EXACT SCIENCES CORP
Form 10-K
March 31, 2009

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended: December 31, 2008

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.)
100 Campus Drive, Marlborough, Massachusetts	**01752**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(508) 683-1200**

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

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

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

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 $43,306,870 (based on the closing price of the Registrant's Common Stock on June 30, 2008 of $1.80 per share).

The number of shares outstanding of the Registrant's $.01 par value Common Stock as of March 27, 2009 was 30,762,520.

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, 2008. Portions of such proxy statement are incorporated by reference into Part III of this Form 10-K.

Table of Contents

EXACT SCIENCES CORPORATION
ANNUAL REPORT ON FORM 10-K
YEAR ENDED DECEMBER 31, 2008

TABLE OF CONTENTS

Table of Contents

PART I

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and are subject to the "safe harbor" created by those sections. These statements relate to, among other things, our expectations concerning our development and commercial strategy, regulatory compliance, our reimbursement efforts and their likely successes, the marketing, sales and reimbursement efforts of our collaborators and their likely future success, our financial condition and the availability of our cash resources, our research and development efforts and the effectiveness and market acceptance of our technologies. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. Some of the forward-looking statements can be identified by the use of forward-looking terms such as "believes," "expects," "may," "will," "should," "seek," "intends," "plans," "estimates," "anticipates," or other comparable terms. These forward-looking statements involve risk and uncertainties. Our actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those set forth in "Item 1A. Risk Factors" and elsewhere in this Annual Report on Form 10-K. Except as may be required by law, we have no plans to update our forward-looking statements to reflect events or circumstances after the date of this report. We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made.

Item 1. Business

Overview

EXACT Sciences Corporation develops proprietary DNA-based technologies for use in the detection of certain cancers. We have selected colorectal cancer as the first application of our technologies. We license certain of our colorectal cancer screening technologies, including improvements to such technologies, on an exclusive basis in the United States and Canada through December 2010 to Laboratory Corporation of America® Holdings, or LabCorp®. LabCorp has developed and commercially offers a non-invasive stool-based DNA colorectal cancer screening service for the average-risk population, which is based on certain of our technologies. Our current focus is on commercially developing, and obtaining U.S. Food and Drug Administration, or FDA, approval for, a colorectal cancer screening product based on our stool-based DNA technologies.

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, however, are more likely to have a complete recovery and to utilize lower levels of expensive medical resources. Accordingly, the American Cancer Society, or ACS, recommends that all persons age 50 and above undergo regular colorectal cancer screening. Of the more than 89 million people in the United States for whom routine colorectal cancer screening is recommended, it is estimated that about one-half have never been screened, and it is believed that a significant portion of the balance have been inadequately screened. We believe that this large population of unscreened patients represents an opportunity to reduce the mortality and healthcare 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, such 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 including representatives of the American College of Gastroenterology, American Gastroenterological Association, American Society for Gastrointestinal Endoscopy and the American College of Physicians/Society of Internal

Table of Contents

Medicine, announced that non-invasive, stool-based DNA screening technology has been 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 above. Accordingly, LabCorp's commercially offered, non-invasive stool-based DNA colorectal cancer screening service is the first DNA-based, non-invasive colorectal cancer screening test to be available for use following the issuance of these new colorectal cancer screening guidelines of the ACS and MSTF-CRC in the United States for the average risk population.

LabCorp developed and commercially offered PreGen-Plus, its first generation non-invasive stool-based DNA colorectal cancer screening service for the average-risk population based on our Version 1 technology, from August 2003 through June 2008. In June 2008, LabCorp stopped offering PreGen-Plus and, in July 2008, LabCorp began to commercially offer ColoSure , its next generation non-invasive, stool-based DNA testing service for the detection of colorectal cancer in the average-risk population, which is also based on certain intellectual property relating to colorectal cancer screening that we license to LabCorp. LabCorp, the second largest commercial laboratory in the United States with more than 37 primary laboratories and over 1,600 patient service centers, is the exclusive licensee, in the United States and Canada, of certain of our intellectual property relating to colorectal cancer screening through December 2010, followed by a non-exclusive license for the life of the licensed patents. LabCorp currently does not offer ColoSure in Canada. LabCorp performs the ColoSure testing service in a single specialized centralized laboratory and, by the terms of the license, pays us a fifteen percent royalty based on its net revenues from sales of ColoSure. Pursuant to the terms of our license agreement with LabCorp, LabCorp has paid us $30 million in upfront license fees and milestones. In addition, we may be eligible for up to an additional $42.5 million in milestones and performance incentives under the agreement, primarily based on the achievement of significant sales thresholds. Pursuant to our amended license agreement with LabCorp, we are permitted to license the intellectual property to any third party in connection with an FDA approved product and to select third-party organizations and commercial service laboratories, for a colorectal cancer testing service, subject to certain pricing protections afforded to LabCorp. LabCorp maintains sole responsibility, at its expense, for all commercial activities including marketing, sales, and reimbursement of ColoSure under the agreement.

In addition to our Version 1 technology underlying the PreGen-Plus testing service formerly offered by LabCorp, we have also developed or licensed technologies related to a Version 2 colorectal cancer screening technology that we believe has greater sensitivity and is more cost effective than Version 1. Our Version 2 technology includes two 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, and DIA®, or long DNA. We have exclusive rights to the Vimentin technology through our license agreement with Case Western Reserve University, or Case Western, under which we are obligated to pay a royalty and certain other fees to Case Western in return for the right to use and sublicense the Vimentin technology. In a research study evaluating stool-based DNA in 82 patients with confirmed colorectal cancer and 363 colonoscopically normal individuals, our Version 2 stool-based DNA technology demonstrated sensitivity of 83 percent and specificity of 82 percent for the detection of colorectal cancer. LabCorp's ColoSure testing service currently relies solely on the Vimentin gene and does not use the DIA marker that is also included in our Version 2 technology. In July 2008, as part of our cost reduction efforts, we suspended our efforts to seek FDA approval or clearance for our Version 2 technology.

In January 2009, we completed a strategic transaction with Genzyme Corporation, or Genzyme, pursuant to which Genzyme acquired from us, for an aggregate of $18.5 million, our intellectual property assets related to the fields of prenatal and reproductive health as well as certain intellectual property outside the fields of colorectal cancer screening and stool-based DNA testing. Genzyme also purchased three million shares of our common stock, or approximately ten percent of our outstanding

Table of Contents

common stock, for an aggregate of $6.0 million. Under our agreement with Genzyme, we retained worldwide rights to our colorectal cancer screening and stool-based DNA testing intellectual property, and will receive a portion of any Genzyme sublicensing income derived from the purchased intellectual property outside the fields of prenatal and reproductive health. We and Genzyme also agreed to form a joint advisory committee to assist Genzyme in the achievement of product development goals related to the purchased intellectual property and to assist us with our product development and regulatory goals.

Following the closing of our strategic transaction with Genzyme in January 2009, we have begun resuming our efforts to develop an FDA-approved in vitro diagnostic test for stool-based DNA colorectal cancer screening. As part of our development efforts, FDA study plans, and ongoing evaluation of stool-based DNA capabilities and market needs, we are exploring the marker combinations and platform requirements necessary for optimal performance of our technology. Objectives around performance, throughput and cost are among the elements that will need to be met in the design and development of an FDA-approved or cleared commercial product based on our technology. We may determine to develop an FDA-approved product containing a Version 3 technology based on BEAMing or digital polymerase chain reaction, or digital PCR, we may use genetic markers that are different from those used currently or in the past, we may focus on increasing the performance of our existing Version 2 technology and/or we may determine that our existing Version 2 technology provides sufficient performance to enable reasonable market penetration for stool-based DNA for colorectal cancer detection. During 2008, a proof of concept study using the BEAMing technology, an advanced form of digital PCR developed by The Johns Hopkins University, in which stool and blood plasma were assessed in a head-to-head comparison for the detection of colorectal cancer, demonstrated 92 percent sensitivity for detecting colorectal cancer in stool samples. These data were published in the August 2008 issue of *Gastroenterology* in a paper entitled "*Analysis of Mutations in DNA Isolated from Plasma and Stool of Colorectal Cancer Patients*." Although we believe that this technology may have the potential to be more sensitive and specific than the current stool-based DNA colorectal cancer screening test commercially offered, Version 3 is still in the prototype stage of development.

Background

Colorectal cancer is the third most common malignant disease and the third most frequent cause of cancer-related death in the United States, with more than 148,000 new cases and more than 49,000 deaths estimated in 2008. We believe that many colorectal cancer deaths occur because people are not screened for colorectal cancer at all, or they use ineffective screening methods that either fail to detect the cancer or detect it at a later stage, when the five-year survival rate falls below 50%. Moreover, the number of people who die annually from the disease has remained materially unchanged over the last 20 years, despite the availability of multiple colorectal cancer screening options, all of which we believe fail to effectively meet the collective needs of patients, doctors and payors.

As reported in the February 3, 2005 issue of the *New England Journal of Medicine*, the tumor-node-metastasis, or TNM, system of the American Joint Committee on Cancer is now the most

Table of Contents

commonly used system for staging colorectal cancer and serves as a benchmark for predicting the likelihood of five-year survival. This staging system is described in the table below.

TNM Staging System for Colorectal Cancer*

Stage	TNM Classification	Five-Year Survival %
I	T1-2, N0, M0	>90
IIA	T3, N0, M0	60 - 85
IIB	T4, N0, M0	
IIIA	T1-2, N1, M0	25 - 65
IIIB	T3-4, N1, M0	
IIIC	T (any), N2, M0	
IV	T (any), N (any), M1	5 - 7

Primary Tumor (T)
TX: Primary tumor cannot be assessed
Tis: Carcinoma in situ
T1: Tumor invades submucosa
T2: Tumor invades muscularis propria
T3: Tumor penetrates muscularis propria and invades subserosa
T4: Tumor directly invades other organs or structures or perforates visceral peritoneum

Nodal status (N)
NX: Regional lymph nodes cannot be assessed
N0: No metastases in regional lymph nodes
N1: Metastases in one to three regional lymph nodes
N2: Metastases in four or more regional lymph nodes

Distant Metastases (M)
MX: Presence or absence of distant metastases cannot be determined
M0: No distant metastases detected
M1: Distant metastases detected

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* Source: Greene FL, Balch CM, Fleming ID, et al., eds. AJCC cancer staging handbook, 6th ed. New York: Springer, 2002.

Detection of pre-cancerous adenomas and colorectal cancer in its earliest stages increases the likelihood of survival and reduces the significant cost associated with treating late-stage colorectal cancer. Accordingly, the ACS recommends that the more than 89 million Americans age 50 and above undergo regular colorectal cancer screening with the methods endorsed by the ACS.

Our Solution

We believe that stool-based DNA detection in the general population offers an opportunity to increase screening rates and decrease mortality and healthcare costs from colorectal cancer. We believe that our proprietary methods and technologies have several advantages over other screening options that may ultimately lead to decreased mortality associated with colorectal cancer, including:

Performance. We have conducted several clinical studies supporting the performance of stool-based DNA detection for colorectal cancer, including a 5,500 patient multi-center study, the results of which were published in the December 23, 2004 issue of the *New England Journal of Medicine*.

Table of Contents

Based on this study data, our then-prototype stool-based DNA detection technology demonstrated sensitivity four times greater than the leading FOBT, Hemoccult II®, which we believe is the most common non-invasive screening method for colorectal cancer, and was more than four times as effective as Hemoccult II in this study in detecting cancer at its early stages, when survival rates approach 90%. The ColoSure stool-based DNA testing service developed by LabCorp and commercially offered today is different than the test that was used in the multi-center study, and, based on the published literature regarding the performance of the Vimentin gene, we believe that LabCorp's ColoSure test may offer higher assay sensitivity than that seen in our multi-center study. Also, our Version 2 stool-based DNA technology demonstrated sensitivity of 83 percent and specificity of 82 percent for the detection of colorectal cancer in a research study evaluating stool-based DNA in 82 patients with confirmed colorectal cancer and 363 colonoscopically normal individuals. In addition, in a proof of concept study published in 2008 in *Gastroenterology*, which will need to be validated in a larger clinical study of average risk, asymptomatic patients as a part of any development of a commercial test, the prototype BEAMing technology showed sensitivity of 92% in detecting colorectal cancer in stool samples.

Simplicity and Convenience. 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. 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. Unlike current invasive screening methods, stool-based DNA screening for colorectal cancer requires no pre-examination bowel cleansing preparation, no invasive procedures or anesthesia, and a sample can be collected in the privacy of one's home. The sample is then shipped to LabCorp for testing, with the results then sent to a patient's physician.

Compliance. Despite having been available as a screening modality for several years, colonoscopy has not been widely embraced by patients. A 2006 post-market survey of patients whom have used PreGen-Plus, LabCorp's prior testing service, indicated that more than half of the people surveyed who were screened with stool-based DNA technology had never been screened for colorectal cancer before. We believe that this indicates that stool-based DNA screening can lead to greater patient screening compliance.

Our stool-based DNA screening technology 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, stool-based DNA technology looks for specific mutations and other abnormalities in that DNA known to be associated with colorectal cancer. A "positive" result from stool-based DNA detection does not necessarily mean that a patient has colorectal cancer. A "positive" result means that one or more of the genetic or epigenetic markers that can be associated with colorectal cancer has been identified. Under such circumstances, the clinical protocol is for the patient to then obtain a colonoscopy for confirmation. Moreover, a "negative" result from stool-based DNA screening does not mean that a person is free of colorectal cancer. Stool-based DNA detection, like virtually all screening tests (including mammography, Prostate Specific Antigen, or PSA, and Papanicolaou smear, or Pap smear) also reports false negatives. See "Clinical Studies" below for specific information on stool-based DNA technology.

The Testing Process

Diagnostic tests typically require sample collection and preparation procedures as well as detection methods. The stool-based DNA testing process involves proprietary sample preparation, DNA isolation, and analytical techniques that apply genomics discoveries to the early detection of colorectal cancer.

Table of Contents

Specimen Collection and Transportation. Certain of our patents relating to stool-based DNA screening for colorectal cancer are based on collecting a single whole stool sample in an easy, non-invasive manner. Utilizing a specially designed specimen container, samples can be collected in the privacy of an individual's home and then sent directly to the laboratory for processing using one of the many national couriers.

