisfy this liability.

In addition, as a result of extending the exclusive license period from August 2008 to December 2010, the amortization of the remaining deferred revenue as of the date of the Second Amendment of \$4.7 million related to up-front technology license fees received from LabCorp was amortized on a straight line basis over the extended exclusive license period beginning in the quarter ended September 30, 2007 through December 31, 2010. The Company recorded revenues of \$1.4 million in both the years ended December 31, 2010 and 2009. The Second Amendment also provided LabCorp with termination rights if stool-based colorectal cancer screening is not accepted as standard of care in the near term (i.e. included in screening guidelines of the American Cancer Society or the American Gastroenterological Association), if the Company's Version 2 technology is not commercially launched in the near term, or if the Company's Version 2 technology does not attain certain sensitivity and specificity thresholds during technology validation.

**Third Amendment to LabCorp License Agreement** On August 31, 2007, the Company entered into a Third Amendment (the "Third Amendment") to its exclusive license agreement with LabCorp that, among other things, added a potential \$2.5 million milestone payment for which the Company may be eligible. The milestone obligation is based upon policy-level reimbursement approval from Medicare at a specified minimum reimbursement rate, inclusion of stool-based DNA screening in clinical practice guidelines and the achievement of certain increases in sales levels of PreGen-Plus over a defined measuring period. In addition, the Third Amendment provided that LabCorp will assume sole responsibility, at its expense, for all commercial activities related to LabCorp's stool-based DNA testing service. In accordance with the foregoing, LabCorp also agreed to offer at-will employment to certain former personnel of the Company.

**Fourth Amendment to LabCorp License Agreement** On March 17, 2008, the Company entered into the fourth amendment (the "Fourth Amendment") to its exclusive license agreement with LabCorp. Among other things, the Fourth Amendment further clarified certain license rights of the parties, amended LabCorp's termination rights relating to the failure to launch the Company's Version 2 technology and restricted certain of the Company's termination rights in the event the FDA limits LabCorp's ability to market products that incorporate technology licensed to LabCorp under the amended license agreement. In addition, the Fourth Amendment eliminated certain of the Company's termination rights for a specified period of time during which LabCorp is not marketing any stool-based DNA test for colorectal cancer as a result of preparing for a commercial launch of a stool-based DNA test for colorectal cancer based on the Company's Version 2 technology.

Table of Contents

**EXACT SCIENCES CORPORATION**

**Notes to Financial Statements (Continued)**

**(6) EQUITY**

In April of 2010, the Company entered into a license agreement with MAYO for market research services and rights to use certain intellectual property related to product development. As part of the license agreement, the Company issued to MAYO 11,186 shares of common stock for an initial payment under the agreement and recognized \$50,000 of expense for the year ended December 31, 2010. If the Company utilizes the licensed intellectual property in the Company's final product design, the Company will be required to make an additional nonrefundable payment to MAYO in the form of unregistered shares of common stock with a fair market value of \$65,000.

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 \$27.1 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.

In February 2011, we adopted a rights agreement that provides that in the event of an acquisition of 15% or more of our outstanding common stock or an announcement of an intention to make a tender offer or exchange offer for 15% or more of our outstanding common stock, our stockholders, other than the potential acquiror, shall be granted rights enabling them to purchase additional shares of our common stock at a substantial discount to the then prevailing market price. The rights agreement could significantly dilute such acquiror's ownership position in our shares, thereby making a takeover prohibitively expensive and encouraging such acquiror to negotiate with our board of directors.

**(7) 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. At December 31, 2010, there were no shares of common stock available for future grants under the 2000 Option Plan. The 2000 Option Plan expired October 17, 2010 and after such date no further awards could be granted under the plan. Under the terms of the 2000 Option Plan, the Company was authorized to grant incentive stock options, as defined under the Internal Revenue Code, non-qualified options, restricted stock awards and other stock awards to employees, officers, directors, consultants and advisors. Options granted under the 2000 Option Plan expire ten years from the date of grant. Grants made from the 2000 Option Plan generally vest over a period of three to four years.

