

EXACT SCIENCES CORP
Form 10-K
March 11, 2011

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

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

For the fiscal year ended: **December 31, 2010**

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

Commission file number 000-32179

EXACT SCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

DELAWARE
(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 o No ý

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 \$168,049,891 (based on the closing price of the Registrant's Common Stock on June 30, 2010 of \$4.40 per share).

The number of shares outstanding of the Registrant's \$.01 par value Common Stock as of March 11, 2011 was 52,191,501.

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, 2010. 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, 2010**

TABLE OF CONTENTS

	Page No.
<u>Part I</u>	
<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>14</u>
<u>Item 2. Properties</u>	<u>14</u>
<u>Item 3. Legal Proceedings</u>	<u>14</u>
<u>Item 4. (Removed and Reserved)</u>	<u>14</u>
<u>Part II</u>	
<u>Item 5. Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities</u>	<u>14</u>
<u>Item 6. Selected Financial Data</u>	<u>14</u>
<u>Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>16</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>66</u>
<u>Item 9A. Controls and Procedures</u>	<u>66</u>
<u>Item 9B. Other Information</u>	<u>66</u>
<u>Part III</u>	
<u>Item 10. Directors, Executive Officers and Corporate Governance</u>	<u>67</u>
<u>Item 11. Executive Compensation</u>	<u>67</u>
<u>Item 12. Security and Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>67</u>
<u>Item 13. Certain Relationships and Related Transactions, and Director Independence</u>	<u>67</u>
<u>Item 14. Principal Accountant Fees and Services</u>	<u>67</u>
<u>Part IV</u>	
<u>Item 15. Exhibits and Financial Statement Schedules</u>	<u>67</u>
<u>SIGNATURES</u>	<u>68</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 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 product 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 detect blood in stool, utilizing an antibody-based fecal immunochemical test (FIT).

Our current focus is on the commercial development of and seeking FDA clearance or approval for 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. As part of our 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 each of the four stages of colorectal cancer as well as pre-cancerous lesions. 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. On October 28, 2010 we announced the results of a validation study involving a total of 1,178 stool samples. In this study, the current version of 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.

Medical experts believe that many colorectal cancer deaths can be avoided. These deaths occur needlessly because people are not screened for colorectal cancer at all, or they are screened using ineffective methods, often outside the recommended screening interval. Poor compliance has meant that approximately 60% of colon 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.

Detection of pre-cancerous adenomas and colorectal cancer in its earliest stages increases the likelihood of survival and reduces the significant cost associated with treating late-stage colorectal cancer. Accordingly, the ACS recommends that the more than 80 million Americans age 50 and above undergo regular colorectal cancer screening with the methods endorsed by the ACS.

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, and the total available U.S. market to be more than \$5 billion.

Table of Contents

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 is 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 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.

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 recent study shows that seven out of 10 people age 50 and older who have been told they should get a colonoscopy still have not had the test 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. Data from a clinical trial of one blood-based test was released in early 2010. It demonstrated only 52-67 percent sensitivity across all stages of cancer, with little sensitivity for pre-cancer.

We are aware of a number of companies that are developing blood-based tests for the detection of colorectal cancer. In addition, sDNA detection 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. Additional screening tests based on a patient's blood sample may also become available.

Reimbursement

We are continuing to work to obtain national coverage for sDNA colorectal cancer screening technologies from the Center for Medicare and Medicaid (CMS) and positive coverage decisions from

Table of Contents

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 stool-based DNA 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 \$9.0 million, \$4.2 million and \$2.0 million for the years ended December 31, 2010, 2009 and 2008, 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 certain technologies. 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). A PMA is generally, but not necessarily a more time-consuming and costlier process than the 510(k) process. A 510(k) may be used if the FDA finds that either (1) the product is substantially similar to a legally marketed product (a "predicate device") or (2) in the absence of a predicate device the FDA concludes that the product may use a process known as a de novo classification, which is reserved for low-risk products. However, the 510(k) process still involves substantial costs and time and may have to be repeated for any number of reasons, including but not limited to, the FDA's discretion or if the product is modified during the process. The PMA process, which is necessary when a device cannot be cleared through the 510(k) 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, 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 currently expect to seek a PMA for our Cologuard test. 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

Table of Contents

will ultimately approve any 510(k) request or approve any PMA submitted by us in a timely manner or at all.

Other Regulations

We are also subject to U.S. and state laws and regulations regarding the operation of clinical laboratories. Federal Clinical Laboratory Improvement Amendments (CLIA) requirements and laws of certain other states impose certification requirements for clinical laboratories, and establish standards for quality assurance and quality control, among other things. Clinical laboratories are subject to inspection by regulators, and to sanctions for failing to comply with applicable requirements. Sanctions available under CLIA include prohibiting a laboratory from running tests, requiring a laboratory to implement a corrective plan, and imposing civil monetary penalties. If we fail to meet any applicable requirements of CLIA or state law, that failure could adversely affect any future CMS consideration of our technologies, prevent their approval entirely, and/or interrupt the commercial sale of any products and otherwise cause us to incur significant expense.

In addition, the specimen transport and storage containers that are used in connection with certain of our products are deemed to be 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. Our portfolio of issued and pending patents broadly protects our position from competitors and yields freedom to operate in this market. 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 colon cancer from the Johns Hopkins University, and have additional licensed intellectual property from MDx Health (formerly Oncomethylome) and Case Western Reserve University.

Our success depends to a significant degree upon our ability to protect our technologies through patent coverage. As of December 31, 2010, we owned 14 issued patents and 3 pending patent applications in the United States, and 49 issued patents and 6 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 10 pending patent applications in the U.S., and 39 patents issued and 17 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.

Table of Contents

Employees

As of December 31, 2010, we had thirty-five full-time employees. None of our employees are represented by a labor union. We consider our relationship with our employees to be good.

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, 2010, we have accumulated a total deficit of approximately \$193.1 million. We expect that our losses will continue for at least the next several years and we will be required to invest significant additional funds toward development of our colorectal cancer screening technology. If our revenue does not grow significantly, we will not be profitable. We cannot be certain that the revenue from the sale of any products based on our technologies will be sufficient to make us profitable.

Our future revenues will depend on our ability to successfully commercialize an FDA-approved product for 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;

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

Table of Contents

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.

Although in our validation study the current version of our Cologuard test detected both pre-cancers and cancers at our 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 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, the current version of our Cologuard test was able to detect both pre-cancers and cancers at or above these target sensitivity rates. However, prior to commercialization of our sDNA colorectal cancer screening product, it will be necessary to obtain FDA approval or clearance, which will depend upon our ability to successfully complete a pivotal clinical trial. Also, this 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). The results achieved in future clinical trials and other studies may differ materially from our validation study results for a number of reasons. 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, and even if we do, 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.

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. Our current focus is on the commercial development of and seeking FDA clearance or approval of our Cologuard sDNA colorectal cancer screening product. We believe obtaining FDA clearance is critical to building broad demand and successful commercialization for our Cologuard test. The 510(k) process means that the FDA will not require a PMA, a generally but not necessarily more time-consuming and costlier process than the 510(k) process, because the FDA finds that either (a) our product is substantially similar to a legally marketed product (a "predicate device") or (b) in the absence of a predicate device that the FDA concludes that our product may use a process known as a de novo classification, which is reserved for low-risk products; however, the 510(k) process still involves substantial costs and time and may have to be repeated for any number of reasons, including but not limited to, the FDA's discretion or if the product is modified during the process. The PMA process, which is necessary when a device cannot be cleared through the 510(k) 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 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. We currently expect to seek a PMA for our colorectal cancer screening product.

In 2011, we will devote significant time and resources finalizing the design and commencing the pivotal FDA clinical trial for our Cologuard test. Currently we expect between 8,600 and 12,000

Table of Contents

patients to be enrolled in the trial. We anticipate commencing patient enrollment in the second half of 2011 and believe the enrollment process will take approximately 12 months to complete. To expedite completion of the trial we anticipate beginning to collect patient samples in the second half of 2011 although we do not expect to start processing these samples until 2012. We expect to spend approximately \$20 million over the next two years to complete the trial. 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.

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 and successful commercialization for 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 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' percentage ownership in us will be reduced. In addition, these transactions may dilute 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 the 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.

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

Successful commercialization of a stool-based DNA screening product will depend, in large part, on the availability of adequate reimbursement from government insurance plans, managed care organizations and private insurance plans. There is significant uncertainty concerning third-party reimbursement for the use of tests incorporating new technology. 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 stool-based DNA testing services or products at

Table of Contents

adequate levels, the commercial success of stool-based DNA screening for colorectal cancer would be compromised and our revenues would be significantly limited.

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

The market for colorectal cancer screening is large, more than 80 million Americans age 50 and above, of which nearly forty percent fail to strictly follow the ACS's screening guidelines for colorectal cancer. As a result, the colorectal cancer screening market has attracted competitors, some of which have significantly greater resources than we have. We are aware of three companies, Epigenomics AG, Gene News and Quest Diagnostics, developing a blood-based test for the detection of 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. In addition, some companies and institutions are developing serum-based tests, or 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 colon cancer. For example, 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. These and other companies may also be working on additional methods of detecting colon 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 and stronger business relationships.

Our business would suffer if we are unable to license certain technologies or obtain raw materials and components or if certain of our licenses were terminated.

Any future commercialization of our stool-based DNA screening technology may require that we license certain third-party intellectual property. There can be no assurance that we can obtain these licenses on acceptable terms, if at all. Furthermore, 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, or not breached or terminated early, or that we will be able to enter into any future relationships necessary to the continued commercial sale of any stool-based DNA testing services or products utilizing our technologies, or necessary to our realization of material revenues. Any failure to obtain necessary technologies or raw materials could require any stool-based DNA testing services or products utilizing our technologies to be re-configured which could halt such service or product entirely, negatively impact its commercial sale and increase the associated costs, any one of which could materially harm our business and adversely affect our future revenues.