Representative Sampling. We have invented proprietary stool homogenization methods designed to ensure that the stool sample that is processed at the laboratory will contain uniformly distributed DNA throughout the portion of the sample being tested which, in turn, helps to ensure that the DNA in the stool sample is representative of the entire stool and colon.

DNA Extraction, Purification and Amplification. The isolation and amplification of human DNA found in stool is technically challenging because over 99% of DNA in stool is not human DNA, but is actually DNA from bacteria normally found in the colon. In addition, there are substances in stool that make the isolation and amplification of human DNA a difficult task. Proprietary methods are used to promote the reproducible isolation and amplification of the human DNA found in stool.

Cancer Detection Methods. Many of the specialized methods used in our Version 2 technology for detecting and identifying genomic markers associated with colorectal cancer can be performed on existing instruments commonly available in clinical laboratories conducting molecular testing. We expect that other methods that may be used for an FDA-approved colorectal cancer screening product, including digital based approaches and BEAMing, may require specialized tools and equipment in the laboratory for testing.

Commercial Focus

Our goal is to become a market leader in the development and licensing of technologies for the early detection of colorectal cancer. To accomplish this goal, we have been pursuing a strategy with respect to our technologies that includes the following components:

Continue the development of our stool-based DNA cancer screening technology. Following our transaction with Genzyme in January 2009, we have begun resuming our efforts to develop an FDA-approved in vitro diagnostic test for stool-based DNA colorectal cancer screening. As part of our product development efforts and ongoing evaluation of stool-based DNA capabilities and market needs, 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. We also continue to explore the use of our proprietary technology in other areas of cancer detection.

Obtain regulatory clearance for a stool-based DNA cancer screening product. Although we continue to assess the development of colorectal cancer screening technologies in our field, including the BEAMing technology being developed by Johns Hopkins University, FDA clearance or approval will be key to our ability to successfully commercialize any stool-based DNA cancer screening product for sale to commercial laboratories, as well as to achieve broad market acceptance of stool-based DNA cancer screening in general. Accordingly, we intend to conduct clinical studies and other activities for our stool-based DNA screening technology that we believe will facilitate our pursuit of such FDA clearance or approval. In April 2008, we submitted a pre-Investigational Device Exemption, or pre-IDE, request to the FDA regarding our Version 2 stool-based DNA technology for the detection of colorectal cancer, and received feedback from the FDA regarding the likely appropriate regulatory pathway, including the parameters for a clinical validation study. Although the information we obtained from the FDA regarding our Version 2 technology may not be directly applicable to our pursuit of FDA clearance or approval of a future colorectal cancer screening product, we intend to leverage, to the extent possible,

Table of Contents

our prior dialogue with the FDA regarding product configuration, regulatory pathway, and study parameters for stool-based DNA testing.

Obtain acceptance of stool-based DNA screening for reimbursement by Medicare and other third-party payors. We believe strong reimbursement from payors at levels generating sufficient gross margin will be necessary to material revenue growth for stool-based DNA screening. We believe that obtaining a positive coverage decision from the Centers for Medicare and Medicaid Services, or CMS, will be a necessary element to achieving commercial success for our technologies. Another critical component will be our ability to obtain adequate reimbursement from commercial third-party payors for our stool-based DNA screening technology. In connection with the April 28, 2008 decision by CMS not to provide coverage with respect to our application for a National Coverage Determination, or NCD, CMS indicated that it would reconsider an application for coverage following FDA clearance or approval of our stool-based DNA screening technology for colorectal cancer. Accordingly, we intend to submit a NCD application for reconsideration following any such FDA clearance or approval and our accumulation of other information and evidence that may be necessary for such submission. We also intend to leverage the inclusion of stool-based DNA screening for colorectal cancer in recent state mandates and the positive coverage decision by CIGNA in the second half of 2008 to help increase coverage for stool-based DNA screening for colorectal cancer by private insurance carriers. Lastly, our reimbursement strategy also consists of, in part, an effort to capitalize on LabCorp's ability to educate large managed care organizations and self-insured employers about the clinical benefits and cost-effectiveness of using stool-based DNA screening for colorectal cancer.

Leverage LabCorp's large sales force. In August 2007, as part of an amendment to our license agreement with LabCorp, we eliminated our sales and marketing functions and transferred to LabCorp responsibility for all sales and marketing activities related to PreGen-Plus, and LabCorp's subsequent testing service, ColoSure. LabCorp is the second largest commercial laboratory in the country and processes hundreds of thousands of patient specimens daily through its system of more than 37 primary laboratories and over 1,600 patient service centers across the United States. LabCorp's large sales force is devoted to selling a wide range of diagnostic tests to physicians across all specialties. In addition to developing and commercializing an FDA-approved in vitro diagnostic test for colorectal cancer screening, our future success will depend on LabCorp's relationships and infrastructure to build market demand for ColoSure and future versions of our stool-based DNA technology.

Establish sales and marketing pathways for an FDA-approved product. Following any FDA approval for a stool-based DNA colorectal cancer screening product, we expect to explore avenues for the sales and marketing of such product to commercial laboratories or other facilities interested in offering a colorectal cancer testing service. Although our exclusive license with LabCorp allows LabCorp to purchase any such FDA-approved product on pricing terms no greater than what we charge others, we retain the right to commercialize an FDA-approved in vitro diagnostic product for colorectal cancer screening to entities other than LabCorp. We may conduct such activities directly, or we may seek to enter into one or more agreements with third parties for the marketing and distribution of such an FDA approved or cleared product.

We believe that the success of each of the foregoing components of our commercial strategy are critical to any future broad acceptance of our technologies. The achievement of certain of these components will also, at least in part, be dependent upon the successful accomplishment of others. For instance, FDA approval or clearance will most likely be one of the key prerequisites for any future CMS approval of reimbursement for our technologies which we believe will, in turn, be among the elements necessary for any broad commercial acceptance of our technologies. Similarly, despite the inclusion of our technologies in the colorectal cancer screening guidelines of the ACS and MSTF-CRC, and state coverage mandates discussed above, private third party payors may require FDA clearance or approval of our technologies prior to issuing formal policy approval for any version of our technology,

Table of Contents

and, absent any such formal policy approval and strong reimbursement, it is unlikely any version of our technology will be broadly used by a payor's members.

Clinical Studies

Stool-based DNA testing has been the subject of extensive research and clinical studies. In numerous studies to date, the performance of our stool-based DNA technology has been examined in thousands stool samples. In addition to several smaller clinical studies designed to measure the sensitivity and specificity of stool-based DNA testing in detecting colorectal cancer, the performance of our bead-based Version 1 stool-based DNA testing technology was compared to the then most widely-used FOBT in a large multi-center study that enrolled approximately 5,500 average-risk, asymptomatic patients from more than 80 sites across the United States. The study was designed to determine whether stool-based DNA testing was clinically superior to Hemoccult II, an FOBT widely used for non-invasive colorectal cancer screening. The primary endpoint of this study was achieved with statistical significance, with a p-value of less than 0.003. Results from the study, which were published in the *New England Journal of Medicine* in December 2004, indicated that our bead-based Version 1 technology was four times more sensitive than Hemoccult II in detecting colorectal cancer (52% for Version 1 versus 13% for Hemoccult II), and more than four times more sensitive in detecting colorectal cancer in its earliest, most curable stages (57% for Version 1 versus 13% for Hemoccult II). There was no difference in specificity between the bead-based Version 1 and this FOBT, with both tests demonstrating a specificity of approximately 95%.

In addition, a study evaluating Version 2 of our stool-based DNA colorectal screening technology in 82 patients with colorectal cancer and 363 colonoscopically normal individuals demonstrated sensitivity of 83 percent and specificity of 82 percent for the detection of colorectal cancer. These study results were statistically consistent with the interim study results on Version 2 published in the January 2007 issue of the American Gastroenterological Association's journal, *Clinical Gastroenterology and Hepatology*, which included a sample subset of 40 cancer patients and 122 normal individuals and demonstrated sensitivity of 88 percent and specificity of 82 percent. Although we are encouraged by the increase in sensitivity shown for Version 2 in this study when compared to previous published studies for stool-based DNA screening, the specificity results in the Version 2 study were closer to 80% whereas prior studies have Version 1 have generally shown specificity above 90%. This performance metric may not be deemed clinically or commercially acceptable. Moreover, the blinded study of Version 2 involved the analysis of 82 post-colonoscopy collected cancer samples from individuals whose colonoscopy results were positive for colorectal cancer. By contrast, our multi-center study in 2004 was comprised of 31 cancer samples collected prior to colonoscopy from an asymptomatic population.

In 2008, a proof of concept study of our Version 3 technology using an approach called BEAMing, an advanced form of digital PCR, in which stool and blood plasma were assessed in a head-to-head comparison for the detection of colorectal cancer, demonstrated 92 percent sensitivity for detecting colorectal cancer in stool samples. These data were published in the August 2008 issue of *Gastroenterology* in a paper entitled "*Analysis of Mutations in DNA Isolated from Plasma and Stool of Colorectal Cancer Patients*." Although we believe that this technology may have the potential to be more sensitive and specific than our Version 2 stool-based DNA colorectal cancer screening test, our Version 3 technology is currently in the prototype stage of development. Accordingly, the results of the proof of concept study will need to be validated in a larger clinical study of average risk, asymptomatic patients as a part of the development of Version 3, the results of which may ultimately be worse than the results achieved in the proof of concept study.

Table of Contents

Sensitivity and specificity results from our clinical studies that have been published are summarized in the table below. The results of these studies may not be directly comparable as these studies were conducted across a variety of patient populations and clinical settings and employed varying sample collection protocols. Moreover, the clinical studies disclosed below do not include any non-published studies regarding stool-based DNA testing, the results of which may differ significantly from those set forth below.

Technology & Study Name	Year Completed/Published	Number of Cancer Samples Analyzed	Number of Genetic Markers	DNA Capture Technology	DNA Stabilization Buffer Used(1)	Sensitivity	Specificity(2)
Version 1 Studies							
Mayo Clinic I Pilot Study	1999/2000	22	17	Bead-based	No	91%	93%
University of Nebraska	2002/2004	16	22	Bead-based	No	69%	(2)
Kaiser Clinic	2002/2003	52	23	Bead-based	No	64%	98%
Boston	2002/2006	68	23	Bead-based	No	63%	(2)
Multi-Center Study	2003/2004	31	23	Bead-based	No	52%(3)	94%
Effipure Technology Validation	2004/2004	86	23	Effipure(4)	No	70%(5)	96%
Mayo NCI (Stool DNA Test 1)	2004/2008	12	23	Bead Based	No	25%(3),(7)	96%
Mayo NCI (Stool DNA Test-2)	2004/2008	19	>33(6)	Effipure(4)	No	58%(7)	84%
Mount Sinai School of Medicine	2005/2007	40	23	Effipure(4)	Yes	73%	89%
Version 2 Studies							
Mount Sinai School of Medicine	2005/2007	40	2	Effipure(4)	Yes	88%	82%
Mount Sinai School of Medicine	2006/2008	82	2	Effipure(4)	Yes	83%	82%
BEAMing Study							
Johns Hopkins School of Medicine	2007/2008	25	33	Bead-based	Yes	92%	(2)

(1) DNA stabilization buffer is used to protect against DNA degradation during sample transport.

(2) Specificity can only be derived in studies that include a certain number of individuals who reported as colorectal cancer-free following colonoscopy. The studies in the table without a specificity figure did not contain the requisite number of disease-free individuals.

(3) Based on published studies, including the Mount Sinai School of Medicine studies, we believe that the sample collection protocols used in this study resulted in DNA degradation that, in turn, resulted in lower sensitivity of our technology than that demonstrated in our prior published studies.

(4) Effipure is a technological improvement that had been utilized in LabCorp's prior commercial testing service, PreGen-Plus, designed to increase human DNA yield. Effipure is not used in LabCorp's current ColoSure testing service.

(5) In November of 2004, we published a study in the *Journal of Molecular Diagnostics* that showed a 5.4 fold increase in the amount of DNA that could be captured using the Effipure technology rather than the older, bead-based technology. The sensitivity result from this study is not a conclusion regarding the sensitivity of LabCorp's prior commercial test, PreGen-Plus.

(6) Included a scanning technique that looked for many mutations simultaneously along a portion of the APC gene.

(7) In October 2001, Mayo Clinic initiated a study of the bead-based version of our technology that was intended to include approximately 4,000 patients at average risk for developing colorectal cancer. This three-year study was designed to compare the results of our original technology with those of Hemoccult II. The Mayo study was principally powered for the detection of "screen relevant neoplasia" (an end-point that includes high grade dysplasia, invasive cancer, and adenomas ≥1cm) rather than invasive cancers as a stand alone category. After this study commenced, Hemoccult Sensa®, another brand of FOBT, was added to the study. Subsequently, we and the Mayo Clinic sought to include the gel-based Effipure DNA isolation technology in the study to improve DNA yield, rather than relying solely on our original bead-based technology. In connection with this technology transition, Mayo Clinic reviewed preliminary data from the study which showed that, while our bead-based technology was nearly twice as sensitive as Hemoccult II and as sensitive as Hemoccult Sensa in detecting screen-relevant neoplasia, Hemoccult II and Hemoccult Sensa appeared to

have outperformed, at a preliminary stage, our bead-based technology in the detection of cancer among the thirteen cancer samples collected in the study. As the study proceeded beyond this preliminary stage, however, Mayo Clinic evaluated additional screen relevant neoplasms and provided the following updated principal findings on the larger data set: (1) stool-based DNA technology detected three times more screen relevant neoplasia than Hemoccult II and two times more screen relevant neoplasia than Hemoccult Sensa, but at a much lower specificity; and (2) the addition of a stabilization buffer to stool samples at the time of collection would most likely have improved lesion detection by long DNA and possibly other analytes as well. We believe that the sample collection protocols used for the vast majority of samples in this study, like the sample collection protocols as those used in our multi-center study, resulted in DNA degradation that, in turn, resulted in lower sensitivity of our

Table of Contents

technology. In addition, although our older technology detected a small but significant percentage of advanced adenomas, this older version of our technology was designed only to detect cancer, not adenomas, both of which are included in the definition of screen-relevant neoplasia. Our Version 2 technology includes the addition of DNA stabilization buffer to the stool at the time of collection.

