EXACT SCIENCES CORP
Form 10-K
March 12, 2010

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, 2009

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

Commission file number 000-32179

EXACT SCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

DELAWARE	**02-0478229**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
441 Charmany Drive, Madison, WI	**53719**
(Address of principal executive offices)	(Zip Code)

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

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

Common Stock, $.01 Par Value	**The NASDAQ Stock Market LLC**

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

None

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period

that the registrant was required to submit and post such files). Yes o No o

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, as of the last business day of the Registrant's most recently completed second fiscal quarter was approximately $87,355,000 (based on the closing price of the Registrant's Common Stock on June 30, 2009 of $2.65 per share).

The number of shares outstanding of the Registrant's $.01 par value Common Stock as of March 11, 2010 was 35,832,021.

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, 2009. Portions of such proxy statement are incorporated by reference into Part III of this Form 10-K.

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EXACT SCIENCES CORPORATION
ANNUAL REPORT ON FORM 10-K
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PART I

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange and Exchange Act of 1934, as amended, that are intended to be covered by the "safe harbor" created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "could," "seek," "intend," "plan," "estimate," "anticipate" or other comparable terms. Forward-looking statements in this Annual Report on Form 10-K may address the following subjects among others: statements regarding the sufficiency of our capital resources, expected operating losses, 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 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 stool-based (sDNA) colorectal pre-cancer and cancer screening test;

advance our product through U.S. Food and Drug Administration, or FDA, clinical trials;

secure insurance coverage and reimbursement for our product; and

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

Our current focus is on the commercial development and seeking U.S. Food and Drug Administration (FDA) clearance and approval of our stool-based DNA (sDNA) colorectal cancer screening product. We believe obtaining FDA approval is critical to building broad demand and successful commercialization for our sDNA colorectal cancer screening technologies. As part of our product development efforts, we are exploring the marker combinations and platform requirements necessary for optimal performance of our technology based on market need. Objectives around performance, throughput and cost are among the elements that will need to be met in the design and development of a commercial product based on our technology.

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Colorectal cancer is the third leading cause of cancer death overall, the second leading cause of death from cancers that affect both men and women in the United States, and the leading cause of cancer death among non-smokers. 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, or ACS, recommends that all people age 50 and older undergo regular colorectal cancer screening. Of the more than 89 million people in the United States for whom routine colorectal cancer screening is recommended, only 25 percent have been screened according to current guidelines. It is estimated that about one-half of those who should be, have never been screened at all. We believe that this large population of unscreened and inadequately screened patients represents an opportunity to reduce colorectal cancers 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, or 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, or MSTF-CRC, 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, announced that non-invasive, sDNA screening technology is included 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.

Our product includes DNA markers, which in published studies have been shown to be associated with colorectal cancer. These markers include the aberrant methylation of the Vimentin gene promoter region, which we refer to as Vimentin. We have exclusive rights to the Vimentin technology through our license agreement with Case Western Reserve University. Our test also will include a fecal immunochemical test, or FIT. This immunoassay will increase sensitivity without affecting specificity, improving the overall sensitivity of our test.

Background

It is widely accepted that colorectal cancer is among the most preventable, yet least prevented cancers. Colorectal cancer typically takes up to 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. As a result, the cancer is either not detected at all or it is detected at a later stage, when the five-year survival rate falls below 50%. The number of people who die annually from the disease has remained materially unchanged during the last 20 years, despite the availability of multiple colorectal cancer screening options, all of which we believe fail to effectively meet the needs of patients, doctors and payors.

There is a significant unmet clinical need related to the diagnosis of colorectal cancer. Only 25 percent of those who should be screened for colorectal cancer are screened according to current guidelines. Half of those age 50 years and older have not been screened at all. 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 54 percent and 8 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

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cancer. Accordingly, the ACS recommends that the more than 89 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 massive market opportunity. Assuming a 30-percent test adoption rate and a three-year screening interval, the potential U.S. market for sDNA screening is $1.2 billion. The total available U.S. market is more than $5 billion which is approximately 89 million people to be screened every three years.

Our Solution

Our screening 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 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 a Fecal Immunochemical Test (FIT). A "positive" result from sDNA detection or a positive FIT result does not necessarily mean that a patient has colorectal cancer. A "positive" result means that one or more of the genetic markers that can be associated with colorectal cancer has been identified. 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 several advantages over other screening options that may lead to decreased mortality associated with colorectal cancer.

The benefits of sDNA-based screening are clear.

It detects both pre-cancers and cancers, and we are targeting sensitivities greater than 50 percent and 85 percent, respectively.

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 also is affordable, particularly compared to colonoscopy.

Of those people for whom screening is recommended, many reject the option of colonoscopy which, while accurate as a means of detecting colorectal cancer, is invasive and requires a bowel preparation. In addition, many FOBT screening tests require unpleasant stool sampling and stool manipulation by the patient, and certain FOBT screening tests also require dietary modifications.

Reimbursement

We are continuing to work to obtain national coverage for sDNA colorectal cancer screening technologies from Medicare and positive coverage decisions from major national and regional managed care organizations and insurance carriers, and self-insured employer groups.