If our clinical studies do not prove the reliability, effectiveness and superiority of stool-based DNA testing, we may experience reluctance or refusal on the part of physicians to order, and third-party payors to pay for, tests based on our technologies.

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 tests using our technologies are reliable, effective and superior to existing screening methods, including Hemoccult II, Hemoccult Sensa and immunochemical FOBT, we may experience reluctance or refusal on the part of physicians to order, and third-party payors to pay for tests using our technologies, which could prevent us from successfully commercializing our technologies.

Table of Contents

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 clinical or other studies that may be required to obtain clearance for our DNA-based colorectal screening technology with the FDA. 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 may not conduct studies in accordance with regulatory requirements or our study design. Our reliance on third parties that we do not control does 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 have prepared and are complying with their own, comparable procedures. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our studies may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our technologies.

We may experience limits on our revenue if only a small number of people decide to be screened for colorectal cancer using our technologies.

Even if our technologies are superior to other colorectal cancer screening options, adequate third-party reimbursement is obtained and we convince medical practitioners 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 stool-based DNA colorectal cancer screening will require people to collect a stool sample, which some people may be reluctant to do. If only a small portion of the recommended population is regularly screened for colorectal cancer or decides to utilize colorectal cancer screening tests using our technologies, we will, despite our efforts, experience limits on our revenue and our business would be materially harmed.

We may be subject to substantial costs and liability or be prevented from licensing our technologies for cancer detection 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 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 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, others may have filed patent applications covering technology 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

Table of Contents

would not be substantial. Claims of intellectual property infringement may require that we, or our strategic partners, enter into royalty or license agreements with third parties that may not be available on acceptable terms, if at all. These claims may also result in injunctions against the further development and commercial sale of services or products containing our technologies, which would have a material adverse effect on our business, financial condition and results of operations.

Also, patents and patent applications owned by us may become the subject of interference proceedings in the U.S. Patent and Trademark Office to determine priority of invention, which could result in substantial cost to us, as well as a possible adverse decision as to the priority of invention of the patent or patent application involved. An adverse decision in an interference proceeding may result in the loss of rights under a patent or patent application subject to such a proceeding.

If we are unable to protect our intellectual property effectively, we may be unable to prevent third parties from using our intellectual property, which would impair our competitive advantage.

We rely on patent protection as well as a combination of trademark, copyright and trade secret protection, and other contractual restrictions to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we fail to protect our intellectual property, we will be unable to prevent third parties from using our technologies and they will be able to compete more effectively against us.

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 in the past been the subject of opposition proceedings relating to our patents. We cannot guarantee you that we will be successful in defending challenges made in connection with our patents and patent applications. Any successful third-party challenge to our patents could result in co-ownership of such patents with a 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 might adversely impact our ability to obtain new patents and facilitate third-party challenges to our existing patents that result in determinations that our existing patents are unenforceable or invalid.

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 stool-based DNA colorectal cancer screening services or products containing our technologies are 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 such services or products in certain jurisdictions.

Moreover, 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 stool-based DNA colorectal cancer screening 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.

Table of Contents

The success of our business and business strategy will be substantially dependent upon the efforts of our senior management team.

Our success will depend largely on the skills, experience and performance of key members of our senior management team including Kevin T. Conroy, our President and Chief Executive Officer, Maneesh Arora, our Senior Vice President and Chief Financial Officer, and Dr. Graham Lidgard, our Senior Vice President and Chief Science Officer. Messrs. Conroy, Arora, and Dr. Lidgard are critical to directing and managing our growth and development in the future. Our success will be substantially dependent upon our senior management team's ability to gain proficiency in leading our company, implement or adapt our corporate strategies and initiatives, and develop key professional relationships, including relationships with our key collaborators and business partners. The efforts of each of these persons will be critical to us as we continue to develop our technologies and work towards the commercialization of an FDA-approved product. If we were to lose any of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies.

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

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

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

The sale and use of 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.

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 us. In addition, certain provisions of our certificate of

Table of Contents

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 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.

Factors that may affect our stock price include the various risks identified in this "Item 1A. Risk Factors".

Because we are a company with no significant operating revenue, any one of these factors may be deemed material.

Sharp drops in the market price of our common stock expose us to securities class-action litigation. Such litigation could result in substantial expenses and a diversion of management's attention and resources, which would seriously harm our business, financial condition, and results of operations.

Table of Contents**Item 1B. Unresolved Staff Comments**

None.

Item 2. Properties

As of December 31, 2010, we occupied approximately 19,300 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-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. (Removed and Reserved)**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
2010		
First quarter	\$ 5.25	\$ 3.36
Second quarter	5.00	3.85
Third quarter	7.40	3.15
Fourth quarter	9.24	5.32
2009		
First quarter	\$ 1.80	\$ 0.53
Second quarter	2.98	0.96
Third quarter	3.15	1.95
Fourth quarter	3.40	2.32

As of March 11, 2011, there were 52,191,501 shares of our common stock outstanding held by approximately 127 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, 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 financial data set forth below for the year ended December 31, 2008 are derived from our financial statements, which have been audited and which are included elsewhere in this Form 10-K. The selected historical balance sheet financial data as of December 31, 2008, 2007 and 2006 and statements of operations data for the years ended December 31, 2007 and 2006 are derived from our audited financial statements not included elsewhere in this Form 10-K.

Edgar Filing: EXACT SCIENCES CORP - Form 10-K

Table of Contents

The selected historical financial data should be read in conjunction with, and are qualified by reference to "Management's Discussion and Analysis of Financial Condition and Results of Operations", our financial statements and notes thereto and the reports of independent registered public accountants included elsewhere in this Form 10-K.

	Year Ended December 31,				
	2010	2009	2008	2007	2006
	(Amounts in thousands, except per share data)				
Consolidated Statements of Operations Data:					
Revenue:					
Product royalty fees	\$ 26	\$ 25	\$ (2,234)	\$ (1,137)	\$ 179
License fees	5,318	4,733	1,351	2,857	4,363
Product			16	78	208
	5,344	4,758	(867)	1,798	4,750
Cost of revenue	24	20	1	49	809
Gross profit (loss)	5,320	4,738	(868)	1,749	3,941
Operating expenses:					
Research and development(1)	9,023	4,213	2,034	4,887	6,735
General and administrative(1)	6,330	9,549	6,469	7,541	6,910
Sales and marketing(1)	1,793	226		991	3,792
Restructuring(1)		(3)	602	1,177	671
	17,146	13,985	9,105	14,596	18,108
Loss from operations	(11,826)	(9,247)	(9,973)	(12,847)	(14,167)
Interest income, net	26	119	232	888	1,252
Other income	244				
Net loss	\$ (11,556)	\$ (9,128)	\$ (9,741)	\$ (11,959)	\$ (12,915)
Net loss per share:					
Basic and diluted	\$ (0.29)	\$ (0.28)	\$ (0.36)	\$ (0.44)	\$ (0.49)
Weighted average common shares outstanding:					
Basic and diluted	40,455	32,791	27,212	26,945	26,509
Consolidated Balance Sheet Data:					
Cash and cash equivalents	\$ 78,752	\$ 21,924	\$ 4,937	\$ 4,486	\$ 4,831
Marketable securities	16,663	2,404		8,101	16,244
Total assets	96,515	25,770	5,898	14,595	23,868
Total long term debt	1,000	1,000			
Total liabilities	16,761	19,676	8,331	8,307	8,910
Stockholders' equity (deficit)	79,754	6,094	(2,433)	6,288	14,958

(1)

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

	2010	2009	2008	2007	2006
Research and development	\$ 1,067	\$ 319	\$ 89	\$ 541	\$ 653
General and administrative	1,132	2,308	918	1,889	1,397
Sales and marketing	50	4		202	956
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 consolidated financial statements and should be read together with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

Overview

Exact Sciences Corporation 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 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 (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 current focus is on the commercial development of and 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. As part of our 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.

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 the population over 50 years of age in the United States.

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. On October 28, 2010 we announced the results of a validation study involving a total of 1,178 stool samples. In this study, the current version of 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 colon 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 lesion can be removed. The sDNA screening model

Table of Contents

has the potential to significantly reduce colorectal cancer deaths. The earlier the pre-cancer or cancer can be detected, the greater the reduction in mortality.

The benefits of sDNA-based screening are clear. It detects both pre-cancers and cancers. The target sensitivity for cancer is equal to or greater than 85 percent at a specificity of 90 percent. 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 recent study shows that seven out of 10 people age 50 and older who have been told they should get a colonoscopy still have not had the test 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. Data from a clinical trial of one blood-based test was released in early 2010. It demonstrated only 52-67 percent sensitivity across all stages of cancer, 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, and the total available U.S. market to be more than \$5 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 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 colon cancer from Johns Hopkins University, and have additional licensed intellectual property from MDx Health (formerly Oncomethylome) and Case Western Reserve University.

We have generated limited operating revenues since inception and, as of December 31, 2010, we had an accumulated deficit of approximately \$193.1 million. We expect to continue to incur losses for the next several years, and it is possible we may never achieve profitability.

2011 Priorities

In 2011, we will devote significant time and resources finalizing the design of and commencing the pivotal FDA clinical trial for our Cologuard test. Currently we expect between 8,600 and 12,000 patients to be enrolled in the trial. We anticipate commencing patient enrollment in the second half of 2011 and believe the enrollment process will take approximately 12 months to complete. To expedite completion of the trial we anticipate beginning to collect patient samples in the second half of 2011 although we do not expect to start processing these samples until 2012. We expect to spend approximately \$20 million over the next two years to complete the trial. However, 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.

Table of Contents

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

We also plan to focus on developing the market for our Cologuard test during 2011. This includes hiring a senior vice president for commercial development, conducting additional product validation studies, publishing scientific papers regarding our sDNA colorectal cancer screening technology and expanding our outreach to physicians, third-party payors and advocates. We plan to concentrate our commercialization efforts initially on "key opinion leader" physicians who are strongly focused on the diagnosis and treatment of colorectal cancer.