Research and Development

We currently have no research and development employees, and any advances in research and development are currently derived from our relationships with third parties. Following the closing of our strategic transaction with Genzyme in January 2009, we have begun resuming our efforts to develop an FDA-approved in vitro diagnostic test for stool-based DNA colorectal cancer screening. As part of our product development efforts and ongoing evaluation of stool-based DNA capabilities and market needs, 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. We may determine to develop a product containing a Version 3 technology that includes BEAMing or digital PCR, we may use genetic markers that are different from those used currently or in the past, we may focus on increasing the performance of our existing Version 2 technology and/or we may determine that our existing Version 2 technology provides sufficient performance to enable reasonable market penetration for stool-based DNA for colorectal cancer detection. If we determine to include a BEAMing or digital based approach in our Version 3 technology, which is currently in the prototype stage or if we determine to pursue a platform or marker configuration materially different from our Version 1 or Version 2 technologies, we will need to conduct extensive additional development related to Version 3, the feasibility of which, for a commercial version, remains uncertain. Accordingly, our goals of improving the performance of our technologies and developing an FDA-approved commercial stool-based DNA screening product for colorectal cancer will require that we either hire research and development personnel and acquire lab space suitable for such development, or outsource such development to third party partners or collaborators, or some combination of both. Research and development activities today, from which we derive benefit, are conducted through outside relationships primarily with Johns Hopkins University. Such research and development efforts would be primarily focused on supporting the development of our colorectal cancer screening technology and the related regulatory submissions required by the FDA for clearance or approval of our technologies. Obtaining FDA clearance or approval of our technologies, and the future commercialization of any version of our technology will likely require additional lengthy studies and, accordingly, the timing and costs of any FDA clearances or approvals and commercialization of our technologies is uncertain. Additionally, the costs of additional clinical or other studies that may be required in connection with FDA approval or clearance of our technology are likely to be material. Moreover, transferring any version of our technology from the laboratory to the commercial setting will also require the negotiation and licensing of necessary third-party intellectual property, as well as the likelihood of additional technical and clinical validations of the technology to demonstrate, among other objectives, the reliability and reproducibility of prior study results around stool-based DNA testing. Our research and development expenses were $2.0 million, $4.9 million and $6.7 million for the years ended December 31, 2008, 2007 and 2006, respectively.

Sales and Marketing

All marketing and promotion of ColoSure is the responsibility of LabCorp. In August 2007, in connection with an amendment to our license agreement with LabCorp, we eliminated our sales and marketing functions and currently employ no sales or marketing personnel. We do not sell or market LabCorp's ColoSure testing service. We are, therefore, materially dependent on LabCorp's sales and marketing efforts to increase our royalty revenue on any sales relating to ColoSure. LabCorp's large sales force calls on primary care physicians and sells numerous products. Our efforts with respect to

Table of Contents

building awareness of stool-based DNA screening for colorectal cancer generally are focused on the following key constituents:

Thought Leaders. Gastroenterologists are highly vocal in advocating colorectal cancer screening, and perform the vast majority of the reference standard diagnostic procedure, colonoscopy. They are also key to establishing new tests as standards of care for inclusion in screening guidelines.

Third-Party Payors. Another important focus includes third party payors, including Medicare, major national and regional managed care organizations, technology assessment groups, insurance carriers and self-insured employer groups. The goals with these target groups are to educate these groups regarding the benefits of stool-based DNA testing to gain formal policy-level reimbursement for stool-based DNA testing which will be important to the long-term commercial success of this new category of colorectal cancer screening.

Advocacy Development. We seek to work with influential advocacy groups to increase their awareness of stool-based DNA testing and its potential long-term value in clinical practice toward the goal of reducing mortality from colorectal cancer. To the extent possible based on our existing resources, we intend to continue to build on growing public awareness of colorectal cancer through our activities with these advocacy groups and, where appropriate, certain media outlets.

The FDA may not approve of certain of our educational initiatives with respect to stool-based DNA screening, which could restrict or negatively impact our ability to build awareness around stool-based DNA testing.

In addition, following any FDA approval for a stool-based DNA colorectal cancer screening product, we expect to explore avenues for the sales and marketing of such product to commercial laboratories or other facilities interested in offering a colorectal cancer testing service. Although our exclusive license with LabCorp allows LabCorp to purchase any such FDA-approved product on pricing terms no greater than that which we may charge other third parties, we retain the right to commercialize an FDA-approved in vitro diagnostic product for colorectal cancer screening to third parties other than LabCorp. We may conduct such activities directly, or we may seek to enter into one or more agreements with third parties for the marketing and distribution of such an FDA-approved or cleared product.

Reimbursement

From the date of commercial launch through June 2008, when LabCorp stopped commercially offering PreGen-Plus, LabCorp had accessioned approximately 14,900 PreGen-Plus samples, including approximately 500 in the six months ended June 30, 2008 and approximately 1,800, 3,700 and 4,000 samples during the years ended December 31, 2007, 2006 and 2005, respectively. During the time period when PreGen-Plus was marketed by LabCorp, LabCorp billed insurers and received payment from numerous third-party payors, including more than 350 health plans. None of these third-party payors ever issued formal policy approval for PreGen-Plus.

We are continuing to work to obtain national coverage for stool-based DNA colorectal cancer screening technologies from Medicare and, primarily through LabCorp's efforts, positive coverage decisions from major national and regional managed care organizations and insurance carriers, and self-insured employer groups. Until such time as we obtain FDA approval for a colorectal cancer screening product, our success will depend primarily on LabCorp's ability to obtain positive payor coverage, and strong reimbursement, for stool-based DNA screening. We seek to complement these efforts through targeted, focused initiatives, educating third parties about stool-based DNA screening in general, that benefit from direct relationships maintained by one or more of our employees.

Table of Contents

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 stool-based DNA 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 stool-based DNA screening among its nationwide covered benefits. While we view inclusion of stool-based DNA 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 CMS for our stool-based DNA screening technology will be a necessary element in achieving any material commercial success. We do not believe that current reimbursement levels from insurers to LabCorp are at levels sufficient to result in material revenue to us.

An important component of our reimbursement strategy is to obtain an NCD from CMS that includes stool-based DNA screening technologies for colorectal cancer in the Medicare program. In December 2004, we submitted our application for national coverage of our Version 1 technology. Our Version 1 technology patents and the DNA capture component, Effipure, were relied on for LabCorp's PreGen-Plus testing service. Following acceptance of our application by CMS, we received a warning letter from the FDA in October 2007 that indicated that PreGen-Plus required premarket clearance. Based in part on the FDA's determination as set forth in the warning letter, CMS issued a proposed decision memorandum regarding our application on January 30, 2008. The final decision memorandum released on April 28, 2008, stated CMS' decision to not provide coverage for our Version 1 technology, but indicated that CMS would reconsider our application for coverage following FDA clearance or approval of our DNA screening technology. There can be no assurance that any version of our technology will be cleared or approved by the FDA. Even if cleared or approved by the FDA, there can be no assurance that CMS will reach a positive national coverage decision for any version of our technologies. Moreover, even if CMS issues a positive coverage decision for any version of our stool-based DNA screening technology, such coverage may not provide adequate levels of reimbursement.

The United States Public Services Task Force, or USPSTF, a U.S. government-funded organization that reviews available peer-reviewed published studies in order to make an assessment of the benefits and risks of performing certain medical procedures, completed its 6-year update of its colorectal cancer screening guidelines in October 2008. At that time, the USPSTF, which can influence coverage decisions by payors, including CMS, determined that the evidence is insufficient (USPSTF Grade: "I" Statement) to assess the benefits and harms of both stool-based DNA and CT colonography, or virtual colonoscopy, as screening modalities for colorectal cancer. No other score was given by the USPSTF to these two new tests added to the ACS and MSTF-CRC colorectal cancer screening guidelines. Many payors base their coverage decisions around colorectal cancer screening on the recommendations of the USPSTF. Accordingly, our future plans may include working to accumulate and publish in peer-reviewed journals additional performance data, and patient compliance and preference data, that will be useful to the USPSTF, as well as to CMS, in conjunction with our request for reconsideration of our NCD application. We could incur significant time and costs to accumulate such additional data, which still may not yield positive results with the USPSTF or CMS. Additionally, despite the fact that our technology is included in the colorectal cancer screening guidelines of the ACS and MSTF-CRC, the FDA warning letter may have a similar impact on private third party payors in that, like CMS, those payors may defer reimbursement policy decisions with respect to our technology until such time, if ever, as our technologies are cleared by the FDA. Finally, certain members of the MSTF-CRC may fail to separately support the position of the MSTF-CRC, which could have a detrimental effect on our commercial and reimbursement efforts related to stool-based DNA screening.

Table of Contents

Government Regulation

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

U.S. Food and Drug Administration

Laboratories that make and perform certain types of laboratory-developed tests, currently known in the industry as LDT's, or historically known as homebrews, have generally *not* been required to submit premarket submissions to the FDA, including performance data on the test, for FDA review and approval or clearance. Instead, the FDA exercised enforcement discretion, which allowed laboratories to commercially market their LDTs without obtaining FDA approval or clearance, although such laboratories were still required to comply with the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and its implementing regulations. We had believed, since LabCorp's commercial launch of PreGen-Plus in 2003, that PreGen-Plus met the requirements to qualify for FDA enforcement discretion as an LDT and that in-house testing utilizing certain of our technologies, and using any analyte specific reagent that we developed, did not require FDA approval or clearance.

From August 2003 through June 2008 through, LabCorp offered the PreGen-Plus testing service as an LDT. On January 13, 2006, the FDA sent correspondence to us and to LabCorp with respect to the PreGen-Plus testing service, as well as the Effipure DNA-capture devices used in conjunction with the PreGen-Plus tests, which indicated that PreGen-Plus is subject to FDA regulation as a medical device. The FDA also indicated that the device cannot be commercially distributed without an appropriate premarket determination from the FDA. Pursuant to our and LabCorp's subsequent discussions with the FDA to clarify the regulatory status of PreGen-Plus, we and LabCorp agreed, among other things, to revise promotional activities with respect to LabCorp's PreGen-Plus testing service. In addition, LabCorp offered to eliminate its use of Effipure in processing PreGen-Plus tests. Based on the actions outlined above, LabCorp continued to market and process the PreGen-Plus test as a laboratory developed test service until June 2008.

On October 11, 2007, the FDA sent the warning letter to us with respect to the PreGen-Plus testing service, indicating that PreGen-Plus was a Class III medical device and that it could not be commercially distributed without an appropriate premarket approval or clearance from the FDA. Effective June 1, 2008, LabCorp stopped offering PreGen-Plus and indicated that it had discontinued its use of Effipure.

In July 2008, LabCorp began offering a new single marker in-house laboratory developed test called ColoSure, which is based on certain of our intellectual property and that does not use components supplied by us. LabCorp has not obtained FDA clearance or approval, but rather, is marketing ColoSure as an LDT. There can be no assurance that the FDA will not take a similar position with respect to ColoSure as it did for PreGen-Plus, and conclude that ColoSure is a medical device requiring premarket clearance or approval. Similarly, there can be no assurance that LabCorp's offering of ColoSure falls within the category of LDT's over which the FDA has historically exercised enforcement discretion. If the FDA deems ColoSure a medical device that requires FDA clearance or approval prior to marketing, LabCorp may be required to discontinue offering ColoSure and, under such circumstances, our business would likely be materially adversely affected.

In April 2008, we began regulatory efforts toward FDA clearance for Version 2 of our technology, a two-marker version that we believe offers greater sensitivity and can be more cost-effective than our earlier, 23 marker Version 1 technology. In this regard, in April 2008, we submitted a pre-IDE request

Table of Contents

to the FDA for our Version 2 technology. The objective of the pre-IDE process was to seek concurrence from the FDA that a 510(k) submission followed by a de novo classification request is an appropriate regulatory path for our Version 2 technology and that the clinical and other studies proposed in our Version 2 pre-IDE submission would likely support such a de novo regulatory path. In July 2008, we received feedback from the FDA as to the clinical performance characteristics and the minimum number of average-risk colorectal cancer samples that likely would be required for validation of our two-marker Version 2 stool-based DNA technology for colorectal cancer screening. In addition, based on our discussions with the FDA, we believe that the de novo pathway would be the appropriate regulatory path for our Version 2 technology. FDA's feedback in response to a pre-IDE as to the pathway to market and data requirements is not legally binding on the agency, and they are free to alter their position at a later time.

Following the consummation of our strategic transaction with Genzyme in January 2009, we have begun resuming our efforts to develop an FDA-approved in vitro diagnostic test for stool-based DNA colorectal cancer screening. As part of our product development efforts and ongoing evaluation of stool-based DNA capabilities and market needs, 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. We may seek to leverage our progress and discussions with the FDA around Version 2 of our technology to assist in determining the likely regulatory path forward for our testing product. The FDA may ultimately determine that a premarket approval application, or PMA, is the appropriate path to market with respect to a testing product containing our stool-based DNA technology instead of a *de novo* pathway. In addition, we will need to determine the appropriate number of colorectal cancer samples from patients that would be required by the FDA in support of any regulatory application for clearance or approval a testing product. We believe that the studies required in connection with any approval or clearance of our technology, regardless of whether the regulatory pathway is de novo classification or a PMA, will be material in cost and time-intensive. There can be no assurance that FDA will ultimately approve any *de novo* classification request or approve any PMA submitted by us in a timely manner or at all.

Other Regulations

We and our strategic partner, LabCorp, 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 or LabCorp 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 ColoSure and otherwise cause us to incur significant expense.

In addition, the specimen transport and storage containers that are used in connection with the ColoSure test 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 the ColoSure 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

Table of Contents

cleared or approved device, the FDA will seek to include the container in the premarket clearance or approval requirement as part of the stool-based DNA test system.

Intellectual Property

To protect our proprietary technologies, we rely on a combination of patent, trademark, and copyright protection, and other contractual restrictions to protect our proprietary technologies, as well as confidentiality agreements with employees, consultants, and third parties.

We have pursued a patent strategy designed to maximize our patent position with respect to third parties. Generally, we have filed patents and patent applications that cover the methods we have designed to detect colorectal cancer as well as other cancers. We have also filed patent applications covering the preparation of stool samples and the extraction of DNA from heterogeneous stool samples. As part of our strategy, we seek patent coverage in the United States and in foreign countries on aspects of our technologies that we believe will be significant to our market strategy or that we believe provide barriers to entry for our competition. We believe that the United States and western Europe represent the most realistic markets for stool-based DNA testing.