Twelve states and the District of Columbia 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. These states include Alaska, Georgia, Illinois, Indiana, Kentucky, Maine, Maryland, Missouri, Nevada, New Jersey, North Carolina, and Rhode Island. 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

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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 Center for Medicare and Medicaid (CMS) for our sDNA screening product will be a necessary element in achieving any material commercial success.

Competition

There are a number of established primary screening methods that are recommended for colorectal cancer. All of the colorectal cancer detection methods in use today are constrained by some combination of poor sensitivity, poor compliance and cost. Colonoscopy remains the most widely used and is considered the 'gold standard' method that is most widely practiced as a primary colorectal cancer screen. However, colonoscopy is uncomfortable and expensive and suffers from a high rate of non-compliance. Following colonoscopy, the next most widely used method of colorectal cancer screening is FOBT or a newer version of FOBT called Fecal Immunochemical Testing (FIT). Fecal blood testing suffers from poor sensitivity, including 50 percent detection rates for cancer and 12 percent detection rates for pre-cancers. Recently, CT colonography (also called virtual colonoscopy) has emerged as an option. CT colonography requires a bowel preparation (as does colonoscopy) and consists of a radiological examination of the colon. CT colonography was recently rejected for reimbursement by the Centers for Medicare and Medicaid (CMS). Another potential alternative method is blood-based DNA testing. The principle disadvantage of blood DNA testing is poor sensitivity for cancer and an inability to detect pre-cancerous lesions. Data from a clinical trial of one blood-based DNA test was released in early 2010. It demonstrated only 50 percent sensitivity across all stages of cancer.

We are aware of three companies, Epigenomics, OncoMethylome Sciences and Gene News, developing screening tests for the detection of colorectal cancer. Additionally, Quest Diagnostics and Abbott Diagnostics have sublicensed technology from Epigenomics and are offering versions of the Epigenomics test to customers as lab developed tests (LDT) and as CE marked kits, respectively. Epigenomics is headquartered in Berlin, Germany and has a U.S. location in Seattle, Washington. OncoMethylome Sciences has several offices located in Belgium and U.S. offices in North Carolina. Gene News is located in Ontario, Canada.

Research and Development

Our current focus is on the commercial development and seeking U.S. Food and Drug Administration (FDA) clearance and approval of our sDNA colorectal cancer screening product. Accordingly, research and development costs account for a substantial portion of our operating expenses. Our research and development expenses were $4.2 million, $2.0 million and $4.9 million for the years ended December 31, 2009, 2008 and 2007, 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.

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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, known as a PMA. Our current focus is on the commercial development and seeking FDA clearance and approval of our sDNA colorectal cancer screening product. 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 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 FDA 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 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, it could adversely affect any future CMS consideration of any of our technologies, prevent its 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.

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Intellectual Property

Our intellectual property portfolio positions us as the leading player in the sDNA market. Our patent estate broadly protects our position in the market, including the platform technology, methods and biomarkers. In 2009, we expanded our intellectual property estate through our collaboration with the Mayo Clinic as well as by licensing Invader detection chemistry from Hologic, which we plan to incorporate into our test. Previously we licensed Case Western's important Vimentin DNA methylation marker, as well as on an exclusive basis, Johns Hopkins' digital PCR technologies for colon cancer detection.

Our success depends to a significant degree upon our ability to protect our technologies through patent coverage. As of December 31, 2009, we owned 14 issued patents and 9 pending applications in the United States, and 51 issued patents and 11 pending patent applications in foreign jurisdictions. In addition, as part of the Genzyme transaction, 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 25 patents issued and 9 pending patent applications in the U.S., and 33 patents issued and 15 pending patent applications in foreign jurisdictions sold to Genzyme.

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

Genzyme Transaction

On January 27, 2009, we entered into a strategic transaction with Genzyme Corporation. As a result of the Genzyme transaction, we assigned certain aspects of our intellectual property applicable to the fields of prenatal and reproductive health to Genzyme. We also granted Genzyme a license to use and sublicense some of our remaining intellectual property in fields other than colorectal cancer detection and stool-based disease detection. With respect to the assigned intellectual property, Genzyme granted us a license to use and sublicense such intellectual property in the fields of colorectal cancer detection and stool-based detection of any disease or condition. Accordingly, we retained our rights in both the assigned and licensed intellectual property in the fields of colorectal cancer detection and stool-based disease detection. In addition, we and Genzyme each granted to the other a license to use and sublicense any improvements we or Genzyme make to the intellectual property. Genzyme agreed to pay a double-digit royalty to us on income received by Genzyme as a result of any licenses or sublicenses to third parties of the assigned or licensed intellectual property.

Employees

As of December 31, 2009, we had nineteen 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 *http://www.exactsciences.com*. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge through the investor relations page of our internet website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. Our Internet website and the information contained therein or connected thereto are not intended to be incorporated into this Annual Report on Form 10-K.

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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/or 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, 2009, we have accumulated a total deficit of approximately $181.6 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 of 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.

Many of these factors are outside our control and, accordingly, we cannot assure you that one or more of the foregoing will occur in the near term, or at all. Failure to achieve one or more of the foregoing events could negatively impact the successful commercialization of stool-based DNA testing services or products utilizing our intellectual property and impair our ability to generate revenues and achieve profitability.