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 for the full year 2011 will be consistent with amounts recorded in 2010. In 2010 we recorded the final amortization of \$1.4 million for the up-front license payment from LabCorp, therefore, we expect that license fee revenue resulting from the amortization of the up-front license payments in 2011 will be less than amounts recorded in 2010, as the only future amortization will be the up-front license fees from Genzyme.

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 consolidated 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 consolidated financial statements included in this report, we believe that 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

Table of Contents

agreement with LabCorp, which, among other modifications to the terms of the license, extended the exclusive license period of the license with LabCorp from August 2008 through December 2010. Accordingly, we amortized the remaining deferred revenue balance at the time of the amendment of \$4.7 million on a straight-line basis over the remaining exclusive license period, which ended in December 2010.

In connection with our January 2009 strategic transaction with Genzyme Corporation, Genzyme agreed to pay us a total of \$18.5 million, of which \$16.65 million was paid on January 27, 2009 and \$1.85 million was subject to a holdback by Genzyme to satisfy certain potential indemnification obligations in exchange for the assignment and licensing of certain intellectual property to Genzyme. Our on-going performance obligations to Genzyme under the Collaboration, License and Purchase Agreement (the "CLP Agreement"), as described below, including our obligation to deliver certain intellectual property improvements to Genzyme 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 paid \$2.00 per share for the 3,000,000 shares of our common stock purchased on January 27, 2009, 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 \$4.0 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, 2010.

Stock-Based Compensation

In accordance with GAAP, all stock-based payments, including grants of employee stock options, restricted stock, and shares purchased under an employee stock purchase plan (ESPP) (if certain parameters are not met), are recognized in the consolidated 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.

Table of Contents

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.

Forfeitures The Company records stock-based compensation expense only for those awards that are expected to vest. No forfeiture rate was utilized for awards granted prior to 2009 due to the monthly vesting terms of the options granted in that timeframe. Because of the vesting terms, the Company was, in effect, recording stock-based compensation only for those awards that were vesting and expected to vest and a forfeiture rate was not necessary. Awards granted in 2010 and 2009 that vest annually are all expected to vest and no forfeiture rate was utilized.

The fair value of each restricted stock award is determined on the date of grant using the closing stock price on that day. The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model based on the assumptions in Note 8 to our consolidated financial statements.

Critical Accounting Estimate 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 consolidated statements of operations.

Critical Accounting Estimate 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 \$71.5 million and \$66.9 million valuation allowance at December 31, 2010 and 2009 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 \$4.6 million. Due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact the Company's effective tax rate.

In 2006 and 2007, 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 or expected to be taken in a tax return. 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, and the amount of unrecognized tax benefits was none. There have been no changes in unrecognized tax benefits since the adoption date, nor are there any tax positions where it is reasonably possible that the total amounts of

Table of Contents

unrecognized tax benefits will significantly increase or decrease within the 12 months following December 31, 2010.

Recent Accounting Pronouncements

In January 2010, the FASB issued Accounting Standards Update ("ASU") 2010-06 *Fair Value Measurement and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements*. This guidance provides for the following new required disclosures related to fair value measurements: 1) the amounts of and reasons for significant transfers in and out of level one and level two inputs and 2) separate presentation of purchases, sales, issuances, and settlements on a gross basis rather than as one net number for level three reconciliations. The guidance also clarifies the existing disclosures as follows: 1) provide fair value measurement disclosures for each class of assets and liabilities and 2) provide disclosures about the valuation techniques and inputs used for both recurring and nonrecurring level two or level three inputs. The Company has adopted this standard and it did not have a material effect on the Company's consolidated balance sheet or required financial statement disclosures.

In September 2009, the Emerging Issues Task Force (EITF) issued their final consensus for *Revenue Arrangements with Multiple Deliverables*, as codified in ASC 605, *Revenue Recognition*. When vendor specific objective evidence or third party evidence of selling price for deliverables in an arrangement cannot be determined, ASC 605 will require the Company to develop a best estimate of the selling price to separate deliverables and allocate arrangement consideration using the relative selling price method. Additionally, this guidance eliminates the residual method of allocation. The new guidance is effective for fiscal years beginning after June 15, 2010. The adoption of this accounting pronouncement is not expected to have a material effect on the determination or reporting of our financial results.

Results of Operations

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. 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 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 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

Table of Contents

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.

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 \$26,000 for the year ended December 31, 2010 from \$0.1 million 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.

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.

2008 Restructuring. In July 2008, we took actions to reduce our cost structure to help preserve our cash resources, which we refer to as the 2008 Restructuring. These actions included suspending the clinical validation study of our Version 2 technology, eliminating eight positions, or 67% of our staff, and seeking the re-negotiation of certain fixed commitments. In connection with the 2008 Restructuring and our cost reduction efforts, in December 2008, we entered into a sublease agreement, with QTEROS, Inc. to sublease to QTEROS the majority of the remaining space at our former corporate headquarters.

In connection with the 2008 Restructuring, we recorded restructuring charges of approximately \$0.5 million during the three months ended September 30, 2008, including \$0.2 million in one-time termination benefits arising under retention and severance agreements with each of the terminated employees and \$0.3 million resulting from the write-off of leasehold improvements abandoned by us in connection with the reduction in force. Our decision to eliminate 67% of our workforce as part of the 2008 Restructuring was deemed to be an impairment indicator under financial accounting standards. As a result of performing the impairment evaluations, non-cash asset impairment charges of \$0.3 million were recorded to adjust the carrying value of the related leasehold improvements to their net realizable value.

The remaining amounts in the 2008 Restructuring accrual were paid out in cash in July 2010. These amounts were recorded under the caption "Accrued expenses" in the Company's consolidated balance sheets. The following table summarizes changes made to the restructuring accrual during the

Edgar Filing: EXACT SCIENCES CORP - Form 10-K

Table of Contents

year ended December 31, 2010 relating to the 2008 Restructuring. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2009	Charges	Cash Payments	Balance, December 31, 2010
Employee separation costs	\$	\$	\$	\$
Facility consolidation costs	73		(73)	
Total	\$ 73	\$	\$ (73)	\$

The following table summarizes changes made to the restructuring accrual during the year ended December 31, 2009 relating to the 2008 Restructuring. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2008	Charges	Cash Payments	Balance, December 31, 2009
Employee separation costs	\$ 16	\$ (2)	\$ (14)	\$
Facility consolidation costs	165	(1)	(91)	73
Total	\$ 181	\$ (3)	\$ (105)	\$ 73

2007 Restructuring. In July 2007, we initiated cost reduction plans and reduced our workforce and other operating expenses, which we refer to as the 2007 Restructuring to help preserve our cash resources. As part of the 2007 Restructuring, we eliminated our sales and marketing functions, terminated six employees, and subleased a portion of our leased space at our corporate headquarters. In connection with the 2007 Restructuring, during the fourth quarter of 2007, we entered into a sublease agreement, which we refer to as the 2007 Sublease Agreement with INTRINSIX Corporation to sublease to INTRINSIX approximately 11,834 square feet of rentable area in our former corporate headquarters. The 2007 Restructuring was principally designed to eliminate the Company's sales and marketing functions to reduce costs and help preserve the Company's cash resources. The remaining amounts in the 2007 Restructuring accrual were paid out in cash in July 2010. These amounts were recorded under the caption "Accrued expenses" in the Company's consolidated balance sheets. The following table summarizes the 2007 Restructuring activities during the year ended December 31, 2010. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2009	Charges	Cash Payments	Balance, December 31, 2010
Employee separation costs	\$	\$	\$	\$
Facility consolidation costs	67		(67)	
Total	\$ 67	\$	\$ (67)	\$

The following table summarizes the 2007 Restructuring activities during the year ended December 31, 2009. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2008	Charges	Cash Payments	Balance, December 31, 2009
Employee separation costs	\$	\$	\$	\$
Facility consolidation costs	161		(94)	67

Edgar Filing: EXACT SCIENCES CORP - Form 10-K

Total	\$	161	\$	\$	(94)	\$	67
-------	----	-----	----	----	------	----	----

Table of Contents

Comparison of the years ended December 31, 2009 and 2008

Revenue. Total revenue increased to \$4.8 million for the year ended December 31, 2009 from \$(0.9) million for the year ended December 31, 2008.

The increase in total revenue for the year ended December 31, 2009 when compared to the same period of 2008 was primarily the result of an increase in license fee revenue of \$3.4 million resulting from the Genzyme strategic transaction.

In addition, product royalty fees were approximately \$2.3 million higher for the year ended December 31, 2009 when compared to the year ended December 31, 2008 due primarily to charges of \$2.25 million recorded during 2008 in the product royalty revenue line item of our consolidated statements of operations in connection with our third-party royalty reimbursement obligation to LabCorp. These charges to product royalty revenue resulted in negative product royalty revenue for the year ended December 31, 2008. We recorded charges of \$13,000 during the year ended December 31, 2009 in the product royalty revenue line item of our consolidated statements of operations in connection with our third-party royalty reimbursement obligation to LabCorp.

Research and development expenses. Research and development expenses increased to \$4.2 million for the year ended December 31, 2009 from \$2.0 million for the year ended December 31, 2008. The increase was primarily the result of increased research and development activities in support of our efforts to develop and seek FDA approval for our Cologuard test. The increase in research and development expenses for the year ended December 31, 2009, as compared to the year ended December 31, 2008, included increases of \$1.9 million in licensing costs of which \$1.8 million was non-cash stock-based expenses related to common stock warrants issued in June 2009 to the Mayo Clinic Foundation pursuant to our license agreement with the Mayo Clinic Foundation, \$0.6 million in personnel related expenses and \$0.2 million in research collaboration expenses which were partially offset by a decrease in other research and development expenses of \$0.5 million.