The 2000 Option Plan was administered by the compensation committee of the Company's board of directors, which selected the individuals to whom equity-based awards would be granted and determined the option exercise price and other terms of each award, subject to the provisions of the 2000 Option Plan. The 2000 Option Plan provides that upon an acquisition of the Company, all options

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Financial Statements (Continued)****(7) STOCK-BASED COMPENSATION (Continued)**

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, 2011, options to purchase 5,417,404 shares were outstanding under the 2000 Option Plan and 81,000 shares of restricted stock remained unreleased.

**2000 Employee Stock Purchase Plan** The 2000 Employee Stock Purchase Plan (the "2000 Purchase Plan") was initially adopted by the Company in October 2000, was subsequently amended and restated, and expired on October 31, 2010. The 2000 Purchase Plan provided participating employees the right to purchase common stock at a discount through a series of offering periods. At December 31, 2011, there were no shares of common stock available for purchase by participating employees under the 2000 Purchase Plan.

The compensation committee of the Company's board of directors administered the 2000 Purchase Plan. Generally, all employees whose customary employment was more than 20 hours per week and more than five months in any calendar year were eligible to participate in the 2000 Purchase Plan. Participating employees authorized 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 was deemed to have exercised the option, at the option exercise price, to the extent of accumulated payroll deductions. Under the terms of the 2000 Purchase Plan, the option exercise price is an amount equal to 85% of the fair market value, as defined under the 2000 Purchase Plan and no employee was permitted to purchase more than \$25,000 of the Company common stock under the 2000 Purchase Plan in any calendar year. Rights granted under the 2000 Purchase Plan terminate upon an employee's voluntary withdrawal from the 2000 Purchase Plan at any time or upon termination of employment. The Company issued the following shares of common stock under the 2000 Purchase Plan for the year ended December 31, 2010. No shares were issued under the 2000 Purchase Plan in 2009.

Offering period ended	Number of Shares	Weighted Average Price per Share
April 30, 2010	34,221	\$ 2.04
October 31, 2010	24,488	\$ 2.40

**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, who remains an employee of the



Table of Contents**EXACT SCIENCES CORPORATION****Notes to Financial Statements (Continued)****(7) STOCK-BASED COMPENSATION (Continued)**

Company or the acquiring entity immediately following consummation of the acquisition, 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, 2011, options to purchase 1,036,240 shares were outstanding under the 2010 Stock Plan, and 320,490 restricted stock and restricted stock unit shares remained unreleased. At December 31, 2011, there were 2,716,475 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, 2011, there were 248,143 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 for 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 option, at the option exercise price, to the extent of accumulated payroll deductions. Under the terms of the 2010 Purchase Plan, the option exercise price is an amount equal to 85% of the fair market value, as defined under the 2010 Purchase Plan and no employee can purchase more than \$25,000 of the 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, 2011, there were 51,857 shares issued under the 2010 Purchase Plan.

Offering period ended	Number of Shares	Weighted Average price per Share
April 30, 2011	27,110	\$ 5.48
October 31, 2011	24,747	\$ 5.78

**Stock-Based Compensation Expense**

The Company recorded approximately \$4.0 million in stock-based compensation expense during the year ended December 31, 2011, in connection with the amortization of 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 \$2.2 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. The Company recorded approximately \$2.6 million in stock-based compensation expense during the year ended December 31, 2009 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 and collaborators, as well as the modification of certain stock options. Non-cash stock-based

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Financial Statements (Continued)****(7) STOCK-BASED COMPENSATION (Continued)**

compensation expense by department for the years ended December 31, 2011, 2010, and 2009 are as follows. Amounts included in the table are in thousands.