Our success depends to a significant degree upon our ability to protect our technologies through patent coverage. As of December 31, 2008, we had 39 patents issued and 17 pending patent applications in the United States and, in foreign jurisdictions, 76 patents issued and 32 pending patent applications. On January 27, 2009, we entered into a transaction with Genzyme Corporation with respect to our intellectual property rights. As part of this transaction, Genzyme Corporation purchased assets including 25 patents issued and 9 pending patent applications in the United States, and 33 patents issued and 15 pending patent applications in foreign jurisdictions. We received an exclusive license back from Genzyme Corporation to each of these issued patents and pending patent applications in the fields of colorectal cancer screening and stool-based detection of any disease or condition. Following the Genzyme transaction, and as of January 27, 2009, we own 14 issued patents and 8 pending applications in the United States, and 43 issued patents and 17 pending patent applications in foreign jurisdictions. Genzyme Corporation has an exclusive license to each of these patents in the field of reproductive and prenatal health, and a non-exclusive license in all fields other than colorectal cancer detection and stool-based detection of diseases. See "Genzyme Transaction" below.

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. We have filed terminal disclaimers in certain later-filed patents, which means that such later-filed patents will expire earlier than the twentieth anniversary of their respective priority filing dates.

We and a third-party institution, Mayo Foundation for Medical Education and Research, have filed a joint patent application under the Patent Cooperation Treaty that will be co-owned by us and the third-party institution relating to the use of various DNA markers, including the DNA Integrity Assay, to detect non-colorectal cancers in stool, including, for example, cancers of the lung, pancreas, esophagus, stomach, small intestine, bile duct, naso-pharyngeal, liver and gall bladder. This patent application does not relate to the detection of colorectal cancer and national rights are being pursued in Japan, Europe and Canada, a United States patent has issued, and a United States continuation patent application is pending.

We license on an exclusive basis, in the field of stool-based colorectal cancer screening, from Matrix Technologies Corporation, d/b/a Apogent Discoveries, certain patents owned by Apogent relating to its Acrydite technologies, which we have sublicensed to LabCorp. The rights provided under this license provided LabCorp with the ability to manufacture and use the Acrydite technology in the PreGen-Plus test, which is no longer on the market. The Acrydite technology is useful in connection with the proprietary electrophoretic DNA gel capture technology used in the isolation of

Table of Contents

nucleic acids and the diagnosis of disease. We no longer manufacture, supervise the manufacture, or ship any components used in connection with the Acrydite or Effipure technologies.

We license on an exclusive basis from Case Western Reserve University certain patents owned by Case Western Reserve University that are related to genetic markers for detecting methylation DNA in the field of detecting colorectal cancer and tumors in stool-based assays. The license provides us with intellectual property rights covering the use of Vimentin, as in our Version 2 technology. We believe that this license will allow us to develop and commercialize novel detection technologies incorporating detection of Vimentin gene methylation and/or HLTF (helicase-like transcription factor) gene methylation to enhance stool-based DNA screening technologies.

We license on a non-exclusive basis from Beckman Coulter certain patents owned by Beckman Coulter that relate to its Single Based Extension, or SBE, technology. The license provided us and our sublicensee, LabCorp, with the ability to use SBE in the PreGen-Plus test, which is no longer on the market.

We license out, on a non-exclusive basis, rights to our DNA stabilization, isolation and extraction technology to OncoMethylome Sciences for commercializing stool-based colorectal cancer screening tests in Europe that utilize OncoMethylome's methylation detection technology (Methylation-Specific PCR, or MSP). In exchange, OncoMethylome has agreed to pay royalties to us based on sales. Separately, we entered into a supply agreement with OncoMethylome in which OncoMethylome will sell reagents to us for use in stool-based colorectal screening services that EXACT may provide in North America. The reagents will enable us to detect methylation at certain DNA markers using MSP technology. In addition, under the terms of this agreement, OncoMethylome also agreed to sell reagents to our commercial partners, subject to their negotiation with OncoMethylome of certain financial terms and other elements.

We also license out, on a non-exclusive basis, our proprietary DIA®, or long-DNA, technology and related know-how to NorDiag ASA for commercializing colorectal cancer screening tests in Europe, Japan and Australia. The collaboration and license also includes the right to develop an in vitro diagnostic test kit as well for these markets.

LabCorp also maintains additional third-party technology license and supply agreements that are necessary for their ColoSure testing service.

Genzyme Transaction

On January 27, 2009, we entered into a strategic transaction with Genzyme Corporation, which included a collaboration, license and purchase agreement with Genzyme, an amended and restated license agreement with Genzyme, and an assignment, sublicense, consent and eighth amendment to the license agreement with Genzyme and JHU.

Pursuant to the collaboration, license and purchase agreement with Genzyme, we assigned to Genzyme all of our intellectual property applicable to the fields of prenatal and reproductive health, which we refer to as the Genzyme Field, and granted Genzyme an irrevocable, perpetual, exclusive, worldwide, fully-paid, royalty-free license to use and sublicense all of our remaining intellectual property in all fields other than colorectal cancer detection and stool-based disease detection. With respect to the assigned intellectual property, Genzyme granted us an irrevocable, perpetual, exclusive, worldwide, fully-paid, royalty-free license to use and sublicense such intellectual property in the fields of colorectal cancer detection and stool-based detection of any disease or condition, which we refer to as the EXACT Fields. Accordingly, we retained our rights in both the assigned and licensed intellectual property in the EXACT Fields. Also, we and Genzyme each granted to the other a perpetual (subject to termination for uncured material breaches), exclusive, worldwide, fully-paid, royalty-free license to use and sublicense any improvements we or Genzyme make to the intellectual property assigned to

Table of Contents

Genzyme that is applicable to the EXACT Field (where we are the licensee) or all fields other than the EXACT Field (where Genzyme is the licensee). 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 in any field other than the Genzyme Field or the EXACT Field.

The collaboration, license and purchase agreement also provides for the formation of a joint advisory committee to assist both parties in the achievement of product development goals and our regulatory goals. The collaboration period may be terminated on the fifth anniversary of the date of the agreement or sooner upon certain events. We and Genzyme granted to each other a perpetual (subject to termination for uncured material breaches), exclusive, worldwide, fully-paid, royalty-free license to use and sublicense intellectual property jointly developed pursuant to the collaboration between the parties. This license to the joint developed technology is exclusive to Genzyme outside of the EXACT Field and is exclusive to us in the EXACT Field. We also granted to Genzyme an exclusive option to obtain an exclusive license, in the Genzyme Field, to certain technology that we may develop or acquire that has applicability in the Genzyme Field.

Pursuant to the terms of the assignment, sublicense, consent and eighth amendment to license agreement with Genzyme and JHU, we assigned to Genzyme our rights under our prior license agreement with JHU, dated March 25, 2003, as amended, which relate to digital amplification of DNA in the EXACT field as well as rights to certain other technologies. We believe that this license may ultimately allow us and our partners to develop and commercialize novel detection technologies to further enhance the performance of stool-based DNA and colorectal cancer screening technologies. In return for the assignment of rights described above, Genzyme sublicensed to us the intellectual property subject to the license agreement with JHU for colorectal cancer detection and stool-based disease detection, including the BEAMing technology for the detection of colorectal cancer. In exchange for the sublicense, we have agreed to pay Genzyme certain royalties on revenues received by us relating to our or our sublicensees' sales of products and services. Pursuant to the assignment, sublicense, consent and eighth amendment, the sublicense to us terminates upon certain uncured defaults by us. The amendment also provides that, in the event the license agreement with JHU terminates upon an uncured default of Genzyme, if we are in good standing under the agreement at such time, the sublicense to us will become a direct license from JHU to us. We and Genzyme will share in the royalty and annual payment obligations to JHU. The assignment, sublicense, consent and eighth amendment terminates upon the later of 20 years from the effective date of the original JHU license agreement and the expiration of the last to expire of the patents for the licensed technology, or upon certain uncured defaults of JHU or Genzyme.

Pursuant to the amended and restated license agreement with Genzyme, which amends and restates the license agreement between the parties dated March 25, 1999, Genzyme granted us a non-exclusive license to use technology related to the use of certain genes, specifically APC and p53, and methodologies related thereto. In exchange for the license, which continues until the expiration of the last to expire licensed patent, we have agreed to pay Genzyme royalties based on net revenues received from performing tests that incorporate the licensed technology and sales of reagents and diagnostic test kits that incorporate the licensed technology, as well as certain minimum royalties, milestone payments and maintenance fees.

Competition

To our knowledge, none of the large genomics or diagnostics companies are developing tests to conduct stool-based DNA screening for colorectal cancer in the United States. We are aware of other companies that have offered or are offering stool-based colorectal cancer tests outside of the United States, and we believe that other companies may be working on similar tests in the United States that have not yet been announced. In addition, other companies may succeed in developing novel technologies or improving existing technologies and marketing products and services that are more

Table of Contents

effective or commercially attractive than ours. Some of these companies may be larger than we are and can commit significantly greater financial and other resources to all aspects of their business, including research and development, marketing, sales and distribution.

Currently, stool-based DNA detection faces competition from procedure-based detection technologies such as flexible sigmoidoscopy, colonoscopy and "virtual" colonoscopy, a radiological imaging approach which visualizes the inside of the bowel by use of spiral computerized axial tomography, known as a CT scan, as well as existing and possibly improved traditional screening tests such as immunochemical FOBT and improvements to colonoscopy. In addition, some competitors are developing serum-based tests, or screening tests based on the detection of proteins or nucleic acids produced by colon cancer in the blood. Screening tests based on a patient's blood sample may prove to be equally effective in detecting colorectal cancer as stool-based DNA screening. For example, it is our understanding that Epigenomics AG is currently conducting a large multi-center study to demonstrate the performance of its blood-based screening test for colorectal cancer. Further, even if blood-based detection is proven less effective at detecting colorectal cancer than DNA-based technologies from a stool sample, a blood test may ultimately prove to have broader market advantage over our DNA-based technologies based on ease of use and other advantages that physicians, patients, third party payors and others find attractive. We believe that several companies are currently developing blood-based technologies for the early detection of colorectal cancer. Separately, we believe that pharmaceutical and medical device marketing efforts directed at physicians represent competition for physician attention for the sales force selling our DNA-based technologies.

We believe the principal competitive factors in the cancer screening market include:

high sensitivity;

high specificity;

non-invasiveness;

ease of use;

acceptance by the medical community, especially primary care medical practitioners;

adequate reimbursement from Medicare and other third-party payors;

price;

adequate profit margins on any of our potential products;

cost-effectiveness; and

patent protection.

Employees

As of December 31, 2008, we had four full-time employees, one of whom has an M.D. All of our employees are engaged primarily in general and administrative activities. None of our employees are represented by a labor union. We consider our relationship with our employees to be good.

Table of Contents

Available Information

We were incorporated in the State of Delaware on February 10, 1995. Our executive offices are located at 100 Campus Drive, Marlborough, Massachusetts 01752. Our telephone number is 508-683-1200. 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.

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, 2008, we have accumulated a total deficit of approximately $172.5 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. Following the closing of our strategic transaction with Genzyme in January 2009, we have begun resuming our efforts to develop an FDA-approved in vitro diagnostic test for stool-based DNA colorectal cancer screening. As part of our product development efforts and ongoing evaluation of stool-based DNA capabilities and market needs, 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. In addition, to market a stool-based DNA cancer screening product for sales to commercial laboratories, we will be required to first obtain FDA clearance or approval of our technology. The FDA approval path for our colorectal cancer screening technology is likely to involve significant time as well as research, development and clinical study expenditures. Given our current levels of cash and revenues, and without raising additional capital, we will not be able to spend the amounts that we believe will likely be necessary to fund the commercialization of an FDA-approved in vitro diagnostic test for stool-based DNA colorectal cancer screening which, if approved by the FDA, will likely require that we invest substantial amounts in sales and marketing. In addition, there can be no assurance that Laboratory Corporation of America Holdings, or LabCorp, will invest sufficient amounts in sales and marketing activities for ColoSure or other future testing services based on our technologies to allow us to receive material revenues on sales of ColoSure. If our revenue does not grow significantly, we will not be profitable. We cannot assure you 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 future revenues will also depend, in part,

Table of Contents

upon whether ColoSure or other testing services offered by LabCorp based on certain of our intellectual property are broadly ordered by medical practitioners and requested by patients. We believe that our ability to successfully commercialize our technologies may be affected by the following:

- the regulatory requirements for our technology, and the timing of any required regulatory filing and approval process;
- our ability to continue to fund our operations;
- whether LabCorp continues to commercially offer ColoSure or any other stool-based DNA testing services or products utilizing our intellectual property;
- our ability to develop a technology platform and approach that optimizes performance, cost, and throughput in a manner that can effectively build market demand for our technologies;
- our ability to achieve performance outcomes through clinical studies that will support FDA clearance or approval that can be effective in marketing stool-based DNA screening and building market demand;
- the absence of competitive non-invasive screening methods for colorectal cancer screening, including blood-based screening tests currently under development;
- acceptance, endorsement and formal policy approval of stool-based DNA screening for reimbursement by Medicare and other third-party payors;
- effective negotiation and contracting by us and LabCorp with Medicare and other third-party payors for coverage and reimbursement of stool-based DNA screening for colorectal cancer;
- whether payors issue favorable coverage policy for stool-based DNA screening if it is included in the screening guidelines of one or more, but not all, of the major guidelines organizations including USPSTF recommendations for colorectal cancer screening;
- effective and sufficient LabCorp sales and sales management personnel, processes and dedication of resources necessary to educate physician staffs regarding ColoSure and patient compliance;
- effective EXACT personnel to educate third-party payors, managed care organizations, and technology assessment groups regarding stool-based DNA screening;
- whether the lack of a screening interval recommendation by the American Cancer Society, or ACS, and the U.S. Multisociety Task Force on Colorectal Cancer, or MSTF-CRC, in the colorectal cancer screening guidelines issued on March 5, 2008 will limit physician ordering or third party reimbursement, including Medicare, of products based on our stool-based DNA intellectual property;

patient acceptance of ColoSure, including its novel sample collection process;

stool-based DNA screening becoming a standard of care among prescribing physicians; and

the quality and service of the LabCorp testing process.