General and administrative expenses. General and administrative expenses increased to \$9.5 million for the year ended December 31, 2009, compared to \$6.5 million for the year ended December 31, 2008. This increase 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. The overall increase was also due to an increase in non-cash stock-based compensation expense of \$1.4 million in 2009 compared to 2008, as well as an increase of \$1.7 million in salary, benefit and other costs due to \$0.8 million in severance payments for our former chief executive officer and chief financial officer and increased headcount during the year ended December 31, 2009, as compared to the same period of 2008. These increases in general and administrative expenses for the year ended December 31, 2009 were partially offset by decreases of \$1.5 million in legal and professional fees, and \$0.5 million other general and administrative costs.

Sales and marketing expenses. Sales and marketing expenses increased to \$0.2 million for the year ended December 31, 2009 from none in 2008 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 \$0.1 million for the year ended December 31, 2009 from \$0.2 million for the year ended December 31, 2008. This decrease was due to less favorable interest rates for cash, cash equivalents and marketable securities balances held during the year ended December 31, 2009 as compared to the same period of 2008.

Table of Contents

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, 2010, we had approximately \$78.8 million in unrestricted cash and cash equivalents.

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. As of December 31, 2010 we had approximately \$16.7 million in marketable securities.

Net cash used in operating activities was \$13.5 million, \$12.6 million, and \$7.9 million for the years ended December 31, 2010, 2009 and 2008, respectively. The principal use of cash in operating activities for each of the years ended December 31, 2010, 2009 and 2008 was to fund our net loss. The increase in net cash used in operating activities for the year ended December 31, 2010 as compared to the year ended December 31, 2009 was primarily due to increased research and development activities. The increase for the year ended December 31, 2009 as compared to the year ended December 31, 2008, was primarily due to increases in research and development activities and to \$2.5 million paid to LabCorp related to our third party royalty obligation. 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 \$14.9 million and \$2.9 million for the years ended December 31, 2010 and December 31, 2009, respectively. Net cash provided by investing activities was \$8.2 million for the year ended December 31, 2008. The increase in cash used in investing activities for the year ended December 31, 2010 when compared to the same period in 2009 was the result of increased purchases of marketable securities and fewer maturities of marketable securities. Excluding the impact of purchases and maturities of marketable securities, net cash used in investing activities was \$0.6 million for the year ended December 31, 2010, compared to net cash used in investing activities of \$0.5 million for the year ended December 31, 2009 which was primarily the result of purchases of property and equipment. Net cash provided by investing activities for the year ended December 31, 2008 was primarily the result of maturities of marketable securities being greater than purchases of marketable securities during the year as well as proceeds from the sale of fully depreciated assets and slightly offset by purchases of property and equipment and patent costs.

Net cash provided by financing activities was \$85.2 million, \$32.5 million and \$0.1 million for the years ended December 31, 2010, 2009 and 2008, respectively. 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. Excluding the impact of the sale of common stock, net cash provided by investing activities was \$2.9 million for the year ended December 31, 2010, compared to net cash provided by investing activities of \$24.4 million for the year ended December 31, 2009. This decrease in cash provided by financing activities was primarily due to a decrease in proceeds from the Genzyme strategic transaction from \$22.7 million for the year ended December 31, 2009 to \$1.9 million for the year ended December 31, 2010, and a decrease in proceeds from the exercise of common stock options from \$0.7 million for the year ended December 31, 2009 to \$0.5 million for the year ended December 31, 2010. For the year ended December 31, 2010, proceeds from long-term debt decreased to none compared to \$1.0 million for the year ended December 31, 2009. The increase in cash provided by financing activities for the year ended December 31, 2009 compared to the same period in 2008 was

Table of Contents

primarily related to proceeds of \$22.7 million from the Genzyme strategic transaction, \$8.1 million from the sale of common stock, \$1.0 million from long term debt, and \$0.7 million from exercise of common stock options during 2009.

We expect that cash and cash equivalents on hand at December 31, 2010, 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-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, 2010:

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)	\$ 1,157	\$	\$	\$ 270	\$ 887
Obligations under license and collaborative agreements(2)	4,493	524	577	592	2,800
Operating lease obligations	1,506	379	788	339	
Total	\$ 7,156	\$ 903	\$ 1,365	\$ 1,201	\$ 3,687

(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 9 in the notes to the consolidated financial statements for further information.

Commitments under license agreements generally expire concurrent with the expiration of the intellectual property licensed from the third party. Operating leases reflect remaining obligations associated with the leased facility at our headquarters in Madison, WI.

Net Operating Loss Carryforwards

As of December 31, 2010, we had net operating loss carryforwards of approximately \$158.8 million and tax credit carryforwards of approximately \$3.7 million. The net operating loss and tax credit carryforwards will expire at various dates through 2030, if not utilized. The Internal Revenue Code and applicable state laws impose substantial restrictions on a corporation's utilization of net operating loss and tax credit carryforwards if an ownership change is deemed to have occurred.

A valuation allowance is provided for deferred tax assets if it is more likely than not these items will either expire before we are able to realize their benefit, or that future deductibility is uncertain. In general, companies that have a history of operating losses are faced with a difficult burden of proof on their ability to generate sufficient future income in order to realize the benefit of the deferred tax assets. We have recorded a valuation against our deferred tax assets based on our history of losses. The deferred tax assets are still available for us to use in the future to offset taxable income, which would result in the recognition of tax benefit and a reduction to our effective tax rate.

Table of Contents

Off-Balance Sheet Arrangements

As of December 31, 2010, 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, all of which are currently invested in the United States and, as of December 31, 2010 and December 31, 2009 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**

	Page
<u>Reports of Independent Registered Public Accounting Firms</u>	<u>29</u>
<u>Consolidated Balance Sheets as of December 31, 2010 and 2009</u>	<u>32</u>
<u>Consolidated Statements of Operations for the Years Ended December 31, 2010, 2009 and 2008</u>	<u>33</u>
<u>Consolidated Statements of Stockholders' (Deficit) Equity for the Years Ended December 31, 2010, 2009 and 2008</u>	<u>34</u>
<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2010, 2009 and 2008</u>	<u>35</u>
<u>Notes to Consolidated Financial Statements</u>	<u>36</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, 2010 and 2009, and the related statements of operations, stockholders' (deficit) equity, and cash flows for each of the two years in the period ended December 31, 2010. 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, 2010 and 2009, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2010, 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, 2010, 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 11, 2011 expressed an unqualified opinion.

/s/ Grant Thornton LLP

Milwaukee, Wisconsin
March 11, 2011

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, 2010, 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, 2010, 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, 2010 and 2009 and the related statements of operations, stockholders' (deficit) equity, and cash flows for each of the two years in the period ended December 31, 2010 and our report dated March 11, 2011 expressed an unqualified opinion.

/s/ Grant Thornton LLP

Milwaukee, Wisconsin
March 11, 2011

Table of Contents

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Exact Sciences Corporation:

We have audited the accompanying consolidated statements of operations, stockholders' (deficit) equity, and cash flows of Exact Sciences Corporation for the year ended December 31, 2008. 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 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 the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated results of operations and cash flows of Exact Sciences Corporation for the year ended December 31, 2008, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 31, 2009

Table of Contents**EXACT SCIENCES CORPORATION****Consolidated Balance Sheets**

(Amounts in thousands, except share data)

	December 31, 2010	December 31, 2009
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 78,752	\$ 21,924
Marketable securities	16,663	2,404
Prepaid expenses and other current assets	246	484
Short term restricted cash		500
Total current assets	95,661	25,312
Property and Equipment, at cost:		
Laboratory equipment	943	492
Office and computer equipment	188	90
Leasehold improvements	89	12
Furniture and fixtures	20	20
	1,240	614
Less Accumulated depreciation and amortization	(386)	(156)
	854	458
	\$ 96,515	\$ 25,770
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 1,028	\$ 155
Accrued expenses	1,987	1,385
Deferred license fees, current portion	4,143	4,986
Total current liabilities	7,158	6,526
Third party royalty obligation, less current portion		988
Long term debt	1,000	1,000
Long term accrued interest	21	1
Deferred license fees, less current portion	8,582	11,161
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, \$0.01 par value Authorized 5,000,000 shares Issued and outstanding none at December 31, 2010 and 2009		
Common stock, \$0.01 par value Authorized 100,000,000 shares Issued and outstanding 52,163,629 and 35,523,140 shares at	522	355

Edgar Filing: EXACT SCIENCES CORP - Form 10-K

December 31, 2010 and 2009,
respectively

Additional paid-in capital	272,380	187,333
Other comprehensive (income) loss	1	(1)
Accumulated deficit	(193,149)	(181,593)
Total stockholders' equity	79,754	6,094
	\$ 96,515	\$ 25,770

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

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

	Year Ended December 31,		
	2010	2009	2008
Revenue:			
Product royalty fees	\$ 26	\$ 25	\$ (2,234)
License fees	5,318	4,733	1,351
Product			16
	5,344	4,758	(867)
Cost of revenue:			
Product royalty fees	24	20	1
Gross profit (loss)	5,320	4,738	(868)
Operating expenses:			
Research and development	9,023	4,213	2,034
General and administrative	6,330	9,549	6,469
Sales and marketing	1,793	226	
Restructuring		(3)	602
	17,146	13,985	9,105
Loss from operations	(11,826)	(9,247)	(9,973)
Interest income, net	26	119	232
Other income	244		
Net loss	\$ (11,556)	\$ (9,128)	\$ (9,741)
Net loss per share basic and diluted	\$ (0.29)	\$ (0.28)	\$ (0.36)
Weighted average common shares outstanding basic and diluted	40,455	32,791	27,212

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

Table of Contents**EXACT SCIENCES CORPORATION****Consolidated Statements of Stockholders' (Deficit) Equity**

(Amounts in thousands, except share data)