	December 31,		
	2011	2010	2009
Research and development	\$ 1,685	\$ 1,067	\$ 319
General and administrative	1,622	1,132	2,308
Sales and marketing	657	50	4

In connection with the December 31, 2011 resignation of John Krayacich as the Company's Senior Vice President of Sales and Marketing, the Company accelerated the vesting of 131,250 shares under Mr. Krayacich's previously unvested stock options. This acceleration was done in accordance with Mr. Krayacich's employment agreement. Mr. Krayacich will have a two year period from December 31, 2011 to exercise these options. The remaining 168,750 stock options from his initial grant will be 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 award 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 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. Awards granted in 2011 and 2010 are all expected to vest and no forfeiture rate was utilized.

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

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Financial Statements (Continued)****(7) STOCK-BASED COMPENSATION (Continued)**

date of grant using the Black-Scholes option pricing model based on the assumptions in the following table.

	December 31,		
	2011	2010	2009
<b>Option Plan Shares</b>			
Risk-free interest rates	0.88% - 2.3%	1.17% - 2.69%	1.76% - 2.69%
Expected term (in years)	6	6	6
Expected volatility	92%	91% - 92%	85 - 92%
Dividend yield	0%	0%	0%
Weighted average fair value per share of options granted during the period	\$ 4.78	\$ 3.07	\$ 0.89
<b>ESPP Shares</b>			
Risk-free interest rates	0.13% - 0.61%	0.16% - 0.38%	(1)
Expected term (in years)	0.5 - 2	0.5 - 2	(1)
Expected volatility	48% - 63%	53% - 127%	(1)
Dividend yield	0%	0%	(1)
Weighted average fair value per share of stock purchase rights granted during the period	\$ 2.83	\$ 2.03	(1)

(1) The Company did not issue stock purchase rights under its employee stock purchase plans during the period indicated.

Table of Contents

## EXACT SCIENCES CORPORATION

## Notes to Financial Statements (Continued)

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

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

A summary of stock option activity under the Stock Plans during the years ended 2011, 2010 and 2009 is as follows:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value(1)
<i>(Aggregate intrinsic value in thousands)</i>				
Outstanding, January 1, 2009	3,518,899	\$ 4.20		
Granted	4,860,000	1.19		
Exercised	(380,355)	1.92		
Cancelled	(2,086,525)	4.51		
Outstanding, December 31, 2009	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	7.2	38,309
Exercisable, December 31, 2011	3,965,380	\$ 1.95	6.8	24,938
Vested and expected to vest, December 31, 2011	6,453,644	\$ 2.27	7.2	38,309

(1)

The aggregate intrinsic value of options outstanding at December 31, 2011 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 6,222,470 options that had exercise prices that were lower than the \$8.12 market price of our common stock at December 31, 2011. The aggregate intrinsic value of options exercisable at December 31, 2011 is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for the 3,860,380 options that had exercise prices that were lower than the \$8.12 market price of our common stock at December 31, 2011. The total intrinsic value of options exercised during the years ended December 31, 2011, 2010 and 2009 was \$1.9 million, \$0.4 million, \$0.2 million, respectively, determined as of the date of exercise.

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Financial Statements (Continued)****(7) STOCK-BASED COMPENSATION (Continued)**

A summary of restricted stock and restricted stock unit activity under the Stock Plans during the years ended 2011, 2010 and 2009 is as follows:

	<b>Restricted Shares</b>	<b>Weighted Average Grant Date Fair Value</b>
Outstanding, January 1, 2009	185,000	\$ 0.39
Granted	411,127	0.98
Released	(510,181)	0.77
Cancelled	(45,946)	0.37
<b>Outstanding, December 31, 2009</b>	<b>40,000</b>	<b>1.72</b>
Granted	326,197	5.73
Released	(102,567)	2.94
<b>Outstanding, December 31, 2010</b>	<b>263,630</b>	<b>6.20</b>
Granted	335,716	6.06
Released	(192,856)	5.89
Forfeited	(5,000)	5.61
<b>Outstanding, December 31, 2011</b>	<b>401,490</b>	<b>\$ 6.24</b>