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 substantially impair our ability to generate revenues and achieve profitability and will negatively impact the successful commercialization of ColoSure or other stool-based DNA testing services or products utilizing our intellectual property.

Table of Contents

Our common stock may be delisted from The NASDAQ Capital Market, which could negatively impact the price of our common stock and our ability to access the capital markets.

Our common stock is currently listed on The NASDAQ Capital Market. On March 6, 2009, we received notice from The NASDAQ Stock Market LLC, or NASDAQ, that we were not in compliance with NASDAQ Marketplace Rule 4310(c)(3), or the Rule, which requires an issuer to maintain a minimum $35 million market value of its listed securities for continued listing on The NASDAQ Capital Market. NASDAQ also noted that we were not in compliance with either of the other alternatives for compliance with the Rule, which require minimum stockholders' equity of $2,500,000 or net income from continuing operations of $500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years, respectively. We were provided a period of 90 calendar days, or until June 4, 2009, to regain compliance with the Rule by evidencing a market value of listed securities of at least $35 million for a minimum of 10 consecutive business days. We are currently evaluating alternatives to resolve the listing deficiency. If the listing deficiency is not resolved by June 4, 2009, we may request a hearing before a NASDAQ Listing Qualifications Panel, or the Panel, to address this issue. Our common stock would remain listed on The NASDAQ Capital Market pending the issuance of a decision by the Panel following such hearing. If this request for continued listing is not granted, our common stock would be delisted from The NASDAQ Capital Market.

We cannot assure you that we will be able to regain compliance with the Rule. On November 28, 2008, our common stock was moved from The NASDAQ Global Market to The NASDAQ Capital Market following a hearing process with the Panel as a result of our inability to maintain the minimum market value of listed securities required for continued listing on The NASDAQ Global Market. It is possible that the Panel may be less willing to grant us an extension to regain compliance as a result of our prior hearing process. The delisting of our common stock could significantly affect the ability of investors to trade our securities and could negatively affect the value and liquidity of our common stock. In addition, the delisting of our common stock could adversely affect our ability to raise additional capital on terms acceptable to us, or at all. Delisting from NASDAQ could also have other negative results, including the potential loss of confidence by licensing partners, the loss of institutional investor interest and fewer business development opportunities.

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 begun resuming our efforts to develop an FDA-approved in vitro diagnostic test for stool-based DNA colorectal cancer screening. As part of our product development efforts and ongoing evaluation of stool-based DNA capabilities and market needs, 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. We may determine to develop a product containing a Version 3 technology that includes BEAMing or digital PCR, we may use genetic markers that are different from those used currently or in the past, we may focus on increasing the performance of our existing Version 2 technology and/or we may determine that our existing Version 2 technology, or some modification of this technology, provides sufficient performance to enable reasonable market penetration for stool-based DNA for colorectal cancer detection. If we determine to include digital PCR or BEAMing technology in the product, we will need to conduct extensive additional development related to Version 3, which is currently in prototype stage.

Our future liquidity and capital requirements will depend upon numerous factors, including the following:

- the cost of developing and refining our technologies;

Table of Contents

the successful commercialization and sales growth of ColoSure, or other stool-based DNA testing services utilizing our intellectual property;

a sustained level of interest and commitment by LabCorp in the commercialization of ColoSure;

the regulatory requirements for ColoSure, or other stool-based DNA testing services utilizing our intellectual property, and the timing and costs associated with any required regulatory approval process;

acceptance, endorsement and formal policy approval of stool-based DNA screening for reimbursement by Medicare and other third-party payors;

our ability to achieve milestones under our strategic agreement with LabCorp;

a determination that additional studies surrounding our technologies are needed;

competitive threats from competing technologies such as blood, plasma, or serum-based screening tests for colorectal cancer;

stool-based DNA screening becoming a standard of care among prescribing physicians; and

the scope of and progress made in our collaborations on the research and development of stool-based DNA detection activities.

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. Since we have no current sources of material ongoing revenue, we believe that we will need to raise additional capital to complete the development, FDA submission for clearance or approval, and commercialization of our technologies, including an FDA-approved in vitro diagnostic test for stool-based DNA colorectal cancer screening. If we are unable to obtain sufficient additional funds to enable us to fund our operations through the completion of the development of such a test, the submission to the FDA for clearance or approval of the test, and commercialization of the test, our results of operations and financial condition would be materially adversely affected and we may be required to delay such efforts and otherwise scale back our operations. In addition, if we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly-issued securities may have rights, preferences or privileges senior to those of existing stockholders. If we raise additional funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies, or grant licenses on terms that are not favorable to us. If we obtain additional debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, and the terms of the debt securities issued could impose significant restrictions on our operations. 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 we or LabCorp fail to comply with FDA requirements, we or LabCorp may be limited or prohibited in our ability to commercialize stool-based DNA testing for colorectal cancer and may be subject to stringent penalties.

Laboratories that make and perform certain types of laboratory-developed tests, currently known in the industry as LDT's, or historically known as homebrews, have generally *not* been required to submit premarket submissions to the FDA, including performance data on the test, for FDA review and

Table of Contents

approval or clearance. Instead, the FDA exercised enforcement discretion, which allowed laboratories to commercially market their LDTs without obtaining FDA approval or clearance, although such laboratories were still required to comply with the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and its implementing regulations. We had believed, since LabCorp's commercial launch of PreGen-Plus in 2003, that PreGen-Plus met the requirements to qualify for FDA enforcement discretion as an LDT and that in-house testing utilizing certain of our technologies, and using any analyte specific reagent that we developed, did not require FDA approval or clearance.

From August 2003 through June 2008 through, LabCorp offered the PreGen-Plus testing service as an LDT. On January 13, 2006, the FDA sent correspondence to us and to LabCorp with respect to the PreGen-Plus testing service, as well as the Effipure DNA-capture devices used in conjunction with the PreGen-Plus tests, which indicated that PreGen-Plus is subject to FDA regulation as a medical device. The FDA also indicated that the device cannot be commercially distributed without an appropriate premarket determination from the FDA. Pursuant to our and LabCorp's subsequent discussions with the FDA to clarify the regulatory status of PreGen-Plus, we and LabCorp agreed, among other things, to revise promotional activities with respect to LabCorp's PreGen-Plus testing service. In addition, LabCorp offered to eliminate its use of Effipure in processing PreGen-Plus tests. Based on the actions outlined above, LabCorp continued to market and process the PreGen-Plus test as a laboratory developed test service until June 2008.

On October 11, 2007, the FDA sent a warning letter to us with respect to the PreGen-Plus testing service, indicating that PreGen-Plus was a Class III medical device and that it could not be commercially distributed without an appropriate premarket approval or clearance from the FDA. Effective June 1, 2008, LabCorp stopped offering PreGen-Plus and indicated that it had discontinued its use of Effipure.

In July 2008, LabCorp began offering a new single marker in-house laboratory developed test called ColoSure, which is based on certain of our intellectual property and that does not use components supplied by us. LabCorp has not obtained FDA clearance or approval, but rather, is marketing ColoSure as an LDT. There can be no assurance that the FDA will not take a similar position with respect to ColoSure as it did for PreGen-Plus, and conclude that ColoSure is a medical device requiring premarket clearance or approval . Similarly, there can be no assurance that LabCorp's offering of ColoSure falls within the category of LDT's over which the FDA has historically exercised enforcement discretion. If the FDA deems ColoSure a medical device that requires FDA clearance or approval prior to marketing, LabCorp may be required to discontinue offering ColoSure and, under such circumstances, our business would likely be materially adversely affected.

In April 2008, we began regulatory efforts toward FDA clearance for Version 2 of our technology, a two-marker version that we believe offers greater sensitivity and can be more cost-effective than our earlier, 23 marker Version 1 technology. In this regard, in April 2008, we submitted a pre-IDE request to the FDA for our Version 2 technology. The objective of the pre-IDE process was to seek concurrence from the FDA that a 510(k) submission followed by a *de novo* classification request is an appropriate regulatory path for our Version 2 technology and that the clinical and other studies proposed in our Version 2 pre-IDE submission would likely support such a *de novo* regulatory path. In July 2008, we received feedback from the FDA as to the clinical performance characteristics and the minimum number of average-risk colorectal cancer samples that likely would be required for validation of our two-marker Version 2 stool-based DNA technology for colorectal cancer screening. In addition, based on our discussions with the FDA, we believe that the *de novo* pathway would be the appropriate regulatory path for our Version 2 technology. FDA's feedback in response to a pre-IDE as to the pathway to market and data requirements is not legally binding on the agency, and they are free to alter their position at a later time.

Table of Contents

Following the consummation of our strategic transaction with Genzyme in January 2009, we have begun resuming our efforts to develop an FDA-approved in vitro diagnostic test for stool-based DNA colorectal cancer screening. As part of our product development efforts and ongoing evaluation of stool-based DNA capabilities and market needs, 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. We may seek to leverage our progress and discussions with the FDA around Version 2 of our technology to assist in determining the likely regulatory path forward for our testing product. The FDA may ultimately determine that a premarket approval application, or PMA, is the appropriate path to market with respect to a testing product containing our stool-based DNA technology instead of a *de novo* pathway. In addition, we will need to determine the appropriate number of colorectal cancer samples from patients that would be required by the FDA in support of any regulatory application for clearance or approval a testing product. We believe that the studies required in connection with any approval or clearance of our technology, regardless of whether the regulatory pathway is de novo classification or a PMA, will be material in cost and time-intensive. There can be no assurance that FDA will ultimately approve any *de novo* classification request or approve any PMA submitted by us in a timely manner or at all.

Our current ability to generate revenue depends on LabCorp's commercial sales of ColoSure and future generations of our technologies.

Other than the funds generated from our transaction with Genzyme in January 2009, all of our current operating revenue is dependent upon LabCorp's commercial sales of ColoSure. We cannot assure you that LabCorp will ever achieve sufficient sales of ColoSure or future generations of our stool-based DNA colorectal cancer screening technology, for us to become profitable.

If LabCorp is unsuccessful in increasing sales of ColoSure, our revenues will be limited and our ability to become profitable will be materially adversely affected. We cannot control whether LabCorp will devote sufficient resources to ColoSure under our strategic agreement. We also cannot control LabCorp's decisions regarding the launch, cessation, or modification of any colorectal cancer testing service that it may offer. Sales performance by LabCorp at historical levels with respect to its DNA-based colorectal cancer screening service and any future ongoing failure of the LabCorp sales force to give continued and sustained focus to ColoSure could harm the demand creation for our stool-based DNA screening technologies and, in turn, could materially adversely affect our revenues and delay any performance-based payments for which we might otherwise be eligible, based on substantial sales volumes, under our strategic agreement with LabCorp. Any change in the senior management or organizational structure within LabCorp could also negatively impact to the successful commercialization of ColoSure.

Further, laboratory operating factors incurred at LabCorp such as turnaround times for the testing process, possible pre- and post-analytical sample and sample processing deficiencies and efforts to obtain third-party reimbursement all influence the rate of market adoption for our technologies. If LabCorp encounters difficulty performing ColoSure tests on an accurate and timely basis or has difficulty obtaining reimbursement, our revenue could be materially and adversely affected. Future demand for the ColoSure test may require LabCorp to further optimize operational and quality assurance processes or genetic marker combinations to support commercial testing. No assurance can be given that such improvements will be successfully implemented by LabCorp, and failure to do so could adversely affect our ability to generate revenues.

Table of Contents

Our business is substantially dependent on the success of our strategic agreements with LabCorp and Genzyme.

We have a strategic alliance with LabCorp, under which we licensed to LabCorp certain of our intellectual property, including improvements that are useful for stool-based DNA testing. If LabCorp were to terminate the agreement, fail to meet its obligations under the agreement, decide to stop processing ColoSure commercially, or otherwise decrease its commitment to ColoSure, our revenues would be materially adversely affected, the commercialization of ColoSure could be interrupted and we could become insolvent. We cannot guarantee that we would be able to enter into a similar agreement with another company to commercialize this technology. Moreover, if we do not achieve certain milestones, or if LabCorp does not achieve certain revenue and performance thresholds within the time periods prescribed in the agreement, we may not fully realize the expected benefits of the agreement.

We and LabCorp have amended our strategic agreement four times to, among other things, effect various changes to the exclusivity terms, payment provisions, milestones and termination and other rights. To accomplish our long-term business objectives, we may be required to enter into additional amendments to our license agreement with LabCorp. We cannot assure you that any additional amendments could be entered into on terms favorable to us. In addition, we cannot assure you that our prior amendments or other strategic initiatives with LabCorp will accomplish the long-term goals of either party. Disagreements with LabCorp could delay or terminate LabCorp's continued commercialization of ColoSure or result in litigation or arbitration, any of which would have a material adverse affect on our business, financial condition and results of operations. Moreover, if the LabCorp relationship terminates, we would be required to enter into other strategic relationships for the commercialization of a colorectal cancer screening service based on our intellectual property or attempt to commercialize a testing service or product ourselves. We cannot assure you that we would be able to license our technology to another commercial laboratory or otherwise successfully commercialize the testing service, and our failure to do either of the foregoing would materially and adversely affect our ability to generate revenues.

We have a collaboration agreement with Genzyme under which we have formed a joint advisory committee to assist both parties in the achievement of product development goals related to the intellectual property transferred in the January 2009 transaction and to assist us with our regulatory goals. If Genzyme were to terminate the agreement, fail to meet its obligations under the agreement or otherwise decrease its commitment to the collaboration, we may be delayed or otherwise materially harmed in our goal of developing product improvements and seeking and obtaining FDA clearance or approval for our stool-based DNA colorectal cancer screening technology.

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 ColoSure or any other stool-based DNA testing services or products utilizing our technologies would be compromised.

Many physicians may decide not to order colorectal cancer screening tests using our technologies if the tests are not adequately reimbursed by third-party payors, including Medicare. 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. Although CIGNA, one of the nation's largest insurers, has included stool-based DNA screening among its covered benefits nationwide, no other third-party payors have issued a broad formal policy approving payment for stool-based DNA testing and we do not believe that current

Table of Contents

reimbursement levels from insurers to LabCorp are at levels sufficient to result in material revenue to us.