	Common Stock			Treasury Stock		Other Comprehensive Income (Loss)	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, 2008	27,225,541	\$ 273	\$ 168,813	85,550	\$ (97)	\$ 23	\$ (162,724)	\$ 6,288	
Exercise of common stock options	5,979		7					7	\$
Issuance of common stock to fund the Company's 2007 401(k) match	27,660		59					59	
Compensation expense related to issuance of stock options and restricted stock awards	263,751	2	972					974	
Compensation expense related to stock option modifications (Note 8)			3					3	
Net loss							(9,741)	(9,741)	(9,741)
Other comprehensive income						(23)		(23)	(23)
Comprehensive loss									\$ (9,764)
Balance, December 31, 2008	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 8)			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 income						(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 income									\$ (11,554)

Edgar Filing: EXACT SCIENCES CORP - Form 10-K

Balance, December 31, 2010 52,163,629 \$ 522 \$ 272,380 \$ \$ 1 \$ (193,149) \$ 79,754

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

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

	Year Ended December 31,		
	2010	2009	2008
Cash flows from operating activities:			
Net loss	\$ (11,556)	\$ (9,128)	\$ (9,741)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and write-offs of fixed assets	230	80	189
Restructuring			66
Amortization and write-offs of patents		95	437
Stock-based compensation	2,249	2,631	1,010
Amortization of deferred license fees	(5,318)	(4,733)	(1,351)
Warrant licensing expense	107	1,779	
Changes in assets and liabilities:			
Prepaid expenses and other current assets	238	(294)	85
Accounts payable	873	(528)	438
Accrued expenses	667	(81)	(1,287)
Accrued interest	20	1	
Third party royalty obligation	(988)	(2,462)	2,250
Net cash used in operating activities	(13,478)	(12,640)	(7,904)
Cash flows from investing activities:			
Purchases of marketable securities	(24,498)	(18,879)	(3,458)
Maturities of marketable securities	10,241	16,474	11,536
Purchases of property and equipment	(626)	(462)	(4)
Proceeds from sales of fixed assets			274
Increase in patent costs and other assets			(100)
Net cash provided by (used in) investing activities	(14,883)	(2,867)	8,248
Cash flows from financing activities:			
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	82,327	8,062	
Proceeds from exercise of common stock options and stock purchase plan	466	732	7
Decrease in restricted cash	500	100	100
Payment for repurchase of stock options		(50)	
Proceeds from long term debt		1,000	
Net cash provided by financing activities	85,189	32,494	107
Net increase in cash and cash equivalents	56,828	16,987	451
Cash and cash equivalents, beginning of period	21,924	4,937	4,486
Cash and cash equivalents, end of period	\$ 78,752	\$ 21,924	\$ 4,937
Supplemental disclosure of non-cash investing and financing activities:			
Unrealized gain (loss) on available-for-sale investments	\$ (2)	\$ 1	\$

Edgar Filing: EXACT SCIENCES CORP - Form 10-K

Retirement of 85,550 treasury shares of common stock	\$	\$	97	\$
--	----	----	----	----

Issuance of 15,460, 24,430, and 27,660 shares of common stock to fund the Company's 401(k) matching contribution for 2009, 2008, and 2007, respectively	\$	65	\$	32	\$	59
---	----	----	----	----	----	----

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

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements

(1) ORGANIZATION

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

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company's wholly-owned subsidiary, Exact Sciences Securities Corporation, a Massachusetts securities corporation. All significant intercompany transactions and balances have been eliminated in consolidation. On September 16, 2009 the Company dissolved Exact Sciences Securities Corporation and all intercompany transactions and balances were permanently eliminated.

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.

Restricted Cash

At December 31, 2009, approximately \$0.5 million of the Company's cash had been pledged as collateral for an outstanding letter of credit in connection with the lease for the Company's facility in Marlborough, Massachusetts. The Company had no restricted cash at December 31, 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 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 effective interest method. Such amortization is included in investment income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in investment income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in investment income.

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

At December 31, 2010 and December 31, 2009 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. Realized gains were \$13,149 and \$6,380 for the years ended December 31, 2010 and 2009, respectively. Unrealized gains on investments recorded in other comprehensive income were \$721 for the year ended December 31, 2010. Unrealized losses on investments recorded in other comprehensive income were \$543 for the year ended December 31, 2009.

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

Patent Costs

Patent costs, which have historically consisted of related legal fees, are capitalized as incurred, only if the Company determines that there is some probable future economic benefit derived from the transaction. The capitalized patents are amortized beginning when patents are approved over an estimated useful life of five years. Capitalized patent costs are expensed upon disapproval, upon a decision by the Company to no longer pursue the patent or when the related intellectual property is either sold or deemed to be no longer of value to the Company. The Company determined that all patent costs incurred during the year ended December 31, 2010 and 2009 should be expensed and not capitalized as the future economic benefit derived from the transactions cannot be determined.

As more fully described in Note 3 below, in connection with the strategic transaction with Genzyme Corporation on January 27, 2009, the Company wrote off the remaining unamortized capitalized patent costs at that time. There are no capitalized patent costs recorded in the Company's financial statements as of December 31, 2010 or 2009.

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

The following table summarizes activity with respect to the Company's capitalized patents for the years ended December 31, 2010, 2009 and 2008. Amounts included in the table are in thousands.

Balance, January 1, 2008	\$ 432
Patent costs capitalized	100
Amortization of patents	(72)
Write-offs of patents	(365)

Balance, December 31, 2008	95
Patent costs capitalized	
Amortization of patents	
Write-offs of patents	(95)

Balance, December 31, 2009	
Patent costs capitalized	
Amortization of patents	
Write-offs of patents	

Balance, December 31, 2010	\$
----------------------------	----

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:

	2010	2009	2008
Shares issuable upon exercise of stock options	6,217,199	5,912,019	3,389,541
Shares issuable upon exercise of outstanding warrants	825,000	1,250,000	
Shares issuable upon the release of restricted stock awards	263,630	40,000	314,358
	7,305,829	7,202,019	3,703,899

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, 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.

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Revenue Recognition

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

As more fully described in Note 3 below, in connection with the Company's transaction with Genzyme Corporation, Genzyme agreed to pay the Company a total of \$18.5 million, of which \$16.65 million was paid on January 27, 2009 and \$1.85 million was subject to a holdback by Genzyme to satisfy certain potential indemnification obligations in exchange for the assignment and licensing of certain intellectual property to Genzyme. The Company's on-going performance obligations to Genzyme under the Collaboration, License and Purchase Agreement (the "CLP Agreement"), as described below, including its obligation to deliver through licenses certain intellectual property improvements to Genzyme 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 paid \$2.00 per share for the 3,000,000 shares of common stock purchased from the Company on January 27, 2009, 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 \$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. The Company recognized \$4.7 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, 2009.

Product royalty fees. The Company has licensed certain of its technologies, including improvements to such technologies, on an exclusive basis through December 2010 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

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 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 consolidated statements of operations.

Product revenue For the year ended December 31, 2008, product revenue from the sale of certain components of the Company's Effipure technology to LabCorp was recognized upon transfer of the components provided that title passed, the price was fixed or determinable and collection of the receivable was probable. LabCorp indicated that Effipure is not used as a component in LabCorp's ColoSure offering and the Company therefore did not record product revenue in connection with Effipure sales in 2010 or 2009.

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. 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 years ended December 31, 2009 and 2008.

Advertising Costs

The Company expenses the costs of media advertising at the time the advertising takes place. The Company expensed approximately \$68,100 and \$9,800 of media advertising during the years ended

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

December 31, 2010 and 2009, respectively. The Company did not incur any media advertising costs during the year ended December 31, 2008.

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, 2010, 2009, and 2008 was as follows:

(In Thousands)	December 31,		
	2010	2009	2008
Net loss	\$ (11,556)	\$ (9,128)	\$ (9,741)
Unrealized gain (loss) on marketable securities	\$ 2	\$ (1)	\$ (23)
Comprehensive loss	\$ (11,554)	\$ (9,129)	\$ (9,764)

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 established and prioritizes the inputs used to measure fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs. Observable inputs are inputs that reflect the assumptions that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances.

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

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

The Company's financial instruments consist primarily of cash and cash equivalents, accounts payable, marketable securities, mutual funds, and debt. Marketable securities primarily consist of fixed income securities and mutual funds primarily consist of both fixed income and equity securities. The carrying values of cash and cash equivalents, accounts payable, and debt approximate their fair values due to either the short-term nature of these instruments, or for the debt because the interest rate approximates the current costs of borrowing for a similar amount on similar terms.

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

The following table presents the Company's fair value measurements as of December 31, 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				
Fixed-income	\$ 6,663	\$	\$ 6,663	\$
Mutual funds	10,000	10,000		
Total	\$ 16,663	\$ 10,000	\$ 6,663	\$

The following table presents the Company's fair value measurements as of December 31, 2009 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, 2009	Fair Value Measurement at December 31, 2009 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				
Fixed-income	\$ 2,404	\$ 650	\$ 1,754	\$
Total	\$ 2,404	\$ 650	\$ 1,754	\$

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. The Company has cash and cash equivalents deposited in financial institutions in which the balances exceed the federal government agency insured limit of \$250,000. 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.

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Recent Accounting Pronouncements

In January 2010, the FASB issued Accounting Standards Update ("ASU") 2010-06 *Fair Value Measurement and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements*. This guidance provides for the following new required disclosures related to fair value measurements: 1) the amounts of and reasons for significant transfers in and out of level one and level two inputs and 2) separate presentation of purchases, sales, issuances, and settlements on a gross basis rather than as one net number for level three reconciliations. The guidance also clarifies the existing disclosures as follows: 1) provide fair value measurement disclosures for each class of assets and liabilities and 2) provide disclosures about the valuation techniques and inputs used for both recurring and nonrecurring level two or level three inputs. The Company has adopted this standard, but it did not have a material effect on the Company's consolidated balance sheet or required financial statement disclosures.