As of December 31, 2011, there was approximately \$6.6 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 \$0.7 million, \$0.5 million, \$0.7 million from stock option exercises during the years ended December 31, 2011, 2010 and 2009, respectively. During the years ended December 31, 2011, 2010 and 2009, 51,857, zero, and zero shares, respectively of common stock were issued under the Company's 2010 Purchase Plan resulting in proceeds to the Company of \$0.3 million, \$0, and \$0, respectively. During the years ended December 31, 2011, 2010 and 2009, zero, 58,709, and zero shares, respectively, of common stock were issued under the Company's 2000 Purchase Plan resulting in proceeds to the Company of \$0, \$0.1 million, and \$0, respectively.

Table of Contents

## EXACT SCIENCES CORPORATION

## Notes to Financial Statements (Continued)

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

The following table summarizes information relating to currently outstanding and exercisable stock options as of December 31, 2011:

Exercise Price	Number of Options	Outstanding		Exercisable	
		Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
\$ - \$1.00	3,795,000	7.2	\$ 0.83	2,623,125	\$ 0.83
\$1.01 - \$2.00	211,163	7.3	\$ 1.44	64,911	\$ 1.44
\$2.01 - \$3.00	1,069,553	6.9	\$ 2.79	717,052	\$ 2.76
\$3.01 - \$4.00	187,066	6.7	\$ 3.55	132,979	\$ 3.54
\$4.01 - \$5.00	395,500	7.6	\$ 4.26	147,625	\$ 4.42
\$5.01 - \$7.00	480,500	9.0	\$ 5.83	150,000	\$ 5.64
\$7.01 - \$9.00	209,862	8.6	\$ 8.15	24,688	\$ 7.76
\$9.01 - \$14.00	105,000	1.3	\$ 12.73	105,000	\$ 12.73
	6,453,644	7.2	\$ 2.27	3,965,380	\$ 1.95

**Option Modifications**

**2009 Modifications** In connection with the March 18, 2009 resignation of Jeffrey R. Luber as the Company's President and Chief Executive Officer and Charles R. Carelli, Jr. as the Company's Chief Financial Officer, the Company's board of directors approved the following stock option modifications: On April 2, 2009, the effective date of Mr. Luber's resignation from the Company, the Company accelerated the vesting of 114,896 shares under Mr. Luber's previously unvested stock options, with a fair value of the share price on the original grant date. On April 2, 2009, the effective date of Mr. Carelli's resignation from the Company, the Company accelerated the vesting of 70,556 shares under Mr. Carelli's previously unvested stock options, with a fair value of the share price on the original grant date. As a result of these modifications, the Company recorded one-time non-cash stock-based compensation expense of approximately \$0.3 million during the quarter ended March 31, 2009. In addition, the Company repurchased 804,026 shares for \$50,000.

During 2009, the restriction for all 445,181 shares of the Board of Directors restricted stock award grants was lifted. The restriction for the awards was lifted before their one year term which is considered a modification under financial accounting standards. The Company recognized the incremental fair value on the date the restriction was lifted, thus resulting in approximately \$0.9 million of non-cash stock-based compensation expense related to the modification.

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Financial Statements (Continued)****(7) STOCK-BASED COMPENSATION (Continued)****Shares Reserved for Issuance**

The Company has reserved shares of its authorized common stock for issuance pursuant to its employee stock purchase and stock option plans, including all outstanding stock option grants noted above at December 31, 2011, as follows:

**Shares reserved for issuance**

2010 Option Plan	2,716,475
2010 Purchase Plan	248,143
	2,964,618

**(8) COMMITMENTS AND CONTINGENCIES****Operating Leases**

During November 2009, the Company entered into a five year lease for a 17,500 sq. ft. 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 sq. ft. of laboratory and office space for a total of 24,572 sq. ft. The amended agreement covers the same term as the original term and is also subject to periodic rent escalation adjustments.