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

Following the closing of our strategic transaction with Genzyme in January 2009, we have resumed our efforts to develop an FDA-approved in vitro diagnostic test for stool-based DNA colorectal cancer screening. The FDA approval path for our colorectal cancer screening technology is likely to take significant time and require significant research, development and clinical study 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 stool-based DNA technology and related FDA submission and commercialization efforts. We do not expect that product royalty payments or milestone payments from LabCorp will materially supplement our liquidity position in the next twelve months, if at all. If we are unable to obtain needed financing on acceptable

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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 shareholders' 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 technology, including an FDA-approved in vitro diagnostic test for stool-based DNA colorectal cancer screening, 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 stool-based DNA colorectal cancer screening technology, 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 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, approximating 89 million Americans age 50 and above, of which we believe approximately one-half 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. Currently, we face competition from procedure-based detection technologies such as flexible sigmoidoscopy, colonoscopy and virtual colonoscopy, a procedure in which a radiologist views the inside of the colon through a scanner, as well as from existing guaic-based FOBT, and improved screening tests such as immunochemical FOBT. 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. Additionally, we understand OncoMethylome Sciences is in the process of enrolling patients for a large blood-based colorectal cancer screening trial. 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.

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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. For example, we have an exclusive license from Case Western Reserve University, or Case Western, for the use of the Vimentin gene in the field of colorectal cancer testing, pursuant to which we are permitted to sublicense such rights to others. If Case Western were to terminate this agreement as a result of a breach by us or otherwise, we would lose our ability to offer any test or testing service based on the Vimentin gene, including the right to develop an FDA-approved colorectal cancer screening product using the Vimentin gene, which would materially harm our business. 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.

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. Accordingly, 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.

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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, a majority of these individuals do not complete a colorectal cancer screening test. 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 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 affect on our business, financial condition and results of operations.

Also, patents and 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.

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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.

In addition to our patents, we rely on contractual restrictions to protect our proprietary technology. We require our employees and third parties to sign confidentiality agreements and employees to sign agreements assigning to us all intellectual property arising from their work for us. Nevertheless, we cannot guarantee that these measures will be effective in protecting our intellectual property rights.

We cannot guarantee that the patents issued to us will be broad enough to provide any meaningful protection nor can we assure you that one of our competitors may not develop more effective technologies, designs or methods to test for colorectal cancer or any other common cancer without infringing our intellectual property rights or that one of our competitors might not design around our proprietary technologies.

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.

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. Effective April 2, 2009, Kevin T. Conroy was appointed as our new President and Chief Executive Officer. Similarly, Effective April 2, 2009, Maneesh Arora was appointed as our new Chief Financial Officer. On August 1, 2009, Dr. Graham Lidgard was hired as 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.

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

We have established relationships with leading scientists at important research and academic institutions, such as Mayo Clinic, Case Western Reserve University, and The John 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.

Certain provisions of our charter, by-laws and Delaware law may make it difficult for you to change our management and may also make a takeover difficult.

Our corporate documents and Delaware law contain provisions that limit the ability of stockholders to change our management and may also enable our management to resist a takeover. These provisions include a staggered board of directors, limitations on persons authorized to call a special meeting of stockholders and advance notice procedures required for stockholders to make nominations of candidates for election as directors or to bring matters before an annual meeting of stockholders. These provisions might discourage, delay or prevent a change of control in our management. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors and cause us to take other corporate actions. In addition, the existence of these provisions, together with Delaware law, might hinder or delay an attempted takeover other than through negotiations with our board of directors.

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.

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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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

As of December 31, 2009, we occupied approximately 12,250 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. 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 Global Market, the market on which our common stock was previously listed until November 27, 2008, and on the NASDAQ Capital Market on and after November 28, 2008.

	High	Low
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
2008		
First quarter	$ 4.25	$ 1.70
Second quarter	3.00	1.73
Third quarter	1.79	0.70
Fourth quarter	1.05	0.22

As of December 31, 2009, there were 35,523,140 shares of our common stock outstanding held by approximately 86 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.

On April 24, 2009, we issued 30,000 shares of our common stock to XMS Capital Partners, LLC ("XMS"), for partial consideration for services rendered to us under a financial advisor agreement with XMS. These shares were issued upon the exemption from the registration provisions of the Securities

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Act of 1933 provided for by Section 4(2) thereof for transactions not involving a public offering. Use of this exemption is based on the following facts:

Neither we nor any person acting on our behalf solicited any offer to buy or sell securities by any form of general solicitation or advertising.

At the time of the purchase, XMS was an accredited investor, as defined in Rule 501(a) of the Securities Act.

XMS has had access to information regarding us and is knowledgeable about us and our business affairs.

All shares issued to XMS were issued with a restrictive legend and may only be disposed of pursuant to an effective registration or exemption from registration in compliance with federal and state securities laws.

Item 6. Selected Financial Data

The selected historical financial data set forth below as of December 31, 2009 and for the year 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 as of December 31, 2008 and for the years ended December 31, 2008 and 2007 are derived from our financial statements, which have been audited by Ernst & Young LLP, an independent registered public accounting firm and which are included elsewhere in this Form 10-K. The selected historical balance sheet financial data as of December 31, 2007, 2006 and 2005 and statements of operations data for the years ended December 31, 2006 and 2005 are derived from our audited financial statements not included elsewhere in this Form 10-K.