In addition, our application to the Centers for Medicare and Medicaid Services, or CMS, for a National Coverage Determination, or NCD, CMS issued a Proposed Decision Memo for Screening DNA Stool Test for Colorectal Cancer (CAG-00144N) on January 30, 2008, stating its decision to not provide coverage for our Version 1 technology because the FDA has determined that our Version 1 technology required FDA premarket clearance. The proposed decision was finalized in a final decision memo, released by CMS on April 28, 2008. The proposed and final decision memoranda indicated that CMS would reconsider providing coverage for our technologies; however, such reconsideration would not take place until after the FDA clears or approves the version of our technology being considered for coverage by CMS. There can be no assurance that any version of our technology will be cleared or approved by the FDA. Even if cleared or approved by the FDA, there can be no assurance that CMS will reach a positive coverage decision regarding our request for an NCD for any version of our technologies. Moreover, even if CMS issues a positive coverage decision for any version of our stool-based DNA screening technology, such coverage may not provide adequate levels of reimbursement. Additionally, despite the fact that our technology is included in the colorectal cancer screening guidelines of the ACS and MSTF-CRC, the FDA warning letter may impact coverage decisions of private third-party payors in a similar manner to CMS' NCD, in that those payors may defer reimbursement policy decisions with respect to our technology until such time, if ever, that we obtain FDA clearance for our technologies.

Moreover, at its February 2008 meeting, the CPT Editorial Panel of the American Medical Association considered a request from gastroenterology specialty physician organizations to create a category III code for a stool-based DNA test. While the CPT Editorial Panel decided to postpone discussion on the issue, the application can be reconsidered at any future meeting, unless it is withdrawn. The CPT Editorial Panel meets three times each year; the next two 2009 meetings are in June and October. Category III codes are temporary codes which are used to designate emerging technologies, services and procedures and are issued semi-annually, unlike Category I codes which are issued annually. Payors tend to not cover services with Category III codes because they consider "emerging" technologies to be an "investigational" service and are therefore not covered services. The creation of Category III code for our stool-based DNA technology could limit the number of payors that reimburse stool-based DNA colorectal cancer screening which would materially limit our revenues and adversely affect our operating results and financial position.

In addition, we believe there are 19 states in the U.S. with state laws mandating reimbursement for colorectal cancer screening tests by group health insurance plans chartered to operate in those states. The Employee Retirement Security Act (ERISA) exempts self-insured health plans from state mandated benefits. In addition, the federal employee health plans and the Medicare program are exempt from state mandates, as they are federally regulated. The state laws vary with regard to whether or not the mandate applies to the State Medicaid program and state employees. Despite the inclusion of our stool-based DNA technology for colorectal cancer screening in the ACS guidelines released in March 2008, we believe that group health insurance plans that may be subject to the state mandates have discretion not to cover certain tests included in the ACS guidelines, including our stool-based DNA screening technology, for a number of reasons including, but not limited to, lack of FDA clearance or approval. Accordingly, group health insurance plans operating in states with colorectal cancer screening mandates may decide not to reimburse for stool-based DNA tests for colorectal cancer.

The United States Public Services Task Force, or USPSTF, a U.S. government-funded organization that reviews available peer-reviewed published studies in order to make an assessment of the benefits and risks of performing certain medical procedures, completed its 6-year update of its colorectal cancer screening guidelines in October 2008. At that time, the USPSTF, which can influence coverage

Table of Contents

decisions by payors, including CMS, determined that the evidence is insufficient (USPSTF Grade: "I" Statement) to assess the benefits and harms of both stool-based DNA and CT colonography, or virtual colonoscopy, as screening modalities for colorectal cancer. No other score was given by the USPSTF to these two new tests added to the ACS and MSTF-CRC colorectal cancer screening guidelines. Many payors base their coverage decisions around colorectal cancer screening on the recommendations of the USPSTF. Accordingly, our future plans may include working to accumulate and publish in peer-reviewed journals additional performance data, and patient compliance and preference data, that will be useful to the USPTF, as well as to CMS, in conjunction with our request for reconsideration of our NCD application. We could incur significant time and costs to accumulate such additional data, which still may not yield positive results with the USPTF or CMS. Additionally, despite the fact that our technology is included in the colorectal cancer screening guidelines of the ACS and MSTF-CRC, the FDA warning letter may have a similar impact on private third party payors in that, like CMS, those payors may defer reimbursement policy decisions with respect to our technology until such time, if ever, as our technologies are cleared by the FDA. Finally, certain members of the MSTF-CRC may fail to separately support the position of the MSTF-CRC, which could have a detrimental effect on our commercial and reimbursement efforts related to stool-based DNA screening.

The National Committee for Quality Assurance, or NCQA, is a private, not-for-profit organization that, among other tasks, measures the performance of U.S. based health care plans. The performance measures quantified by the NCQA result in the Healthcare Effectiveness Data and Information Set, or HEDIS. We believe that HEDIS measures could be a factor used by consumers and employers when selecting among alternative healthcare plans in which to enroll. If our stool-based DNA screening technology for colorectal cancer screening is not recognized by NCQA as a test that contributes to a health plan's score for the colorectal cancer screening measure, health plans may not reimburse for stool-based DNA testing. Despite being included in the recently updated colorectal cancer screening guidelines of the ACS and the MSTF-CRC, there can be no assurance that stool-based DNA screening for colorectal cancer will be adopted by the NCQA as a test that contributes to increasing the score of the HEDIS colorectal cancer screening measure. The NCQA is currently reviewing the colorectal cancer screening measure and made its proposed changes available for public comment February 17, 2009 through March 17, 2009. The NCQA has determined not to include stool-based DNA screening in the draft 2010 HEDIS measure that will be used to evaluate 2009 health plan performance (a retrospective measure that in 2010 "looks back" at 2009 performance). A final 2010 HEDIS measure will be issued sometime after the results of the public comment period are analyzed. Such exclusion could materially limit our ability to secure third-party reimbursement and as a result, materially limit our revenues.

Neither we nor LabCorp have secured any broad-based policy-level reimbursement approval from Medicare or enough third-party payors at adequate levels to ensure the long-term commercial success of stool-based DNA screening for colorectal cancer. If we or LabCorp are unable to obtain a positive policy decision from CMS or other 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.

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.

Our common stock is listed on The NASDAQ Capital Market under the symbol "EXAS." Factors affecting our stock price may include:

- FDA regulation of our or LabCorp's products and services;

Table of Contents

technological innovations or new products and services by us or our competitors;

clinical trial results relating to the stool-based DNA testing in general, or technologies of our competitors;

stool DNA screening becoming a standard of care among prescribing physicians;

reimbursement decisions by Medicare and other third party payors;

the establishment of collaborative partnerships;

health care legislation;

intellectual property disputes and other litigation;

additions or departures of key personnel;

the performance characteristics of our technologies;

general market conditions;

the rate of market acceptance of ColoSure; and

sales of our common stock or debt securities.

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

In addition, the stock market in general, and The NASDAQ Capital Market and the market for life sciences companies in particular, have recently experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating performance of the listed companies. There have been dramatic fluctuations in the market prices of securities of biotechnology companies such as us. These price fluctuations may be rapid and severe and may leave investors little time to react. Broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. 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.

The lack of a recommended screening interval for stool-based DNA screening in the guidelines of the American Cancer Society and the U.S. Multisociety Task Force on Colorectal Cancer, as well as annual updates to such guidelines limiting technical versions of stool-based DNA screening, may limit the acceptance of our technologies among physicians and third-party payors, including Medicare.

The inclusion of stool-based DNA screening in the colorectal cancer screening guidelines of the ACS and the MSTF-CRC, a consortium of several organizations including representatives of the American College of Gastroenterology, American Gastroenterological Association, American Society for Gastrointestinal Endoscopy and American College of Physicians/Society of Internal Medicine, issued on March 5, 2008 did not specify any recommended screening interval. By contrast, the ACS and MSTF-CRC guidelines made specific interval recommendations for each of the other six other colorectal cancer screening modalities included in such guidelines. In addition, it is possible that the ACS, in connection with its future annual updates to the colorectal cancer screening guidelines, may recommend a screening interval that would prevent our technologies from being cost-effective or may limit broad inclusion of our technologies or particular versions of our technologies in the

guidelines. Lack of a definitive screening interval recommendation, a future recommendation for a screening interval that is not cost-effective or any limitation on the inclusion of our technologies, including particular versions of our technology, in future guidelines may lead to reluctance on the part of doctors to order and reorder colorectal cancer screening tests using our technologies, which would limit our revenues and materially harm our business and financial results. Such events may also lead to a

Table of Contents

reluctance by third-party payors, including Medicare, to provide adequate reimbursement for our technologies, if at all, which would also have a material adverse effect on our results of operations and financial position.

In addition, the ACS and MSTF-CRC guidelines indicated that new technologies and new technical versions of approved technologies need to detect a majority of colorectal cancers in a screening population to meet guidelines criteria. Neither we nor LabCorp have performed a stand-alone colorectal cancer screening study of LabCorp's ColoSure test and there can be no assurance that the guidelines groups will agree that existing studies using our Version 2 technology, and any related data supporting ColoSure, will meet the requirements set forth in the current ACS and MSTF-CRC guidelines for inclusion of such technologies in future guidelines of such organizations. If the guidelines groups indicate a lack of acceptance for these more advanced technologies, such action could have a materially adverse impact on our business.

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

LabCorp's current configuration of ColoSure requires access to certain technologies and supplies of raw materials, including rights to the Vimentin gene, for which licensing or supply agreements are required. We cannot assure you that LabCorp has proper licensing or supply agreements in place for such technologies and raw materials, including the sublicensing rights necessary from us for elements of its ColoSure testing service. In addition, any future commercialization of our stool-based DNA screening technology may require that we or LabCorp license certain third-party intellectual property. There can be no assurance that we, or LabCorp, can obtain these technologies and raw materials on acceptable terms, if at all. Furthermore, there can be no assurance that any current contractual arrangements between us and third parties, us and LabCorp, LabCorp and vendors in the supply chain, or between our strategic partners and other third parties, will be continued, or not breached or terminated early, or that we or LabCorp will be able to enter into any future relationships necessary to the continued commercial sale of ColoSure or any other 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, including LabCorp for use in Labcorp's ColoSure colorectal cancer testing service. 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, and LabCorp would be unable to continue offering ColoSure with Vimentin, either of which would materially harm our business. Any failure to obtain necessary technologies or raw materials could require ColoSure or any other 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 superiority, reliability, or effectiveness 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 LabCorp's sales and marketing activities relating to communication of these results, do not convince third-party payors, physicians and thought leaders of the clinical value of our stool-based DNA technologies, stool-based DNA colorectal cancer screening may never be successfully commercialized and, as a consequence, we may not be able to remain a viable business. For instance, the point sensitivity from our 5,500 patient multi-center study of the bead-based method of Version 1 of our technology was lower than that seen in our previous

Table of Contents

research and clinical studies. Moreover, in connection with a preliminary review of data from a study conducted by the Mayo Clinic of the bead-based method of Version 1, Hemoccult II and Hemoccult Sensa appeared to have outperformed, at a preliminary stage, our original Version 1 technology in the detection of cancer among the thirteen cancer samples collected in the study up to that point. We believe that the sample collection protocols used in this study, which were the same as those used in our multi-center study, resulted in DNA degradation that, in turn, resulted in lower sensitivity of our technology. Thought-leading gastroenterologists, guidelines organizations, primary care physicians, payors and others may, despite the small sample size referenced above, assign significance to this preliminary data, which may significantly adversely affect continued commercialization of stool-based DNA colorectal cancer screening.

In addition, in a recent research study that we conducted, designed to test the efficacy of technological advances to enhance colorectal cancer detection in stool, Version 2 of our stool-based DNA screening technology demonstrated sensitivity and specificity results of 83 percent and 82 percent, respectively, for detecting colorectal cancer. Previous published studies for stool-based DNA screening have generally shown specificity above 90 percent, and the specificity results of 82 percent may not be deemed clinically or commercially acceptable. There can be no assurance that the overall performance characteristics, or that the design of the Version 2 research study, will be viewed favorably by thought leaders, physicians, and consumers or that LabCorp will be able to achieve similar levels of performance if Version 2 is commercialized as part of its testing service. Moreover, this study involved the analysis of cancer samples from individuals whose colonoscopy results were positive for colorectal cancer. By contrast, our previous multi-center study, published in the *New England Journal of Medicine* in 2004, was comprised of cancer samples from an asymptomatic population. Cancer samples derived from a purely asymptomatic, average risk population prior to colonoscopy are typically accorded greater clinical weight when considered by thought-leaders in evaluating study performance. There can be no assurance that the population from which the cancer samples were obtained for the Version 2 study will be viewed as sufficient to support clinical or market acceptance of the Version 2 research study results.

If the results of our research and clinical studies 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/or superior to existing screening methods, including Hemoccult II, Hemoccult Sensa and immunochemical fecal occult blood testing, or FOBT, or show that our technologies are superior but not by a large enough margin to affect prevailing clinical practice, 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 slow the demand for ColoSure or any other stool-based DNA testing services or products utilizing our intellectual property.

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

Table of Contents

extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our technologies.

If ColoSure or any other stool-based DNA testing services or products based on our intellectual property cannot be effectively sold at a price acceptable to the market, the successful commercialization of such services or products would be materially harmed.

The success of ColoSure or other testing services based on our intellectual property depends, in material part, on the ability of the seller, whether us, LabCorp or a third party, to price the test at a level acceptable to consumers, physicians and third-party payors. Currently, screening for colorectal cancer using our technologies is more expensive than FOBT because it is labor-intensive and uses highly complex processes and expensive reagents. The price differential between stool-based DNA testing and FOBT, when compared with the performance differential between the two screening modalities, may be viewed as too significant to encourage payors to issue positive coverage policy and adequate reimbursement. To make stool-based DNA testing services or products utilizing our technologies less costly and more commercially attractive to consumers, physicians and third party payors, the providers will need to reduce the costs of tests using our technologies through significant automation of key operational processes or other cost savings procedures and obtain sufficiently strong reimbursement. There can be no assurance that such parties, including Medicare, will pay for such services or products at levels that will enable providers or us to earn a profit, if at all, regardless of the performance of the technology. For example, we believe that the amount currently being paid by CIGNA to LabCorp for ColoSure are not at levels sufficient for LabCorp to earn a profit on its sale of ColoSure. If LabCorp fails to create and improve technologies that sufficiently reduce costs, LabCorp's sales of ColoSure may be limited. As a result, our revenues may be limited. Moreover, if we or LabCorp are unable to sell a sufficient number of tests at favorable pricing levels, we will not be successful and we may not be able to remain viable as a company.