Future minimum payments under operating leases as of December 31, 2011 are as follows. Amounts included in the table are in thousands.

Year Ending December 31,	
2012	\$ 389
2013	399
2014	339
2015	
2016	
Thereafter	
Total lease obligations	\$ 1,127

Rent expense included in the accompanying statements of operations was approximately \$0.3 million, \$0.2 million, and \$0.2 million for the years ended December 31, 2011, 2010 and 2009, respectively.

During the fourth quarter of 2007, the Company entered into a sublease agreement with INTRINSIX, Inc. to sublease approximately 11,834 square feet of rentable area in the Company's Marlborough facility. The term of the sublease agreement ran from December 2007 to August 2010. The Company received approximately \$0.6 million in sublease payments over the life of the sublease agreement.

During the fourth quarter of 2008, the Company entered into the 2008 Sublease Agreement with QTEROS to sublease to QTEROS approximately 25,537 square feet of rentable area in the Company's Marlborough facility. The term of the 2008 Sublease Agreement ran from December 2008 to August 2010. The Company received approximately \$1.0 million in sublease payments over the life of the 2008

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Financial Statements (Continued)****(8) COMMITMENTS AND CONTINGENCIES (Continued)**

Sublease Agreement. The Company no longer occupies space at the Marlborough facility as the lease expired in August 2010.

During the fourth quarter of 2009, the Company entered into a sublease agreement (the "2009 Sublease Agreement") with Aldevron Madison 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, is 36 months. The Company expects to receive approximately \$0.2 million in sublease payments over the life of the 2009 Sublease Agreement. Pursuant to the Sublease Agreement, Aldevron has no rights to renew or extend the 2009 Sublease Agreement. The Company received \$78,500, \$76,600 and \$13,000 in sublease payments in 2011, 2010 and 2009, respectively. Under the terms of the 2009 Sublease Agreement, Aldevron is required to provide a security deposit of \$6,000 and will be required to pay its pro rata share of any increases in building operating expenses and real estate taxes. Future sublease receipts under sublease agreements as of December 31, 2011 are as follows. Amounts included in the table are in thousands.

Year ending December 31,	
2012	\$ 67
2013	
2014	
2015	
2016	
Thereafter	
	\$ 67

**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.

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.

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. Pursuant to the terms of this licensing agreement, the Company made an up-front payment of \$80,000 on July 12, 2009. 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



Table of Contents

**EXACT SCIENCES CORPORATION**

**Notes to Financial Statements (Continued)**

**(8) COMMITMENTS AND CONTINGENCIES (Continued)**

June 12, 2012 and \$25,000 on June 12, 2013 and each year thereafter through 2029. The Company granted Mayo a warrant to purchase 1,000,000 shares of common stock at \$1.90 per share which vested immediately. The expense related to those warrants is recognized and recorded as research and development expense in 2009. The Company also granted a warrant to purchase 250,000 shares of common stock at \$1.90 per share which vest over a four year period. The related expense will be recognized and recorded over a four year period as research and development expense. The Company began enrollment in its FDA trial in June of 2011 and the milestone payment of \$250,000 was made in June of 2011. It is uncertain as to when the FDA will approve the Company's cancer screening test. Therefore, the \$500,000 milestone payment has not been recorded as a liability. The Company periodically evaluates the status of the FDA trial.

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. Pursuant to the terms of this license agreement, the Company paid an up-front payment of \$50,000. The Company is required to pay Hologic a royalty fee based on a percentage of the Company's net sales of the licensed products. The Company began enrollment in its FDA trial in June of 2011 and the milestone payment of \$100,000 was made in June of 2011. It is uncertain as to when the FDA will approve the Company's cancer screening test. Therefore, the \$100,000 milestone payment has not been recorded as a liability. The Company periodically evaluates the status of the FDA trial.