The selected historical financial data should be read in conjunction with, and are qualified by reference to "Management's Discussion and Analysis of Financial Condition and Results of

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

	Year Ended December 31,				
	2009	2008	2007	2006	2005
	(in thousands, except per share data)				
Consolidated Statements of Operations Data:					
Revenue:					
Product royalty fees	$ 25	$ (2,234)	$ (1,137)	$ 179	$ 206
License fees	4,733	1,351	2,857	4,363	3,828
Product		16	78	208	216
	4,758	(867)	1,798	4,750	4,250
Cost of revenue	20	1	49	809	566
Gross profit (loss)	4,738	(868)	1,749	3,941	3,684
Operating expenses:					
Research and development(1)	4,213	2,034	4,887	6,735	7,956
General and administrative(1)	9,549	6,469	7,541	6,910	5,497
Sales and marketing(1)	226		991	3,792	5,239
Restructuring(1)	(3)	602	1,177	671	626
	13,985	9,105	14,596	18,108	19,318
Loss from operations	(9,247)	(9,973)	(12,847)	(14,167)	(15,634)
Investment income	119	232	888	1,252	1,114
Net loss	$ (9,128)	$ (9,741)	$ (11,959)	$ (12,915)	$ (14,520)
Net loss per share:					
Basic and diluted	$ (0.28)	$ (0.36)	$ (0.44)	$ (0.49)	$ (0.55)
Weighted average common shares outstanding:					
Basic and diluted	32,791	27,212	26,945	26,509	26,270
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 21,924	$ 4,937	$ 4,486	$ 4,831	$ 11,987
Marketable securities	2,404		8,101	16,244	21,112
Total assets	25,770	5,898	14,595	23,868	37,845
Total liabilities	19,676	8,331	8,307	8,910	13,224
Stockholders' equity (defecit)	6,094	(2,433)	6,288	14,958	24,621

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

	2009	2008	2007	2006	2005
Research and development	$ 319	$ 89	$ 541	$ 653	$ 113
Sales and marketing	4		202	956	152
General and administrative	2,308	918	1,889	1,397	240
Restructuring		3	174		

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

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

Overview

Exact Sciences Corporation 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 current focus is on the commercial development and seeking U.S. Food and Drug Administration (FDA) clearance and approval of our stool-based DNA, or sDNA, colorectal cancer screening product. We believe obtaining FDA approval is critical to building broad demand and successful commercialization for our sDNA colorectal cancer screening technologies.

It is widely accepted that colorectal cancer is among the most preventable, yet least prevented cancers. Colorectal cancer typically takes up to 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.

Our sDNA, screening 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 5 percent of the population over 50 years of age in the United States.

There is a significant unmet clinical need related to the diagnosis of colorectal cancer. Only 25 percent of those who should be screened for colorectal cancer are screened according to current guidelines. Half of those age 50 years and older have not been screened at all.

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 54 percent and 8 percent, respectively.

Our sDNA screening 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 the sDNA-based test, affected patients can be referred to colonoscopy, during which the polyp or lesion can be removed. The sDNA screening model has the potential to significantly reduce colorectal cancer deaths. The earlier the pre-cancer or cancer can be detected, the greater the reduction in mortality.

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. Fifty-five percent of the patients who responded to one recent study said that colonoscopy was very unacceptable or unacceptable. Fecal blood testing suffers from poor sensitivity, including 50 percent detection rates for cancer and 12 percent detection rates for pre-cancers. Blood-based DNA testing also is disadvantaged by its sensitivity. Data from a clinical trial of one blood-based test was released earlier this year. It demonstrated only 50 percent sensitivity across all stages of cancer.

The competitive advantages of sDNA-based screening provide a massive market opportunity. Assuming a 30-percent test adoption rate and a three-year screening interval, the potential U.S. market for sDNA screening is $1.2 billion. The total available U.S. market is more than $5 billion.

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The benefits of sDNA-based screening are clear. It detects both pre-cancers and cancers, at target sensitivities greater than 50 percent and 85 percent, respectively. 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.

Our intellectual property portfolio positions us as the leading player in the sDNA market. Our patent estate broadly protects our position in the market, including the platform technology, methods and biomarkers. In 2009 we expanded our intellectual property estate through our collaboration with the Mayo Clinic. We had previously licensed on an exclusive basis Johns Hopkins' digital PCR technologies for colon cancer detection, as well as Case Western's important Vimentin DNA methylation marker. In 2009, we also licensed the Hologic Inc.'s Invader detection chemistry, which we plan to incorporate into our test.

We have generated limited operating revenues since inception and, as of December 31, 2009, we had an accumulated deficit of approximately $181.6 million. Losses have historically resulted from costs incurred in conjunction with research, development and clinical study initiatives; salaries and benefits associated with the hiring of personnel; the initiation of marketing programs; and prior to August 31, 2007, the build-out of our sales infrastructure to support the commercialization of sDNA screening. We expect to continue to incur losses for the next several years, and it is possible we may never achieve profitability.