If technological advancements do not increase the performance of ColoSure or other stool-based DNA testing services or products utilizing our technologies in a cost effective manner, the demand for such services or products may be negatively impacted.

There can be no assurance that ColoSure or any future services or products based on our intellectual property will have sufficient performance to be commercially successful. There also can be no assurance that the sample handling protocols employed by LabCorp for ColoSure are adequate to prevent DNA degradation and resulting negative impacts on test performance. If future stool-based DNA testing services or products utilizing our intellectual property do not demonstrate a sufficiently significant increase in the sensitivity or performance over that of the original technology in a cost effective manner, sufficient demand for our stool-based DNA screening technologies may never be realized or such demand could be significantly reduced, either of which would have a material adverse affect on our revenues.

If an insufficient number of medical practitioners order and reorder tests using our technologies, our revenue and profitability will be limited.

If a sufficient number of medical practitioners are not convinced to order and reorder ColoSure or other stool-based DNA testing services or products based on our intellectual property, we will not become profitable. Although stool-based DNA testing has been included in the colorectal cancer screening guidelines of the ACS and MSTF-CRC, gastroenterologists and primary care physicians will still have to be made aware of the benefits of stool-based DNA testing through published papers, presentations at scientific conferences, favorable results from clinical studies and obtaining reimbursement from insurers. Our failure to be successful in these efforts would make it difficult to convince medical practitioners to order and reorder such services or products for their patients which would limit our revenues and materially adversely affect our business.

Table of Contents

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 being performed 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 is currently conducting a large multi-center study to demonstrate the performance of its blood-based screening test for colorectal cancer. These and other companies may also be working on additional methods of detecting colon cancer that have not yet been announced. We may be unable to compete effectively against these competitors either because their test is superior or because they may have more expertise, experience, financial resources and stronger business relationships.

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. 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 of these suits or that the damages or other remedies, if any, awarded against

Table of Contents

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 United States 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.

As of December 31, 2008, we had 39 patents issued and 17 pending patent applications in the United States and, in foreign jurisdictions, 76 patents issued and 32 pending patent applications. Following our transaction with Genzyme, and as of January 27, 2009, we own 14 issued patents and 8 pending applications in the United States, and 43 issued patents and 17 pending patent applications in foreign jurisdictions. 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. In addition, one or more of our U.S. patents may be held as invalid if the inventorship is found to be incorrect, although correction is generally possible even after issuance of the patent. We cannot assure you that patent validity will not be challenged on the basis of incorrectly named inventors, nor can we assure you that a necessary correction could be made. 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, we have jointly filed and jointly own, with a third-party institution, an issued U.S. patent, a pending U.S. continuation patent application and a PCT patent application that has been nationalized and is pending in Canada, Europe, and Japan, which patent applications relate to the use of various DNA markers, including one of our detection methods, to detect supracolonic aerodigestive cancers such as cancers of the lung, pancreas, esophagus, stomach, small intestine, bile duct, naso-oro-pharyngeal airways, liver, and/or gall bladder in stool samples. As joint owners of this patent and patent applications, both we and the third party institution have the rights provided to joint owners under applicable patent law, including the right to use, transfer, and license any issuing patent rights.

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.

Table of Contents

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.

We rely on third-party contract manufacturers and suppliers and may experience a scarcity of raw materials and components.

We have historically relied on contract manufacturers and suppliers for certain components for our technologies. We believe that there are relatively few manufacturers that are currently capable of supplying commercial quantities of the raw materials and components necessary for certain elements used in LabCorp's ColoSure testing service. Although we or LabCorp have identified suppliers that we believe are capable of supplying these raw materials and components in sufficient quantity today for our respective stool-based DNA colorectal cancer screening activities, there can be no assurance that we, or LabCorp, will be able to enter into or maintain these agreements and relationships with such suppliers on a timely basis on acceptable terms, if at all. Furthermore, prior to August 2003, stool-based DNA testing had never been offered on a commercial scale, and there can be no assurance that the raw materials, laboratory personnel, space for processing tests and other components necessary to meet demand will be available in sufficient quantities or on acceptable terms, if at all. If LabCorp should encounter delays or difficulties in securing the necessary raw materials and components for LabCorp's ColoSure testing service, LabCorp may need to reconfigure its ColoSure testing service which would result in delays in commercialization or an interruption in sales and would materially adversely impact our revenues.

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. In addition, LabCorp is subject to the Clinical Laboratory Improvement Amendments of 1988, or CLIA. CLIA is a federal law which regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA is intended to ensure the quality and reliability of clinical laboratories in the U.S. by mandating specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management, quality control, quality assurance and inspections. If LabCorp were to lose its CLIA certification, it may no longer be able to offer ColoSure, which would have a material adverse affect on our business.

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. Changes in healthcare policy could substantially interrupt the sales of ColoSure, increase costs, and divert management's attention. For instance, based on the correspondence and discussions with the FDA during 2006, we believed that LabCorp's PreGen-Plus testing service was an LDT over which the FDA would exercise its enforcement discretion. In October 2007, we then received a warning letter from the FDA indicating that PreGen-Plus is a Class III medical device and that it cannot be commercially distributed without an appropriate pre-market approval or clearance from the

Table of Contents

FDA. 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 new senior management team.

Our success will depend largely on the skills, experience and performance of key members of our senior management team. On March 18, 2009, Jeffrey R. Luber agreed to resign as our President and Chief Executive Officer, effective April 2, 2009, the date of the appointment of Kevin T. Conroy as our new President and Chief Executive Officer. Similarly, on March 18, 2009, Charles R. Carelli, Jr. agreed to resign as our Chief Financial Officer effective April 2, 2009, the date of the appointment of Maneesh Arora as our new Chief Financial Officer. Messrs. Conroy and Arora, who joined us in March 2009, are key additions to our senior management team and will be critical to directing and managing our growth and development in the future. Our success will be substantially dependent upon our new 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 either of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies.

Our operating results may fluctuate, which may adversely affect our share price.

Fluctuations in our operating results may lead to fluctuations, including declines, in our share price. Our operating results may fluctuate from period to period due to a variety of factors, including:

- demand by physicians and consumers for ColoSure;
- new technology introductions;
- reimbursement acceptance success;
- changes in our agreement with LabCorp;
- the number and timing of milestones that we achieve may under collaborative agreements;
- impairment of our intellectual property;
- the level of our development activity conducted for, and our success in commercializing these developments; and
- the level of our spending on commercialization efforts, licensing and acquisition initiatives, clinical studies, and internal research and development relating to our stool-based DNA colorectal cancer screening technology.

Variations in the timing of our future revenue and expenses could also cause significant fluctuations in our operating results from period to period and may result in unanticipated earning shortfalls or losses. In addition, The NASDAQ Capital Market in general, and the market for biotechnology companies in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies.

Table of Contents

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, The John Hopkins University and Case Western Reserve 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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

As of December 31, 2008, we occupied approximately 1,100 square feet of space in our headquarters located in Marlborough, Massachusetts under a lease which expires in July 2010. These facilities are adequate to meet our space requirements with respect to administrative needs. We believe that the development of an FDA-approved product for colorectal cancer screening will require that we lease additional space. In this regard, we are currently exploring additional space in Madison, Wisconsin.

Table of Contents

Item 3. Legal Proceedings

From time to time we are a party to various legal proceedings arising in the ordinary course of our business. The outcome of litigation cannot be predicted with certainty and some lawsuits, claims or proceedings may be disposed of unfavorably to us. Intellectual property disputes often have a risk of injunctive relief which, if imposed against us, could materially and adversely affect our financial condition, or results of operations. From time to time, third parties have asserted and may in the future assert intellectual property rights to technologies that are important to our business and have demanded and may in the future demand that we license their technology. 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. Submission of Matters to a Vote of Security Holders

No matters were submitted to a vote of security holders during the fourth quarter of fiscal 2008.

Table of Contents

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock is currently listed on the NASDAQ Capital Market under the symbol "EXAS." The following table provides, for the periods indicated, the high and low sales prices per share as reported on the NASDAQ 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
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
2007		
First quarter	$3.21	$2.31
Second quarter	3.48	2.33
Third quarter	3.89	2.61
Fourth quarter	6.17	2.81

As of December 31, 2008, there were approximately 27,437,381 shares of our common stock outstanding held by approximately 80 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.

During the quarter ended December 31, 2008, there were no repurchases made by us or on our behalf, or by any "affiliated purchaser," of shares of our common stock registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended.

Item 6. Selected Financial Data

The selected historical financial data set forth below as of December 31, 2008 and 2007 and for the years ended December 31, 2008, 2007 and 2006 are derived from our financial statements, which have been audited by Ernst & Young LLP, independent registered public accountants and which are included elsewhere in this Form 10-K. The selected historical balance sheet financial data as of December 31, 2006, 2005 and 2004 and statements of operations data for the years ended December 31, 2005 and 2004 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

Table of Contents

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,				
	2008	2007	2006	2005	2004
Statements of Operations Data:					
Revenue:					
Product royalty fees	$ (2,234)	$ (1,137)	$ 179	$ 206	$ 166
License fees	1,351	2,857	4,363	3,828	4,514
Product	16	78	208	216	255
	(867)	1,798	4,750	4,250	4,935
Cost of revenue	1	49	809	566	487
Gross profit	(868)	1,749	3,941	3,684	4,448
Operating expenses:					
Research and development(1)	2,034	4,887	6,735	7,956	11,122
Sales and marketing(1)		991	3,792	5,239	5,202
General and administrative(1)	6,469	7,541	6,910	5,497	7,319
Restructuring(1)	602	1,177	671	626	
	9,105	14,596	18,108	19,318	23,643
Loss from operations	(9,973)	(12,847)	(14,167)	(15,634)	(19,195)
Interest income	232	888	1,252	1,114	672
Net loss	$ (9,741)	$ (11,959)	$ (12,915)	$ (14,520)	$ (18,523)
Net loss per share:					
Basic and diluted	$ (0.36)	$ (0.44)	$ (0.49)	$ (0.55)	$ (0.73)
Weighted average common shares outstanding:					
Basic and diluted	27,212	26,945	26,509	26,270	25,334
Balance Sheet Data:					
Cash and cash equivalents	$ 4,937	$ 4,486	$ 4,831	$ 11,987	$ 12,077
Marketable securities		8,101	16,244	21,112	37,188
Total assets	5,898	14,595	23,868	37,845	56,111
Total liabilities	8,331	8,307	8,910	13,224	18,128
Stockholders' equity	(2,433)	6,288	14,958	24,621	37,983

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

	2008	2007	2006	2005	2004
Research and development	$ 89	$ 541	$ 653	$ 113	$ 221
Sales and marketing		202	956	152	
General and administrative	918	1,889	1,397	240	277

Restructuring	3	174
	39	

Table of Contents

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

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

Overview

EXACT Sciences Corporation develops proprietary DNA-based technologies for use in the detection of certain cancers. We have selected colorectal cancer as the first application of our technologies. We license certain of our colorectal cancer screening technologies, including improvements to such technologies, on an exclusive basis in the United States and Canada through December 2010 to Laboratory Corporation of America® Holdings, or LabCorp®. LabCorp has developed and commercially offers a non-invasive stool-based DNA colorectal cancer screening service for the average-risk population, which is based on certain of our technologies. Our current focus is on commercially developing, and obtaining U.S. Food and Drug Administration, or FDA, approval for, a colorectal cancer screening product based on our stool-based DNA technologies.

In January 2009, we completed a strategic transaction with Genzyme Corporation, pursuant to which Genzyme acquired from us, for an aggregate of $18.5 million, our intellectual property assets related to the fields of prenatal and reproductive health as well as certain intellectual property outside the fields of colorectal cancer screening and stool-based DNA testing. Genzyme also purchased three million shares of our common stock, or approximately ten percent of our outstanding common stock, for an aggregate of $6.0 million. Under our agreement with Genzyme, we retained worldwide rights to our colorectal cancer screening and stool-based DNA testing intellectual property, and will receive a double-digit royalty on any Genzyme sublicensing income that may derived from the purchased intellectual property outside the fields of prenatal and reproductive health. We and Genzyme also agreed to form a joint advisory committee to assist Genzyme in the achievement of product development goals related to the purchased intellectual property and to assist us with our regulatory goals.

Since our inception in February 1995, our principal activities have included:

- researching and developing our technologies for colorectal cancer screening;
- conducting clinical studies to validate our colorectal cancer screening technologies;
- negotiating licenses for intellectual property of others;
- developing relationships with opinion leaders in the scientific and medical communities;
- pursuing reimbursement for stool-based DNA screening with third-party payors, including the Centers for Medicare and Medicaid Services, or CMS;
- conducting market studies and analyzing various markets for our technologies;
- raising capital;
- licensing our certain of our intellectual property to LabCorp, Genzyme and others;
- working to further the adoption of stool-based DNA testing for colorectal cancer, including obtaining inclusion of our technology in the guidelines of the major guidelines organizations;

pursuing U.S. Food and Drug Administration, or FDA, clearance or approval, or exemptions therefrom, for our stool-based DNA screening technology for colorectal cancer;

working on activities in support of the awareness around stool-based DNA screening; and

pursuing strategic alternatives for our business, resulting in the Genzyme Transaction.

Table of Contents

We have generated limited operating revenues since our inception and, as of December 31, 2008, we had an accumulated deficit of approximately $172.5 million. Our losses have historically resulted from costs incurred in conjunction with our 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 stool-based DNA screening. We expect that our losses will continue for the next several years and we may never achieve profitability.

From the date of commercial launch through June 2008, when LabCorp stopped commercially offering PreGen-Plus, LabCorp had accessioned approximately 14,900 PreGen-Plus samples, including approximately 1,800, 3,700 and 4,000 samples during the years ended December 31, 2007, 2006 and 2005, respectively. In July 2008, LabCorp began to commercially offer ColoSure , its next generation non-invasive, stool-based DNA testing service for the detection of colorectal cancer in the average-risk population, which is based on certain of our intellectual property. From such date through February 28, 2009, LabCorp has accessioned approximately 995 ColoSure samples, including approximately 512 ColoSure samples during the quarter ended December 31, 2008, and approximately 391 ColoSure samples during January and February 2009.