On July 26, 2010, the Company entered into a technology license and royalty agreement with MDx Health (formerly Oncomethylome Sciences). 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 made an up-front payment of \$100,000. The Company also paid \$100,000 for the intent to utilize certain patent rights. 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 \$0.8 million, \$0.4 million, and \$1.9 million, respectively, for the years ended December 31, 2011,

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Financial Statements (Continued)****(8) COMMITMENTS AND CONTINGENCIES (Continued)**

2010 and 2009. Future minimum payments due under the Company's technology licenses as of December 31, 2011 are as follows. Amounts included in the table are in thousands.

Year ending December 31,	
2012	\$ 281
2013	296
2014	296
2015	296
2016	256
Thereafter	2,544
	\$ 3,969

The Company has also entered into several clinical research agreements, under which it is obligated to fund certain research activities for purposes of technology development. As of December 31, 2011 and 2010, the Company had no outstanding sample collection commitments. The Company has recorded research and development expense associated with clinical research agreements of approximately \$1.0 million, \$1.3 million, and \$0.5 million, respectively, for the years ended December 31, 2011, 2010 and 2009. As of December 31, 2011, the Company did not have any remaining obligation under these agreements.

**(9) ACCRUED EXPENSES**

Accrued expenses at December 31, 2011 and 2010 consisted of the following. Amounts included in the table are in thousands.

	December 31,	
	2011	2010
Compensation	\$ 2,041	\$ 902
Research and trial related expenses	440	573
Licenses	338	173
Professional fees	182	271
Other	37	46
Occupancy costs	31	22
	\$ 3,069	\$ 1,987

**(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. If the Company creates 100 full time positions as of June 30, 2015, the principal shall be reduced at the rate of \$5,405 for each new position created. 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

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Financial Statements (Continued)****(10) LONG TERM DEBT (Continued)**

subject to an increase to 4% if the Company does not meet certain job creation requirements. Both principal and interest payments under the loan agreement are deferred for five years. Based on the Company's estimation of the loan obligation, the table below represents the future principal obligations as of December 31, 2011:

Year ending December 31,	
2012	\$
2013	
2014	
2015	145
2016	217
Thereafter	638
	\$ 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 2011, 2010 and 2009 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 \$0.3 million, \$0.2 million, and \$0.1 million, respectively, in the statements of operations for the years ended December 31, 2011, 2010 and 2009 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, 2011, the Company had federal net operating loss and state net operating loss carryforward of approximately \$194.4 million and \$170.1 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 \$3.3 million, respectively which may be used to offset future income tax liability. The federal and state carryforwards expire beginning 2015 through 2031 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.

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Financial Statements (Continued)****(12) INCOME TAXES (Continued)**

As of December 31, 2011 and 2010, the Company had \$10.6 million and \$6.3 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.

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
Deferred tax assets:		
Operating loss carryforwards	\$ 71,471	\$ 60,390
Tax credit carryforwards	7,511	6,829
Deferred revenue	3,399	5,041
Other temporary differences	2,257	2,365
Tax assets before valuation allowance	84,638	74,625
Less Valuation allowance	(84,638)	(74,625)
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 \$84.6 million and \$74.6 million valuation allowance at December 31, 2011 and 2010 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 \$10.0 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:

	<b>December 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>2009</b>
U.S. Federal statutory rate	34.0%	34.0%	34.0%
State taxes	5.6	5.6	5.6
Research and development tax credit	2.4	2.6	0.9
AMT Tax			(1.0)
AMT Credit			1.0
Stock-based compensation expense	(2.4)	(1.9)	(1.0)
Other adjustments	0.1	(0.1)	
Valuation allowance	(39.7)	(40.1)	(40.5)
Effective tax rate	0.0%	0.1%	(1.0)%

In June 2006, the FASB issued guidance that clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements, and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken

Table of Contents

**EXACT SCIENCES CORPORATION**

**Notes to Financial Statements (Continued)**

**(12) INCOME TAXES (Continued)**

or expected to be taken in a tax return. Additionally, the FASB provided guidance on subsequent derecognition of tax positions, financial statement classification, recognition of interest and penalties, accounting in interim periods, and disclosure and transition requirements. The Company adopted these provisions on January 1, 2007. As required by the new guidance issued by the FASB, 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. At the adoption date, the Company applied this guidance to all tax positions for which the statute of limitations remained open. The amount of unrecognized tax benefits as of January 1, 2007 was none. There have been no changes in unrecognized tax benefits since January 1, 2007, 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, 2011.