Management

During 2009 we assembled a new management team with significant experience in molecular oncology diagnostics.

Kevin T. Conroy was elected a member of our board of directors in March 2009 and appointed our President and Chief Executive Officer in April 2009. Maneesh Arora was appointed as our Senior Vice President and Chief Financial Officer in April 2009. Mr. Conroy and Mr. Arora previously served as Chief Executive Officer and Chief Financial Officer, respectively, at Third Wave Technologies, Inc., a leading molecular diagnostics company which was acquired for $581 million by Hologic, Inc. in June 2008.

In August 2009, we hired Dr. Graham Lidgard as senior vice president and chief science officer. Dr Lidgard brings more than 3 decades of clinical diagnostic experience to Exact. His experience covers both immunoassay and molecular diagnostics, from pioneering chemiluminescent magnetic particle immunoassay at Ciba Corning, to leading the research and development for the Procleix HIV/HCV blood screening assays, the APTIMA Combo 2 STD assays and the TIGRIS automated nucleic acid Instrument at Gen-Probe.

In August 2009, we entered into a new employment agreement with Dr. Barry Berger as our senior vice president and chief medical officer. Dr. Berger is Board Certified in Anatomic Clinical and Cytologic Pathology and has a visiting teaching appoint at Brigham and Women's Hospital (Boston, MA) and Harvard Medical School. He joined Exact in 1999 as VP of Laboratory Medicine following a long career as the Director of Pathology and Laboratory Medicine for a million member MCO, Harvard Pilgrim Healthcare (Boston, MA).

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

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technology. We expect that product royalty fees for the full year 2010 will be consistent with amounts recorded in 2009. We expect that license fee revenue resulting from the amortization of the up-front license payment from LabCorp and Genzyme in 2010 will be higher than amounts recorded in 2009 as a result of a full year of revenue from the Genzyme transaction and from the expected receipt of holdback amounts from Genzyme during 2010.

Our Cost Structure

Our general and administrative expenses have consisted primarily of non-research personnel salaries, office expenses, professional fees and, non-cash stock-based compensation. Effective August 31, 2007, we eliminated our sales and marketing functions and therefore, did not incur any sales and marketing expenses in 2008. We incurred sales and marketing expenses of $0.2 million in 2009 as a result of increased sales and marketing activities in support of developing an FDA-approved in vitro diagnostic test for the early detection and prevention of colon cancer.

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 intangible assets. 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 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 are amortizing the remaining deferred revenue balance at the time of the amendment ($4.7 million) on a straight-line basis over the remaining exclusive license period, which ends in December 2010.

In connection with our January 2009 strategic transaction with Genzyme, Genzyme agreed to pay us a total of $18.5 million, of which $16.65 million was paid at closing and $1.85 million is 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

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$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. Receipt of any holdback amounts, as defined below, will similarly be deferred and 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. We recognized approximately $3.4 million in license fee revenue in connection with the amortization of the up-front payments from Genzyme during the year ended December 31, 2009.

Other revenue. Revenue from milestone and other performance-based payments is recognized as revenue when the milestone or performance is achieved and collection of the receivable is estimable and probable based on specific agreements and circumstances.

Stock-Based Compensation. In accordance with GAAP, all share-based payments to employees, including grants of employee stock options and shares purchased under an employee stock purchase plan (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 the fair value of stock option grants:

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 term, described in the SEC's Staff Accounting Bulletin 107 and 110, as the Company does not currently have sufficient historical exercise data on which to base an estimate of expected term. Using this method, the expected term is determined using the average of the vesting period and the contractual life of the stock options granted.

Expected Volatility Expected volatility is based on the Company's historical stock volatility data over the expected term of the awards.

Risk-Free Interest Rate The Company bases the risk-free interest rate used in the Black-Scholes valuation method on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent remaining term.

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 2009 that vest annually are all expected to vest and no forfeiture rate was utilized.

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. As of December 31, 2009 we had paid $2.5 million in payments to LabCorp. We will be required to pay at a maximum the remaining $1.0 million balance in January of 2011. Based on anticipated sales volumes of ColoSure, as of

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December 31, 2009, we accrued a total of $988,000 related to the total potential remaining $1.0 million obligation to LabCorp. We recorded charges of $13,000 and $2.25 million during the years ended December 31, 2009 and 2008, 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. Future increases in this obligation, to the extent necessary, will continue to be recorded as charges to the product royalty revenue line item of our consolidated statements of operations.

Recent Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board ("FASB") issued FASB Accounting Standards Codification 105, "Generally Accepted Accounting Principles." FASB ASC 105 approved the FASB Accounting Standards Codification ("ASC") as the source of authoritative nongovernmental GAAP. All existing accounting standards have been superseded and all other accounting literature not included in the FASB ASC will be considered non-authoritative. FASB ASC 105 is effective for financial statements issued for interim or annual periods ending after September 15, 2009. Accordingly, all references to accounting standards have been conformed to the new ASC hierarchy.

On April 9, 2009, the FASB issued FASB ASC 825 "Financial Instruments" and FASB ASC 270 "Interim Reporting." FASB ASC 825 requires disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. FASB ASC 825 also amends FASB ASC 270, "Interim Reporting", to require those disclosures in summarized financial information at interim reporting periods. The adoption of this accounting pronouncement did not have a material effect on the determination or reporting of our financial results.