In September 2009, the Emerging Issues Task Force (EITF) issued their final consensus for *Revenue Arrangements with Multiple Deliverables*, as codified in ASC 605, *Revenue Recognition*. When vendor specific objective evidence or third party evidence of selling price for deliverables in an arrangement cannot be determined, ASC 605 will require the Company to develop a best estimate of the selling price to separate deliverables and allocate arrangement consideration using the relative selling price method. Additionally, this guidance eliminates the residual method of allocation. The new guidance is effective for fiscal years beginning after June 15, 2010. The adoption of this accounting pronouncement is not expected to have a material effect on the determination or reporting of financial results.

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 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

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

(3) GENZYME STRATEGIC TRANSACTION (Continued)

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 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 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.

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

(3) GENZYME STRATEGIC TRANSACTION (Continued)

The Company recognized approximately \$4.0 million and \$3.4 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, 2010 and 2009, 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 will also 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. The assumptions for the Black-Scholes pricing model are represented in the table below.

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Consolidated Financial Statements (Continued)****(4) MAYO LICENSING AGREEMENT (Continued)**

Assumptions for Black-Scholes Pricing Model:

Exercise Price	\$	1.90
Stock Price	\$	1.99
Volatility		86.30%
Life of warrant (in years)		10
Treasury rate		3.88%
Yield		0%
Fair value per warrant	\$	1.72

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

In September of 2010, MAYO partially exercised its warrant covering the remaining 800,000 shares by utilizing the cashless exercise provision contained in the agreement. As a result of this exercise for a gross amount of 300,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its rights with respect to 97,853 shares leaving it with a net amount of 202,147 shares. The warrant now covers a total of 500,000 shares.

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. It is uncertain as to when the FDA trial will begin, therefore; the \$250,000 milestone payment has not been recorded as a liability. 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, 2010, as part of the Company's research collaboration with MAYO, the Company has incurred charges of \$1.8 million and has made payments of \$1.2 million. The Company has recorded an estimated liability in the amount of \$0.5 million for research and development efforts as of December 31, 2010.

(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

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

(5) LABCORP STRATEGIC ALLIANCE AGREEMENT (Continued)

technologies for the early detection of colorectal cancer in the average-risk population. Pursuant to the 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

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

(5) LABCORP STRATEGIC ALLIANCE AGREEMENT (Continued)

organizations and commercial service laboratories to whom the Company may license its DNA technology for colorectal cancer screening.

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 recorded charges of \$5,000, \$13,000, and \$2.3 million during the years ended December 31, 2010, 2009, and 2008 respectively, in connection with this third-party royalty obligation. These charges were recorded under the caption "Product royalty fees" in the Company's consolidated 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

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

(5) LABCORP STRATEGIC ALLIANCE AGREEMENT (Continued)

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.

(6) RESTRUCTURING

On July 16, 2008, the Company implemented certain cost reduction initiatives, including the suspension of the clinical validation study for its Version 2 technology and the elimination of eight positions, or 67% of the Company's workforce (the "2008 Restructuring"), in connection with the Company's revised corporate strategy at the time of reducing costs to better preserve existing cash.

In connection with the 2008 Restructuring, the Company recorded restructuring charges of approximately \$0.5 million during the three months ended September 30, 2008, including \$0.2 million in one-time termination benefits arising under retention and severance agreements with terminated employees and \$0.3 million resulting from the write-off of leasehold improvements abandoned by the Company in connection with the reduction in force. The Company's decision to eliminate 67% of its workforce was deemed to be an impairment indicator. As a result of performing the impairment evaluations, non-cash asset impairment charges of \$0.3 million were recorded to adjust the carrying value of the related leasehold improvements to their net realizable value.

In addition, in connection with the 2008 Restructuring, the Company accelerated the vesting of 15,523 shares under terminated employees' previously unvested stock options, with a weighted average exercise price of \$2.65 per share, and extended the expiration date of all the terminated employees' outstanding options as of their date of termination, covering an aggregate of 181,828 shares with a weighted average exercise price of \$4.50 per share, through August 1, 2009. Due to the nature of the transaction, the Company recorded one-time non-cash stock-based compensation charges of approximately \$3,000 in the "Restructuring" line item of the Company's consolidated statements of operations during the year ended December 31, 2008.

During the fourth quarter of 2008, the Company entered into a sublease agreement (the "2008 Sublease Agreement") with QTEROS, Inc. ("QTEROS") to sublease to QTEROS approximately 25,537 square feet of rentable area in the Company's former corporate headquarters. The term of the 2008 Sublease Agreement, which commenced on December 9, 2008, was 20 months with a base rent of \$625,657 per year. Pursuant to the 2008 Sublease Agreement, QTEROS had no rights to renew or extend the 2008 Sublease Agreement. Under the terms of the 2008 Sublease Agreement, QTEROS was required to pay its pro rata share of any increases in building operating expenses and real estate taxes and to provide a security deposit in the form of an irrevocable, standby letter of credit from a national commercial bank reasonably acceptable to the Company in the amount of approximately \$52,000 naming the Company as beneficiary. The 2008 Sublease Agreement provided for the Company's employees to continue to occupy approximately 1,100 square feet in the premises subleased to QTEROS.

In connection with the 2008 Sublease Agreement, the Company also recorded the following restructuring charges during the fourth quarter of 2008 (included opposite the caption "Facility consolidation costs" in the table below): approximately \$0.1 million in future cash payments related to the difference between the Company's committed lease payments and the estimated sublease rental income under the 2008 Sublease Agreement; approximately \$0.1 million in one-time real estate transaction and laboratory decommissioning fees; and approximately \$0.1 million of non-cash charges

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Consolidated Financial Statements (Continued)****(6) RESTRUCTURING (Continued)**

related to the write-off of leasehold improvements abandoned by the Company in connection with the 2008 Sublease Agreement. These charges were offset by cash receipts of approximately \$0.3 million received in connection with sales of fully depreciated fixed assets upon commencement of the 2008 Sublease Agreement. During 2009, certain of the cost estimates related to the 2008 Restructuring were adjusted, resulting in a credit of approximately \$3,000 to the restructuring line item in the Company's consolidated statements of operations.

The remaining amounts in the 2008 Restructuring accrual were paid out in cash in July 2010. These amounts were recorded under the caption "Accrued expenses" in the Company's consolidated balance sheets. The following table summarizes changes made to the restructuring accrual during the year ended December 31, 2010 relating to the 2008 Restructuring. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2009	Charges	Cash Payments	Balance, December 31, 2010
Employee separation costs	\$	\$	\$	\$
Facility consolidation costs	73		(73)	
Total	\$ 73	\$	\$ (73)	\$

The following table summarizes changes made to the restructuring accrual during the year ended December 31, 2009 relating to the 2008 Restructuring. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2008	Charges	Cash Payments	Balance, December 31, 2009
Employee separation costs	\$ 16	\$ (2)	\$ (14)	\$
Facility consolidation costs	165	(1)	(91)	73
Total	\$ 181	\$ (3)	\$ (105)	\$ 73

2007 Restructuring

During the third quarter of 2007, in connection with the Third Amendment to the LabCorp agreement, the Company notified six employees of their termination from the Company (the "2007 Restructuring"). The 2007 Restructuring was principally designed to eliminate the Company's sales and marketing functions to reduce costs and help preserve the Company's cash resources.

The remaining amounts in the 2007 Restructuring accrual were paid out in cash in July 2010. These amounts were recorded under the caption "Accrued expenses" in the Company's consolidated balance sheets. The following table summarizes the 2007 Restructuring activities during the year ended December 31, 2010. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2009	Charges	Cash Payments	Balance, December 31, 2010
Employee separation costs	\$	\$	\$	\$
	67		(67)	

Edgar Filing: EXACT SCIENCES CORP - Form 10-K

Facility
consolidation costs

Total	\$	67	\$	\$	(67)	\$
-------	----	----	----	----	------	----

50

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Consolidated Financial Statements (Continued)****(6) RESTRUCTURING (Continued)**

The following table summarizes the 2007 Restructuring activities during the year ended December 31, 2009. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2008	Charges	Cash Payments	Balance, December 31, 2009
Employee separation costs	\$	\$	\$	\$
Facility consolidation costs	161		(94)	67
Total	\$ 161	\$	\$ (94)	\$ 67

(7) ISSUANCES OF COMMON STOCK

On June 11, 2009, the Company completed a private placement transaction pursuant to which the Company sold 4.3 million shares of common stock at a per share price of \$1.90 for net proceeds of \$8.1 million after issuance costs \$0.1 million. On April 19, 2010 the Company completed an underwritten public offering of 4.2 million shares of common stock at a price of \$4.50 per share to the public. The Company received approximately \$17.6 million of net proceeds from the offering, after deducting \$1.3 million for the underwriting discount and other stock issuance costs paid by the Company. The Company expects to use the net proceeds from these offerings for general corporate and working capital purposes, including the funding of strategic initiatives that the Company may undertake from time to time, for product development and the furtherance of the Company's efforts to obtain FDA clearance in its sDNA colorectal cancer screening product.

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. The Company expects to use the net proceeds from the offering to fund its clinical trials for its product, general corporate and working capital purposes, including the funding of strategic initiatives that the Company may undertake from time to time, for product development and the furtherance of the Company's efforts to obtain FDA clearance in its sDNA colorectal cancer screening product.

(8) 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").

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Consolidated Financial Statements (Continued)****(8) STOCK-BASED COMPENSATION (Continued)**

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 may be granted under the plan. Under the terms of the 2000 Option Plan, the Company was authorized to grant incentive stock options, as defined under the Internal Revenue Code, non-qualified options, restricted stock awards and other stock awards to employees, officers, directors, consultants and advisors. Options granted under the 2000 Option Plan expire ten years from the date of grant. Grants made from the 2000 Option Plan generally vest over a period of three to four years.