As of December 31, 2011, 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 2011, and to state income tax examinations for the tax years 1995 through 2011. 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, 2011, 2010 and 2009.

**(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, 2011. In the opinion of management, this information has been prepared on the same basis as the audited financial statements appearing elsewhere in this Form 10-K, and all necessary adjustments, consisting only of normal recurring adjustments, have been included in the amounts stated below to present fairly the unaudited quarterly results of operations. The quarterly

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Financial Statements (Continued)****(13) QUARTERLY RESULTS OF OPERATIONS (UNAUDITED) (Continued)**

data should be read in conjunction with our audited financial statements and the notes to the financial statements appearing elsewhere in this Form 10-K.

	Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
	(Amounts in thousands, except per share data)			
<b>2011</b>				
Revenue	\$ 1,040	\$ 1,042	\$ 1,039	\$ 1,042
Cost of revenue	6	6	6	6
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)
Interest 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
<b>2010</b>				
Revenue	\$ 1,299	\$ 1,314	\$ 1,356	\$ 1,375
Cost of revenue	6	6	6	6
Research and development	1,795	2,123	2,635	2,470
General and administrative	1,512	1,339	1,796	1,683
Sales and marketing	109	330	315	1,039
Loss from operations	(2,123)	(2,484)	(3,396)	(3,823)
Interest income, net	(1)	7	14	6
Other income				244
Net loss	\$ (2,124)	\$ (2,477)	\$ (3,382)	\$ (3,573)
Net loss per share basic and diluted	\$ (0.06)	\$ (0.06)	\$ (0.08)	\$ (0.08)
Weighted average common shares outstanding basic and diluted	35,607	39,067	40,155	46,869

Table of Contents

**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 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 such information is accumulated and communicated to management, including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

*Management's Report on Internal Control over Financial Reporting.*

Management of the Company is responsible for establishing and maintaining effective internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. The Company's internal control over financial reporting is designed to provide reasonable assurance to the Company's management and board of directors regarding the preparation and fair presentation of published financial statements in accordance with generally accepted accounting principles.

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

Management, with the participation of our principal executive officer and principal financial officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2011. 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 this assessment, our management concluded that, as of December 31, 2011, the Company's internal control over financial reporting was effective based on those criteria.

Our independent registered public accounting firm, Grant Thornton LLP, has issued an audit report on the effectiveness of our internal control over financial reporting, which is included herein.

*Changes in Internal Control over Financial Reporting.*

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2011, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

None.

Table of Contents

**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 2012 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 2012 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 2012 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 2012 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 2012 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).





Edgar Filing: EXACT SCIENCES CORP - Form 10-K

Table of Contents

Name	Title	Date
/s/ KATHERINE NAPIER	Director	March 9, 2012
Katherine Napier		
/s/ LIONEL STERLING	Director	March 9, 2012
Lionel Sterling		
/s/ DAVID THOMPSON	Director	March 9, 2012
David Thompson		