On May 28, 2009, the FASB issued FASB ASC 855, "Subsequent Events" ("FASB ASC 855"). FASB ASC 855 establishes principles and requirements for subsequent events, in particular: (i) the period after the balance sheet date during which management of a reporting entity shall evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements; (ii) the circumstances under which an entity shall recognize events or transactions occurring after the balance sheet date in its financial statements; and (iii) the disclosures that an entity shall make about events or transactions that occurred after the balance sheet date. The adoption of this accounting pronouncement did not have a material effect on the determination or reporting of our financial results.

In September 2009, the 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, 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. 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 is being amortized on a straight-line basis over the remaining exclusive license period, which ends in December 2010. The unamortized Genzyme up-front payment is being amortized on a straight-line basis over the initial Genzyme collaboration period, which ends in

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January 2014. Revenues also include royalties on LabCorp's sales of PreGen-Plus and ColoSure and sales of Effipure units to LabCorp as well as charges for our third-party royalty reimbursement obligation to LabCorp which are recorded as reductions to revenue under financial accounting guidance. Effective June 1, 2008, LabCorp stopped offering PreGen-Plus and informed us that it had discontinued its use of Effipure.

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 an FDA-approved in vitro diagnostic test for the early detection and prevention of colon cancer. 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 to 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 developing an FDA-approved in vitro diagnostic test for the early detection and prevention of colon cancer.

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.

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Comparison of the years ended December 31, 2008 and 2007

Revenue. Total revenue decreased to $(0.9) million for the year ended December 31, 2008 from $1.8 million for the year ended December 31, 2007.

The decrease in total revenue was primarily the result of a decrease of approximately $1.5 million in license fee revenue resulting from the June 2007 extension of the exclusive period under our license agreement with LabCorp from August 2008 to December 2010. As a result of this extension, the remaining unamortized up-front license fees that LabCorp previously paid to us are being recognized over a longer period of time, resulting in lower non-cash license fee amortization as compared to prior periods.

A $1.1 million increase in negative product royalty revenue due to our third-party royalty reimbursement obligation to LabCorp also contributed to the decline in revenues.

Research and development expenses. Research and development expenses decreased to $2.0 million for the year ended December 31, 2008 from $4.9 million for the year ended December 31, 2007. The decrease was primarily the result of the continuing effect of the cost reduction plans undertaken in 2007 and 2008 described below. The decrease in research and development expenses, included decreases of $1.1 million in licensing costs, $0.7 million in lab-related operating expenses, $0.6 million in personnel-related expenses, and $0.5 million in non-cash stock-based expenses.

General and administrative expenses. General and administrative expenses decreased to $6.5 million for the year ended December 31, 2008, compared to $7.5 million for the year ended December 31, 2007. This decrease was due to a decrease in non-cash stock-based compensation expense of $0.9 million as well as a decrease of $0.9 million in salary, benefit and other costs due to lower general and administrative headcount. The decrease in non-cash stock-based compensation was due primarily to the non-recurrence of one-time non-cash stock-based compensation charges of $0.7 million taken in the third quarter of 2007 related to the acceleration and the extension of the expiration date of certain stock options held by Don M. Hardison, our former President and Chief Executive Officer, pursuant to a separation agreement between us and Mr. Hardison in connection with his resignation in August 2007. These decreases in general and administrative expenses for the year ended December 31, 2008 were partially offset by an increase of $0.8 million in professional fees in connection with our strategic review process, our reimbursement efforts with CMS and our regulatory efforts with the FDA.

Sales and marketing expenses. Sales and marketing expenses decreased to $0 for the year ended December 31, 2008, compared to $1.0 million for the year ended December 31, 2007 as a result of the elimination of our sales and marketing functions effective August 31, 2007, as described under the heading "2007 Restructuring" below.

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 Marlborough, Massachusetts.

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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 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.

Amounts remaining in the 2008 Restructuring accrual at December 31, 2009, which are expected to be paid out in cash through July 2010, are recorded under the caption "Accrued expenses" in our consolidated balance sheets. 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	Non-cash Write-offs	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, we recorded restructuring charges of approximately $0.8 million during the three months ended September 30, 2007, related to one-time termination benefits arising under retention and severance agreements with terminated employees, including $0.6 million in severance and related benefit costs which were paid in cash through May 2008, and $0.2 million in non-cash stock-based compensation charges associated with extending the period of exercise for vested stock option awards for terminated employees.

In addition, during the fourth quarter of 2007, we entered into a sublease agreement, which we refer to as the 2007 Sublease Agreement with INTRINSIX Corporation, or INTRISIX, to sublease to the INTRINSIX approximately 11,834 square feet of rentable area in our corporate headquarters. Amounts remaining in the 2007 Restructuring accrual at December 31, 2009, which are expected to be paid out through July, 2010, are recorded under the caption "Accrued expenses" in our condensed consolidated balance sheets. 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	Non-cash Write-offs	Balance, December 31, 2009
Employee separation costs	$	$	$	$	$
Facility consolidation costs	161		(94)		67
Total	$ 161	$	$ (94)	$	$ 67

The charges outlined in the table above exclude $0.2 million in non-cash stock-based compensation expense recorded in connection with the stock option modifications discussed above.