The 2000 Option Plan was administered by the compensation committee of the Company's board of directors, which selected the individuals to whom equity-based awards would be granted and determined the option exercise price and other terms of each award, subject to the provisions of the 2000 Option Plan. The 2000 Option Plan provides that upon an acquisition of the Company, all options to purchase common stock will accelerate by a period of one year. In addition, upon the termination of an employee without cause or for good reason prior to the first anniversary of the completion of the acquisition, all options then outstanding under the 2000 Option Plan held by that employee will immediately become exercisable. At December 31, 2010, options to purchase 5,803,133 shares were outstanding under the 2000 Option Plan and 108,000 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, 2010, 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	Price per Share
April 30, 2010	34,221	\$ 2.04
October 31, 2010	19,320	\$ 2.04
October 31, 2010	5,168	\$ 3.74

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

(8) STOCK-BASED COMPENSATION (Continued)

2010 Omnibus Long-Term Incentive Plan The Company adopted the 2010 Omnibus Long-Term Incentive Plan (the "2010 Stock Plan") on July 16, 2010. At December 31, 2010, a total of 4,400,000 shares of common stock were authorized and reserved for issuance under the 2010 Stock Plan. The 2010 Stock Plan will expire on July 16, 2020 and after such date no further awards may be granted under the plan. Under the terms of the 2010 Stock Plan, the Company is authorized to grant incentive stock options, as defined under the Internal Revenue Code, non-qualified options, restricted stock awards and other stock awards to employees, officers, directors, consultants and advisors. Options granted under the 2010 Stock Plan expire ten years from the date of grant. Grants made from the 2010 Stock Plan generally vest over a period of three to four years.

The 2010 Stock Plan is administered by the compensation committee of the Company's board of directors, which selects the individuals to whom equity-based awards will be granted and determines the option exercise price and other terms of each award, subject to the provisions of the 2010 Stock Plan. The 2010 Stock Plan provides that upon an acquisition of the Company, all equity will accelerate by a period of one year. In addition, upon the termination of an employee without cause or for good reason prior to the first anniversary of the completion of the acquisition, all equity awards then outstanding under the 2010 Stock Plan held by that employee will immediately vest. At December 31, 2010, options to purchase 414,066 shares were outstanding under the 2010 Stock Plan, and 155,630 shares of restricted stock remained unreleased. At December 31, 2010, there were 3,724,864 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, 2010, there were 300,000 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. No shares were issued under the 2010 Purchase Plan in 2010.

Stock-Based Compensation Expense

The Company recorded approximately \$2.2 million in stock-based compensation expense during the year ended December 31, 2010, in connection with the amortization of restricted common stock awards, stock purchase rights granted under the Company's employee stock purchase plans and stock options granted to employees, non-employee directors and non-employee consultants. The Company recorded \$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

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

(8) STOCK-BASED COMPENSATION (Continued)

options granted to employees, non-employee directors and non-employee consultants as well as the modification of certain stock options and restricted stock awards. The Company recorded approximately \$1.0 million in stock-based compensation expense during the year ended December 31, 2008 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 compensation expense by department for the years ended December 31, 2010, 2009, and 2008 are as follows. Amounts included in the table are in thousands.

	December 31,		
	2010	2009	2008
Research and development	\$ 1,067	\$ 319	\$ 89
General and administrative	1,132	2,308	918
Sales and marketing	50	4	
Restructuring			3

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. No forfeiture rate was utilized for awards granted prior to 2009 due to the monthly vesting terms of the options granted in that timeframe. Because of the vesting terms, the Company was, in effect, recording stock-based compensation only for those awards that were vesting and expected to vest and a forfeiture rate was not necessary. Awards granted in 2010 and 2009 that vest annually are all expected to vest and no forfeiture rate was utilized.

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Consolidated Financial Statements (Continued)****(8) STOCK-BASED COMPENSATION (Continued)**

The fair value of each restricted stock award is determined on the date of grant using the closing stock price on that day. The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model based on the assumptions in the following table.

	December 31,		
	2010	2009	2008
Option Plan Shares			
Risk-free interest rates	1.17% - 2.69%	1.76% - 2.69%	2.80% - 3.02%
Expected term (in years)	6	6	6
Expected volatility	91% - 92%	85 - 92%	70% - 75%
Dividend yield	0%	0%	0%
Weighted average fair value per share of options granted during the period	\$ 3.07	\$ 0.89	\$ 1.08
ESPP Shares			
Risk-free interest rates	0.16% - 0.38%	(1)	(1)
Expected term (in years)	0.5 - 2	(1)	(1)
Expected volatility	53% - 127%	(1)	(1)
Dividend yield	0%	(1)	(1)
Weighted average fair value per share of stock purchase rights granted during the period	\$ 2.03	(1)	(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 Consolidated Financial Statements (Continued)

(8) STOCK-BASED COMPENSATION (Continued)

Stock Option and Restricted Stock Activity

A summary of stock option activity under the Stock Plans during the years ended 2010, 2009 and 2008 is as follows:

Options (Aggregate intrinsic value in thousands)	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value(1)
Outstanding, January 1, 2008	3,977,937	\$ 4.90		
Granted	573,600	1.68		
Exercised	(5,979)	1.19		
Cancelled	(1,026,659)	5.54		
Outstanding, December 31, 2008	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		
Cancelled				
Outstanding, December 31, 2010	6,217,199	\$ 1.93	7.9	26,346
Exercisable, December 31, 2010	2,823,005	\$ 2.24	7.2	11,721
Vested and expected to vest, December 31, 2010	6,217,199	\$ 1.93	7.9	26,346

(1)

Edgar Filing: EXACT SCIENCES CORP - Form 10-K

The aggregate intrinsic value of options outstanding at December 31, 2010 is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for the 5,995,011 options that had exercise prices that were lower than the \$5.98 market price of our common stock at December 31, 2010. The aggregate intrinsic value of options exercisable at December 31, 2010 is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for the 2,619,317 options that had exercise prices that were lower than the \$5.98 market price of our common stock at December 31, 2010. The total intrinsic value of options exercised during the years ended December 31, 2010, 2009 and 2008 was \$0.4 million, \$0.2 million, and \$4,000, respectively, determined as of the date of exercise.

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements (Continued)

(8) STOCK-BASED COMPENSATION (Continued)

A summary of restricted stock activity under the Stock Plans during the years ended 2010, 2009 and 2008 is as follows:

	Restricted Shares	Weighted Average Grant Date Fair Value
Outstanding, January 1, 2008	18,751	\$ 2.90
Granted	245,000	0.46
Released	(78,751)	1.21
Outstanding, December 31, 2008	185,000	0.39
Granted	411,127	0.98
Released	(510,181)	0.77
Cancelled	(45,946)	0.37
Outstanding, December 31, 2009	40,000	1.72
Granted	326,197	5.73
Released	(102,567)	2.94
Outstanding, December 31, 2010	263,630	\$ 6.20

As of December 31, 2010, there was approximately \$5.3 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 2.9 years.

The Company received approximately \$0.5 million, \$0.7 million, and \$7,000 from stock option exercises during the years ended December 31, 2010, 2009 and 2008, respectively. During the years ended December 31, 2010, 2009 and 2008, 58,709, zero, and zero shares, respectively, of common stock were issued under the Company's 2000 Purchase Plan resulting in proceeds to the Company of \$0.1 million, \$0, and \$0, respectively.

The following table summarizes information relating to currently outstanding and exercisable stock options as of December 31, 2010:

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	3,825,000	8.2	\$ 0.83	1,715,625	\$ 0.82
\$1.01 - \$ 2.00	358,377	8.1	\$ 1.51	118,375	\$ 1.58
\$2.01 - \$ 2.50	170,000	5.5	\$ 2.17	155,000	\$ 2.17
\$2.51 - \$ 3.00	1,025,000	8.0	\$ 2.86	488,749	\$ 2.86
\$3.01 - \$ 4.00	194,566	7.8	\$ 3.56	60,000	\$ 3.61
\$4.01 - \$ 5.00	422,068	8.4	\$ 4.29	81,568	\$ 4.80
\$5.01 - \$ 7.00	33,500	6.4	\$ 6.82	15,000	\$ 6.78

Edgar Filing: EXACT SCIENCES CORP - Form 10-K

\$7.01 - \$ 9.00	24,688	2.7	\$	7.76	24,688	\$	7.76
\$9.01 - \$14.33	164,000	1.6	\$	12.79	164,000	\$	12.79
	6,217,199	7.9	\$	1.93	2,823,005	\$	2.24

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Consolidated Financial Statements (Continued)****(8) STOCK-BASED COMPENSATION (Continued)****Option Modifications**

2008 Modifications In connection with the 2008 Restructuring (See Note 6), the Company accelerated the vesting of 15,523 shares under terminated employees' previously unvested stock options, with a weighted average exercise price of \$2.65 per share, and extended the expiration date of all the terminated employees' outstanding options as of their date of termination, covering an aggregate of 181,828 shares with a weighted average exercise price of \$4.50, through August 1, 2009. Pursuant to financial accounting standards, the Company recorded one-time stock-based compensation charges of approximately \$3,000 in the "Restructuring" line item of the Company's consolidated statements of operations during the quarter ended September 30, 2008.

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.

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, 2010, as follows:

Shares reserved for issuance

2010 Option Plan	3,724,864
2010 Purchase Plan	300,000

	4,024,864
--	-----------

(9) 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

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Consolidated Financial Statements (Continued)****(9) COMMITMENTS AND CONTINGENCIES (Continued)**

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, 2010 are as follows. Amounts included in the table are in thousands.

Year Ending December 31,	
2011	\$ 379
2012	389
2013	399
2014	339
2015	
Thereafter	
Total lease obligations	\$ 1,506

Rent expense included in the accompanying consolidated statements of operations was approximately \$0.2 million, \$0.2 million, and \$0.6 million for the years ended December 31, 2010, 2009 and 2008, 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 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 sublease agreement ran from December 2008 to August 2010. The Company received approximately \$1.0 million in sublease payments over the life of the sublease agreement.

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 \$76,600 and \$13,000 in sublease payments in 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

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Consolidated Financial Statements (Continued)****(9) COMMITMENTS AND CONTINGENCIES (Continued)**

sublease receipts under sublease agreements as of December 31, 2010 are as follows. Amounts included in the table are in thousands.