## Edgar Filing: EXACT SCIENCES CORP - Form 10-K

### Table of Contents

#### **Exhibit Index to Annual Report on Form 10-K**

<b>Exhibit Number</b>	<b>Description</b>
3.1	Sixth Amended and Restated Certificate of Incorporation of the Registrant (previously filed as Exhibit 3.3 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
3.2	Amended and Restated By-Laws of the Registrant (previously filed as Exhibit 3.1 to our Report on Form 10-Q for the period ended March 31, 2009, which is incorporated herein by reference)
3.3	Certificate of Designations of Series A Junior Participating Preferred Stock of Exact Sciences Corporation (previously filed as Exhibit 3.1 to our Registration Statement on Form 8-A filed on February 23, 2011, which is incorporated herein by reference)
4.1	Specimen certificate representing the Registrant's Common Stock (previously filed as Exhibit 4.1 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
4.2	Warrant No. W-1 issued to MAYO Foundation for Medical and Educational Research dated June 11, 2009 (previously filed as Exhibit 4.1 to our Report on Form 10-Q for the period ended June 30, 2009, which is incorporated herein by reference)
4.3	Warrant No. W-2 issued to MAYO Foundation for Medical and Educational Research dated June 11, 2009 (previously filed as Exhibit 4.2 to our Report on Form 10-Q for the period ended June 30, 2009, which is incorporated herein by reference)
4.4	Rights Agreement, dated as of February 22, 2011, by and between Exact Sciences Corporation and American Stock Transfer & Trust Company, LLC (previously filed as Exhibit 4.1 to our Registration Statement on Form 8-A filed on February 23, 2011, which is incorporated herein by reference)
10.1*	2000 Stock Option and Incentive Plan (previously filed as Exhibit 10.2 to our Annual Report on Form 10-K filed for the period ended December 31, 2008, which is incorporated herein by reference)
10.2**	Agreement between the Registrant and Laboratory Corporation of America Holdings, Inc. dated June 26, 2002 (previously filed as Exhibit 10.10 to our Annual Report on Form 10-K for the period ended December 31, 2007, which is incorporated herein by reference)
10.3**	First Amendment to License Agreement by and between the Registrant and Laboratory Corporation of America Holdings, Inc. dated January 19, 2004 (previously filed as Exhibit 10.12 to our Annual Report on Form 10-K filed for the period ended December 31, 2008, which is incorporated herein by reference)
10.4*	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)
10.5*	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)
10.6*	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)

## Edgar Filing: EXACT SCIENCES CORP - Form 10-K

### Table of Contents

<b>Exhibit Number</b>	<b>Description</b>
10.7**	Second Amendment to Agreement between the Registrant and Laboratory Corporation of America Holdings, dated as of June 27, 2007 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on July 3, 2007, which is incorporated herein by reference)
10.8**	Third Amendment to Agreement between the Registrant and Laboratory Corporation of America Holdings, dated as of August 31, 2007 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on September 7, 2007, which is incorporated herein by reference)
10.9*	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)
10.10**	Fourth Amendment to Agreement between the Registrant and Laboratory Corporation of America Holdings, dated as of March 17, 2008 (previously filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the period ended March 31, 2008, which is incorporated herein by reference)
10.11**	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)
10.12**	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-Q for the period ended September 30, 2008, which is incorporated herein by reference)
10.13**	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)
10.14**	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)
10.15**	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)
10.16**	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)
10.17	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)
10.18*	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)

## Edgar Filing: EXACT SCIENCES CORP - Form 10-K

### Table of Contents

<b>Exhibit Number</b>	<b>Description</b>
10.19*	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)
10.20*	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)
10.21**	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)
10.22	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)
10.23**	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)
10.24	Loan Agreement, dated November 10, 2009, between the Wisconsin Department of Commerce and the Registrant (previously filed as Exhibit 10.13 to our Annual Report on Form 10-K filed for the period ended December 31, 2009, which is incorporated herein by reference)
10.25	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)
10.26*	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)
10.27*	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)
10.28*	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)
10.29*	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)
10.30*	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)

## Edgar Filing: EXACT SCIENCES CORP - Form 10-K

### Table of Contents

<b>Exhibit Number</b>	<b>Description</b>
10.31*	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)
10.32*	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)
10.33*	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)
23.1+	Consent of Grant Thornton LLP
24.1	Power of Attorney (included on signature page)
31.1+	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934
31.2+	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934
32+	Certification Pursuant to 18 U.S.C Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	Interactive Data File

---

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

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

+  
Filed herewith.