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Interest income. Interest income decreased to $0.2 million for the year ended December 31, 2008 from $0.9 million for the year ended December 31, 2007. This decrease was due to lower average cash, cash equivalents and marketable securities balances held during the year ended December 31, 2008 as compared to the same period of 2007, as well as less favorable interest rates on investments held during the year ended December 31, 2008 as compared to the same period of 2007.

Liquidity and Capital Resources

We have financed our operations since inception primarily through private and public offerings of our equity securities, cash received from LabCorp in connection with our license agreement, and cash received in January 2009 from Genzyme in connection with the Genzyme strategic transaction. As of December 31, 2009, we had approximately $21.9 million in unrestricted cash and cash equivalents and $0.5 million in restricted cash, which has been pledged as collateral for an outstanding letter of credit.

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, 2009 we had approximately $2.4 million in marketable securities.

Net cash used in operating activities was $12.6 million, $7.9 million, and $8.8 million for the years ended December 31, 2009, 2008 and 2007, respectively. The principal use of cash in operating activities for each of the years ended December 31, 2009, 2008 and 2007 was to fund our net loss. The increase in net cash used in operating activities for the year ended December 31, 2009 as compared to the year ended December 31, 2008 was due to increased research and development activities and to $2.5 million paid to LabCorp related to our third party royalty obligation. The decrease for the year ended December 31, 2008 as compared to the year ended December 31, 2007, was primarily due to decreases in research and development and sales and marketing spending as a result of multiple restructuring and cost reduction actions taken during 2008 and 2007. 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 $2.9 million for the year ended December 31, 2009. Net cash provided by investing activities was $8.2 million and $8.0 million for the years ended December 31, 2008 and 2007, respectively. The increase in cash used in investing activities for the year ended December 31, 2009 when compared to the same periods in 2008 and 2007 was the result of purchases of marketable securities being greater than maturities of marketable securities during the year. Excluding the impact of purchases and maturities of marketable securities, net cash used in investing activities was $0.5 million for the year ended December 31, 2009, net cash provided by investing activities was $0.2 million for the year ended December 31, 2008, and net cash used in investing activities was $0.1 million for the year ended December 31, 2007. Purchases of property and equipment of approximately $0.5 million during the year ended December 31, 2009 were significantly higher than purchases of property and equipment for the years ended December 31, 2008 and 2007 as a result of increased research and development activities combined with the cost reduction efforts undertaken in 2008 and 2007. Net cash provided by investing activities for the year ended December 31, 2008 was primarily the result of cash receipts from sales of fully depreciated equipment in connection with our 2008 sublease agreement.

Net cash provided by financing activities was $32.5 million, $0.1 million and $0.4 million for the years ended December 31, 2009, 2008 and 2007, respectively. The increase in cash provided by financing activities for the year ended December 31, 2009 was primarily related to proceeds of

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$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.

We expect that cash and cash equivalents on hand at December 31, 2009, 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 will need to raise additional capital to fully fund our current strategic plan, the centerpiece of which is the commercialization of our sDNA technology through completion of the development of an FDA-approved in vitro diagnostic test for sDNA colorectal pre-cancer and cancer screening. 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, 2009:

		Payments Due by Period			
Description	**Total**	**Less Than One Year**	**1 - 3 Years**	**3 - 5 Years**	**More Than 5 Years**
			(in Thousands)		
Long-term debt obligations(2)	$ 1,157	$	$	$ 270	$ 887
Obligations under license and collaborative agreements(1)	3,871	542	1,537	196	1,596
Operating lease obligations	1,938	866	831	241	
Severance obligations	10	10			
Total	$ 6,976	$ 1,418	$ 2,368	$ 707	$ 2,483

(1) We have entered into several license and collaborative agreements with Johns Hopkins University, the Mayo Foundation, Genzyme, and Hologic, Inc. See Note 10 to our consolidated financial statements included elsewhere in this report for further information.

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

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 leased facilities in Marlborough, Massachusetts and our headquarters in Madison, Wisconsin.

Severance obligations represent remaining commitments to personnel terminated in connection with the change in management team in March of 2009.

Net Operating Loss Carryforwards

As of December 31, 2009, we had federal and state net operating loss and research tax carryforwards of approximately $142.3 million and $3.4 million, respectively. The net operating loss and tax credit carryforwards will expire beginning 2015 through 2029, 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

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their ability to generate sufficient future income in order to realize the benefit of the deferred tax assets. We have recorded a valuation against our deferred tax assets based on our history of losses. The deferred tax assets are still available for us to use in the future to offset taxable income, which would result in the recognition of tax benefit and a reduction to our effective tax rate.

Off-Balance Sheet Arrangements

As of December 31, 2009, 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 U.S. and, as of December 31, 2009, were classified as available-for-sale. We held no investments at December 31, 2008. 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. We have no investments denominated in foreign country currencies and therefore are not presently subject to foreign exchange risk.