Year ending December 31,	
2011	\$ 79
2012	67
2013	
2014	
2015	
Thereafter	
	\$ 146

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 June 12, 2012 and \$25,000 on June 12, 2013 and each year thereafter. 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. At the commencement of patient enrollment in the human cancer screening clinical trial the Company must pay MAYO \$250,000 in milestone fees and upon U.S. Food and Drug Administration (FDA) approval the Company must pay MAYO \$500,000 in milestone fees.

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,

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Consolidated Financial Statements (Continued)****(9) COMMITMENTS AND CONTINGENCIES (Continued)**

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 also agreed to pay \$100,000 upon commencement of an FDA clinical trial for a licensed product and an additional \$100,000 at the time of final FDA pre-market approval or clearance for a licensed product.

On July 26, 2010, the Company entered into a technology license and royalty agreement with MDx Health (formerly Oncomethylome Sciences, S.A.). Under the license agreement, MDx Health granted the Company a royalty bearing exclusive, worldwide license to certain patents. Under the licensing agreement, the Company is obligated to make commercially reasonable efforts to bring products covered by the license agreement to market. The Company paid 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 \$0.4 million, \$1.9 million, and \$(0.2) million, respectively, for the years ended December 31, 2010, 2009 and 2008. Future minimum payments due under the Company's technology licenses as of December 31, 2010 are as follows. Amounts included in the table are in thousands.

Year ending December 31,	
2011	\$ 524
2012	281
2013	296
2014	296
2015	296
Thereafter	2,800
	\$ 4,493

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, 2010 and 2009, the Company had no outstanding sample collection commitments. The Company has recorded research and development expense associated with clinical research agreements of approximately \$1.3 million, \$0.5 million, and \$20,000, respectively, for the years ended December 31, 2010, 2009 and 2008. As of December 31, 2010, the Company did not have any remaining obligation under these agreements.

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Consolidated Financial Statements (Continued)****(10) ACCRUED EXPENSES**

Accrued expenses at December 31, 2010 and 2009 consisted of the following. Amounts included in the table are in thousands.

	December 31,	
	2010	2009
Compensation	\$ 902	\$ 460
Research and trial related expenses	573	238
Professional fees	271	153
Licenses	173	131
Other	46	110
Occupancy costs	22	153
Restructuring		140
	\$ 1,987	\$ 1,385

(11) 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 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, 2010:

Year ending December 31,	
2011	\$
2012	
2013	
2014	
2015	145
Thereafter	855
	\$ 1,000

(12) 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.

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Consolidated Financial Statements (Continued)****(12) EMPLOYEE BENEFIT PLAN (Continued)**

The Company's Board of Directors approved 401(k) Plan matching contributions for 2008 in the form of Company common stock equal to 50% of each participant's elective deferrals. The Company's Board of Directors approved 401(k) Plan matching contributions for 2009 and 2010 in the form of Company common stock equal to 100% up to 6% of the participant's salary for that year. The Company recorded compensation expense of approximately \$0.2 million, \$0.1 million, and \$34,000, respectively, in the consolidated statements of operations for the years ended December 31, 2010, 2009 and 2008 in connection with 401(k) Plan matching contributions.

(13) INCOME TAXES

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

Under financial accounting standards, deferred tax assets or liabilities are computed based on the differences between the financial statement and income tax bases of assets and liabilities using the enacted tax rates. Deferred income tax expense or benefit represents the change in the deferred tax assets or liabilities from period to period. At December 31, 2010, the Company had federal and state net operating loss and research tax credit carryforwards of approximately \$158.8 million and \$3.7 million, respectively, for financial reporting purposes, which may be used to offset future taxable income. The federal and state carryforwards expire beginning 2015 through 2030 and are subject to review and possible adjustment by the Internal Revenue Service. In the event of a change of ownership, the federal and state net operating loss and research and development tax credit carryforwards may be subject to annual limitations provided by the Internal Revenue Code and similar state provisions.

As of December 31, 2010 and 2009, the Company had \$6.3 million and \$5.3 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.

	December 31,	
	2010	2009
Deferred tax assets:		
Operating loss carryforwards	\$ 60,390	\$ 54,276
Tax credit carryforwards	3,749	3,459
Deferred revenue	5,041	6,396
Other temporary differences	2,365	2,777
Tax assets before valuation allowance	71,545	66,908
Less Valuation allowance	(71,545)	(66,908)
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

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Consolidated Financial Statements (Continued)****(13) INCOME TAXES (Continued)**

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 \$71.5 million and \$66.9 million valuation allowance at December 31, 2010 and 2009 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 \$4.6 million. Due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact the Company's effective tax rate.

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

	December 31,		
	2010	2009	2008
U.S. Federal statutory rate	34.0%	34.0%	34.0%
State taxes	5.6	5.6	5.6
Research and development tax credit	2.6	0.9	0.6
AMT Tax		(1.0)	
AMT Credit		1.0	
Stock-based compensation expense	(1.9)	(1.0)	(2.2)
Other adjustments	(0.1)		2.4
Valuation allowance	(40.1)	(40.5)	(40.4)
Effective tax rate	0.1%	(1.0)%	0.0%

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 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, 2010.

As of December 31, 2010, 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 2010, and to state income tax examinations for the tax years 1995 through 2010. 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, 2010, 2009 and 2008.

Table of Contents**EXACT SCIENCES CORPORATION****Notes to Consolidated Financial Statements (Continued)****(14) QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)**

The following table sets forth unaudited quarterly statement of operations data for each of the eight quarters ended December 31, 2010. 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 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)			
2010				
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
2009				
Revenue	\$ 1,000	\$ 1,258	\$ 1,256	\$ 1,244
Cost of revenue		8	5	7
Research and development	108	2,015	837	1,253
Sales and marketing	4,768	1,638	1,478	1,665
General and administrative		40	12	174
Restructuring	(3)			
Loss from operations	(3,873)	(2,443)	(1,076)	(1,855)
Interest income, net	34	49	35	1
Net loss	\$ (3,839)	\$ (2,394)	\$ (1,041)	\$ (1,854)
	\$ (0.13)	\$ (0.08)	\$ (0.03)	\$ (0.05)

Net loss per
share basic and
diluted

Weighted average
common shares
outstanding basic and
diluted

30,230

31,283

34,932

35,429

65

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 material information relating to the Company is accumulated and communicated to management, including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting.

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2010, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting.

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

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

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2010. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control Integrated Framework*. Based on our assessment, we concluded that, as of December 31, 2010, 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.

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 2011 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 2011 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 2011 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 2011 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 2011 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 11, 2011
Katherine Napier		
/s/ LIONEL STERLING	Director	March 11, 2011
Lionel Sterling		
/s/ DAVID THOMPSON	Director	March 11, 2011
David Thompson		

Edgar Filing: EXACT SCIENCES CORP - Form 10-K

Table of Contents

Exhibit Index to Annual Report on Form 10-K

Exhibit Number	Description
3.1	Sixth Amended and Restated Certificate of Incorporation of the Registrant (previously filed as Exhibit 3.3 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
3.2	Amended and Restated By-Laws of the Registrant (previously filed as Exhibit 3.1 to our Report on Form 10-Q for the period ended March 31, 2009, which is incorporated herein by reference)
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)
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*	Sixth Amended and Restated Registration Rights Agreement between the Registrant and the parties named therein dated as of April 7, 2000 (previously filed as Exhibit 10.4 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.3**	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)
10.4**	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)
10.5*	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)
10.6*	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)
10.7*	The Registrant's 2000 Employee Stock Purchase Plan (previously filed as Exhibit 10.13 to our Annual Report on Form 10-K filed for the period ended December 31, 2009, which is incorporated herein by reference)
10.8**	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)

Edgar Filing: EXACT SCIENCES CORP - Form 10-K

Table of Contents

Exhibit Number	Description
10.9*	Non-Employee Director Compensation Policy (previously filed as Exhibit 10.17 to our Annual Report on Form 10-K filed for the period ended December 31, 2009, which is incorporated herein by reference)
10.10**	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)
10.11*	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)
10.12**	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)
10.13**	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)
10.14**	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)
10.15**	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)
10.16**	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)
10.17**	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)
10.18**	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)
10.19	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)
10.20*	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

Exhibit Number	Description
10.21*	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)
10.22*	Release Agreement between Jeffrey R. Luber and the Registrant, dated as of March 31, 2009 (previously filed as Exhibit 10.36 to our Annual Report on Form 10-K filed for the period ended December 31, 2008, which is incorporated herein by reference)
10.23*	Release Agreement between Charles R. Carelli, Jr. and the Registrant, dated as of March 31, 2009 (previously filed as Exhibit 10.37 to our Annual Report on Form 10-K filed for the period ended December 31, 2008, which is incorporated herein by reference)
10.24*	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)
10.25**	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)
10.26	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)
10.27**	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)
10.28	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)
10.29	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)
10.30*	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)
10.31*	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)
10.32+*	Amended and Restated Employment Agreement by and between Barry Berger, M.D. and the Registrant, dated as of October 28, 2010
10.33*	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)

Edgar Filing: EXACT SCIENCES CORP - Form 10-K

Table of Contents

Exhibit Number	Description
10.34*	2010 Omnibus Long-Term Incentive Plan Form Restricted Stock Award Agreement (previously filed as Exhibit 4.6 to our Registration Statement on Form S-8 (File No. 333-168909), which is incorporated herein by reference)
10.35+*	2010 Omnibus Long-Term Incentive Plan Form Restricted Stock Unit Award Agreement
10.36+*	Director Compensation Policy of Exact Sciences Corporation dated as of July 16, 2010
23.1+	Consent of Grant Thornton LLP
23.2+	Consent of Ernst & Young LLP
24.1	Power of Attorney (included on signature page)
31.1+	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934
31.2+	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934
32+	Certification Pursuant to 18 U.S.C Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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

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

+
Filed herewith.