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

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Item 8. Financial Statements and Supplementary Data

EXACT SCIENCES CORPORATION
Index to Financial Statements

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Exact Sciences Corporation

We have audited the accompanying consolidated balance sheet of Exact Sciences Corporation (a Delaware Corporation) (the Company) as of December 31, 2009, and the related consolidated statements of operations, stockholders' (deficit) equity, and cash flows for the year ended December 31, 2009. 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 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 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 audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2009, and the results of their operations and their cash flows for the year ended December 31, 2009, 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, 2009, 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 12, 2010 expressed an unqualified opinion thereon.

/s/ Grant Thornton LLP

Madison, Wisconsin
March 12, 2010

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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, 2009, 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, 2009, 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 consolidated financial statements of the Company as of December 31, 2009 and for the year ended December 31, 2009 and our report dated March 12, 2010 expressed an unqualified opinion on those consolidated financial statements.

/s/ Grant Thornton LLP

Madison, Wisconsin
March 12, 2010

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Exact Sciences Corporation:

We have audited the accompanying consolidated balance sheets of Exact Sciences Corporation as of December 31, 2008, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the two years in the period 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 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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits 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 audits provide a reasonable basis for our opinion.

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

/s/ Ernst & Young LLP

Boston, Massachusetts
March 31, 2009

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EXACT SCIENCES CORPORATION

Consolidated Balance Sheets

(Amounts in thousands, except share data)

	December 31, 2009	December 31, 2008
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 21,924	$ 4,937
Marketable securities	2,404	
Prepaid expenses and other current assets	484	190
Short term restricted cash	500	
Total current assets	25,312	5,127
Property and Equipment, at cost:		
Laboratory equipment	492	174
Office and computer equipment	90	13
Leasehold improvements	12	
Furniture and fixtures	20	
	614	187
Less Accumulated depreciation and amortization	(156)	(111)
	458	76
Patent costs, net of accumulated amortization of $2,820 at December 31, 2008		95
Long term restricted cash		600
	$ 25,770	$ 5,898
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current Liabilities:		
Accounts payable	$ 155	$ 683
Accrued expenses	1,385	1,498
Third party royalty obligation, current portion		1,500
Deferred license fees, current portion	4,986	1,350
Total current liabilities	6,526	5,031
Third party royalty obligation, less current portion	988	1,950
Long term debt	1,000	
Long term accrued interest	1	
Deferred license fees, less current portion	11,161	1,350
Commitments and contingencies		
Stockholders' (Deficit) Equity:		
Preferred stock, $0.01 par value Authorized 5,000,000 shares Issued and outstanding none at December 31, 2009 and 2008		
Common stock, $0.01 par value Authorized 100,000,000 shares Issued and outstanding 35,523,140 and 27,522,931 shares at December 31, 2009 and 2008, respectively	355	275
Additional paid-in capital	187,333	169,854
Treasury stock, at cost, Outstanding none and 85,550 shares at December 31, 2009 and 2008, respectively		(97)
Other comprehensive loss	(1)	
Accumulated deficit	(181,593)	(172,465)

Total stockholders' (deficit) equity	6,094	(2,433)
	$ 25,770	$ 5,898

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

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EXACT SCIENCES CORPORATION

Consolidated Statements of Operations

(Amounts in thousands, except per share data)

	Year Ended December 31,		
	2009	**2008**	**2007**
Revenue:			
Product royalty fees	$ 25	$ (2,234)	$ (1,137)
License fees	4,733	1,351	2,857
Product		16	78
	4,758	(867)	1,798
Cost of revenue:			
Product royalty fees	20	1	4
Product			45
	20	1	49
Gross profit (loss)	4,738	(868)	1,749
Operating expenses:			
Research and development	4,213	2,034	4,887
General and administrative	9,549	6,469	7,541
Sales and marketing	226		991
Restructuring	(3)	602	1,177
	13,985	9,105	14,596
Loss from operations	(9,247)	(9,973)	(12,847)
Investment income	119	232	888
Net loss	$ (9,128)	$ (9,741)	$ (11,959)
Net loss per share basic and diluted	$ (0.28)	$ (0.36)	$ (0.44)
Weighted average common shares outstanding basic and diluted	32,791	27,212	26,945

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

EXACT SCIENCES CORPORATION

Consolidated Statements of Stockholders' (Deficit) Equity

(Amounts in thousands, except share data)

	Common Stock			Treasury Stock					
	Number of Shares	$0.01 Par Value	Additional Paid In Capital	Number of Shares	Value	Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders (Deficit) Equity	Other Comprehensive (Loss) Income
Balance, January 1, 2007	26,863,363	$ 269	$ 165,545	85,550	$ (97)	$ 6	$ (150,765)	$ 14,958	
Issuance of shares under stock purchase plan	16,987		27					27	$
Issuance of restricted common stock to collaborators in lieu of cash	156,675	2	464					466	
Exercise of common stock options	88,237	1	258					259	
Issuance of common stock to fund the Company's 2006 401(k) match	34,030		102					102	
Compensation expense related to issuance of stock options and restricted stock awards	66,249	1	1,565					1,566	
Compensation expense related to stock option modifications (Note 9)			852					852	
Net loss							(11,959)	(11,959)	(11,959)
Other comprehensive income						17			