We have developed or licensed technologies related to a Version 2 colorectal cancer screening technology that we believe has greater sensitivity and is more cost effective than our Version 1 technology underlying the PreGen-Plus testing service formerly offered by LabCorp. Our Version 2 technology includes two DNA markers that, 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, and DIA®, or long DNA. We have exclusive rights to the Vimentin technology through our license agreement with Case Western Reserve University, or Case Western, under which we are obligated to pay a royalty and certain other fees to Case Western in return for the right to use and sublicense the Vimentin technology. We own the rights to DIA and do not pay any royalties on the use of DIA. In a research study evaluating stool-based DNA in 82 patients with confirmed colorectal cancer and 363 colonoscopically normal individuals, our Version 2 stool-based DNA technology demonstrated sensitivity of 83 percent and specificity of 82 percent for the detection of colorectal cancer. LabCorp's ColoSure testing service relies solely on the Vimentin gene and does not use the DIA marker that is also included in our Version 2 technology.

Following the closing of our strategic transaction with Genzyme in January 2009, we have begun resuming our efforts to develop an FDA-approved in vitro diagnostic test for stool-based DNA colorectal cancer screening testing service. As part of our development efforts and ongoing evaluation of stool-based DNA capabilities and market needs, 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. We believe obtaining FDA approval for our stool-based DNA colorectal cancer screening technologies is critical to building broad demand for stool-based DNA colorectal cancer screening technologies and for the successful commercialization of stool-based DNA colorectal cancer screening nationally. We do not currently have sufficient funds to fully achieve this goal. We may determine to develop an FDA-approved product containing a Version 3 technology based on BEAMing or digital polymerase chain reaction, or digital PCR, we may use genetic markers that are different from those used currently or in the past, we may focus on increasing the performance of our existing Version 2 technology and/or we may determine that our existing Version 2 technology provides sufficient performance to enable reasonable market penetration for stool-based DNA for colorectal cancer detection. During 2008, a proof of concept study using the BEAMing technology, an advanced form of digital PCR developed by The Johns Hopkins University, in which stool and blood plasma were assessed in a head-to-head comparison for the detection of colorectal cancer, demonstrated 92 percent sensitivity for detecting colorectal cancer in

Table of Contents

stool samples. These data were published in the August 2008 issue of *Gastroenterology* in a paper entitled "*Analysis of Mutations in DNA Isolated from Plasma and Stool of Colorectal Cancer Patients*." Although we believe that this technology may have the potential to be more sensitive and specific than the current stool-based DNA colorectal cancer screening test commercially offered, Version 3 is still in the prototype stage of development.

Recent Developments

New Senior Management Team

On March 18, 2009, Jeffrey R. Luber agreed to resign as our President and Chief Executive Officer effective April 2, 2009. Also on March 18, 2009, Mr. Luber agreed to resign from our Board of Directors, effective April 2, 2009. In addition, on March 18, 2009, Charles R. Carelli, Jr. agreed to resign as our Chief Financial Officer, effective April 2, 2009.

In connection with their departure, Messrs. Luber and Carelli were entitled to receive severance benefits pursuant to their previously disclosed retention agreements, including salary continuation of $472,500 and $287,500, which is equal to eighteen months and fifteen months, respectively, of their base salaries as of the date of termination. On March 31, 2009, we entered into release agreements with Messrs. Luber and Carelli that provided, in exchange for a general release in favor of us, for the accelerated payment of the salary continuation obligations on March 31, 2009. In addition, the release agreements also provided for the repurchase by us of options held by Messrs. Luber and Carelli for an aggregate of 895,000 shares of common stock, in lieu of accelerated vesting and an extension of the option exercise period arising from the prior retention agreements. We paid Messrs. Luber and Carelli approximately $39,000 and $11,000, respectively, to repurchase Mr. Luber's options to purchase 620,000 shares and Mr. Carelli's options to purchase 275,000 shares. The purchase price of the outstanding options represented a 75 percent discount from the estimated fair value of the vested options as of March 31, 2009. Messrs. Luber and Carelli retained the balance of their existing options, which will remain exercisable for two years following, and will be subject to nine months acceleration of vesting upon, the termination of their respective employment with us. We expect to record in our first quarter financial results the charges associated with the acceleration of the severance payments to Messrs. Luber and Carelli and the redemption and modification of their options.

On March 18, 2009, our board of directors appointed Kevin T. Conroy as President and Chief Executive Officer, effective April 2, 2009. Also on March 18, 2009, based on the recommendation of our corporate governance and nominating committee, the board of directors elected Mr. Conroy to our board. Our board of directors also appointed Maneesh Arora as our Senior Vice President and Chief Financial Officer, effective April 2, 2009.In connection with their appointments, Messrs. Conroy and Arora entered into employment agreements with us on March 18, 2009. Messrs. Conroy and Arora are employed as vice presidents until April 2, 2009, when they begin service in their positions as President and Chief Executive Officer and Senior Vice President and Chief Financial Officer, respectively.

Genzyme Strategic Transaction

In January 2009, we completed a strategic transaction with Genzyme Corporation, pursuant to which we assigned to Genzyme all of our intellectual property applicable to the fields of prenatal and reproductive health, which we refer to as the Genzyme Field, and granted Genzyme an irrevocable, perpetual, exclusive, worldwide, fully-paid, royalty-free license to use and sublicense all of our remaining intellectual property in all fields other than colorectal cancer detection and stool-based disease detection. We retained our rights in both the assigned and licensed intellectual property in the fields colorectal cancer detection and stool-based disease detection. We and

Table of Contents

Genzyme also agreed to form a joint advisory committee to assist Genzyme in the achievement of product development goals related to the purchased intellectual property and to assist us with our regulatory goals. The collaboration period may be terminated on the fifth anniversary of the date of the agreement or sooner upon certain events.

As part of the strategic transaction, we assigned to Genzyme our rights under our prior license agreement with JHU, dated March 25, 2003, as amended. In return, Genzyme sublicensed to us the intellectual property subject to the license agreement with JHU for colorectal cancer detection and stool-based disease detection, including the BEAMing technology for the detection of colorectal cancer. We and Genzyme will share in the royalty and annual payment obligations to JHU. We also amended and restated our prior non-exclusive license from Genzyme dated March 25, 1999 related to the use of certain genes, specifically APC and p53, and methodologies related thereto. In exchange for the license, which continues until the expiration of the last to expire licensed patent, we have agreed to pay Genzyme royalties based on net revenues received from performing tests that incorporate the licensed technology and sales of reagents and diagnostic test kits that incorporate the licensed technology, as well as certain minimum royalties, milestone payments and maintenance fees.

Genzyme agreed to pay us an aggregate 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 of Exact. Subject to terms of the strategic agreement, one-half of the holdback amount will be released to us in 12 months and one-half will be released in 18 months. Genzyme also 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 in any field other than prenatal and reproductive health or colorectal cancer detection and stool-based disease detection.

In addition, we issued and sold to Genzyme 3,000,000 shares of our common stock at a per share price of $2.00, for an aggregate purchase price of $6.0 million. Genzyme also has the right until December 31, 2010 to participate in certain future private offerings of equity securities by us up to the amount necessary to maintain Genzyme's pro-rata percentage ownership of us, at a price per share equal to the greater of $2.00 or the trading price of our common stock at the time notice is provided to Genzyme of its right to purchase additional shares. This right is subject to certain customary exclusions, including issuances to employees pursuant to a stock plan, issuances in connection with a change of control transaction and issuances in connection with strategic partnerships. Genzyme also has the right to include the shares purchased from us on a registration statement filed by us and, under certain circumstances, to cause us to file a registration statement covering the resale of such shares.

Reimbursement for Stool-based DNA Screening for Colorectal Cancer

Since August 2003, the date of commercial launch by LabCorp of its stool-based DNA colorectal cancer screening service, LabCorp billed insurers and received payment from numerous third-party payors for its screening service, including more than 350 health plans. However, none of these third-party payors ever issued formal policy approval for stool-based DNA screening for colorectal cancer..

Following the inclusion of stool-based DNA screening in the colorectal cancer screening guidelines of the ACS and MSTF-CRC, twelve states and the District of Columbia have adopted legislative mandates requiring that stool-based DNA screening be included in available colorectal cancer screening options offered by certain categories of insurers in these states. These states include Alaska, Georgia, Illinois, Indiana, Kentucky, Maine, Maryland, Missouri, Nevada, New Jersey, North Carolina and Rhode Island. In addition, in the second half of 2008, CIGNA, one of

Table of Contents

the nation's largest insurers, included stool-based DNA screening among its covered benefits nationally. While we view inclusion of stool-based DNA 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 strong reimbursement from payors and a positive coverage decision from CMS for our stool-based DNA screening technology will be among the necessary elements to achieving any material commercial success. Despite the positive coverage decision from CIGNA and the state mandates noted above, we do not anticipate material sales relating to ColoSure until strong reimbursement is negotiated between LabCorp and CIGNA and between LabCorp and other payors with which it maintains contracts.

The United States Public Services Task Force, or USPSTF, a U.S. government-funded organization that reviews available peer-reviewed published studies to make an assessment of the benefits and risks of performing certain medical procedures, completed its 6-year update of its colorectal cancer screening guidelines in October 2008. At that time, the USPSTF, which can influence coverage decisions by payors, including CMS, determined that the evidence is insufficient (USPSTF Grade: "I" Statement) to assess the benefits and harms of both stool-based DNA and CT colonography, or virtual colonoscopy, as screening modalities for colorectal cancer. The USPSTF gave no score to these two new tests added to the ACS and MSTF-CRC colorectal cancer screening guidelines. Many payors base their coverage decisions around colorectal cancer screening on the recommendations of the USPSTF. Accordingly, our future plans may include working to accumulate and publish in peer-reviewed journals additional performance data, and patient compliance and preference data, that will be useful to the USPSTF, as well as to CMS, in conjunction with our request for reconsideration of our NCD application. We could incur significant time and costs to accumulate such additional data, which still may not yield positive results with the USPSTF or CMS. Additionally, despite the fact that our technology is included in the colorectal cancer screening guidelines of the ACS and MSTF-CRC, the FDA warning letter we received with respect to the PreGen-Plus testing service may have a similar impact on private third party payors in that, like CMS, those payors may defer reimbursement policy decisions with respect to our technology until such time, if ever, as our technologies are cleared by the FDA. Finally, certain members of the MSTF-CRC may fail to separately support the position of the MSTF-CRC, which could have a detrimental effect on our commercial and reimbursement efforts related to stool-based DNA screening.

The National Committee for Quality Assurance, or NCQA, is a private, not-for-profit organization that, among other tasks, measures the performance of U.S. based health care plans. The performance measures quantified by the NCQA result in the Healthcare Effectiveness Data and Information Set, or HEDIS. We believe that HEDIS measures could be a factor used by consumers and employers when selecting among alternative healthcare plans in which to enroll. If our stool-based DNA screening technology for colorectal cancer screening is not recognized by NCQA as a test that contributes to a health plan's score for the colorectal cancer screening measure, health plans may not reimburse for stool-based DNA testing. Despite being included in the recently updated colorectal cancer screening guidelines of the ACS and the MSTF-CRC, there can be no assurance that stool-based DNA screening for colorectal cancer will be adopted by the NCQA as a test that contributes to increasing the score of the HEDIS colorectal cancer screening measure. The NCQA is currently reviewing the colorectal cancer screening measure and made its proposed changes available for public comment February 17, 2009 through March 17, 2009. The NCQA has determined not to include stool-based DNA screening in the draft 2010 HEDIS measure that will be used to evaluate 2009 health plan performance (a retrospective measure that in 2010 "looks back" at 2009 performance). A final 2010 HEDIS measure will be issued sometime after the results of the public comment period are analyzed. Such exclusion could materially limit our ability to secure third-party reimbursement and as a result, materially limit our revenues.

Table of Contents

Compliance with NASDAQ Listing Requirements

On July 10, 2008, we received notice from The NASDAQ Stock Market LLC, or NASDAQ, that we were not in compliance with NASDAQ Marketplace Rule 4450(b)(1)(A), which requires an issuer to maintain a minimum $50 million market value of its listed securities for continued listing on The NASDAQ Global Market. We requested a hearing before the NASDAQ Listing Qualifications Panel, which was held on October 2, 2008, and on November 26, 2008, the NASDAQ Listing Qualifications Panel determined to list our securities on The NASDAQ Capital Market on a conditional basis, pending its review of additional information regarding our plan to evidence compliance with the requirements for continued listing on that market. On January 29, 2009, we received a determination from The NASDAQ Stock Market indicating that we had evidenced full compliance with all requirements for continued listing on The NASDAQ Capital Market.

On March 6, 2009, we received notice from NASDAQ that we were not in compliance with NASDAQ Marketplace Rule 4310(c)(3), or the Rule, which requires an issuer to maintain a minimum $35 million market value of its listed securities for continued listing on The NASDAQ Capital Market. NASDAQ also noted that we were not in compliance with either of the other alternatives for compliance with the Rule, which require minimum stockholders' equity of $2,500,000 or net income from continuing operations of $500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years, respectively. This notification has no effect on the listing of our common stock at this time. We were provided a period of 90 calendar days, or until June 4, 2009, to regain compliance with the Rule. If at any time before June 4, 2009, the market value of our listed securities is $35 million or more for a minimum of 10 consecutive business days, the NASDAQ staff will determine if we comply with the Rule. If we do not regain compliance with the Rule by June 4, 2009, NASDAQ will provide us with written notification that our common stock will be delisted from the NASDAQ Capital Market. At that time, we may appeal the delisting determination to a NASDAQ Listings Qualifications Panel pursuant to applicable NASDAQ rules. We are currently evaluating our alternatives to resolve the listing deficiency.

Colorectal Cancer Screening Guidelines

Professional colorectal cancer screening guidelines in the United States, including those of the American Cancer Society, or ACS, the American College of Gastroenterology and the American Gastroenterological Association, recommend regular screening by a variety of methods. Historically, such recommendations consisted of colonoscopy, flexible sigmoidoscopy, double contrast barium enema and fecal occult blood testing (FOBT), as well as combinations of some of these methods. In 2008, the ACS, the U.S. Multi-Society Task Force on Colorectal Cancer, a consortium of several organizations including 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, collectively, the MSTF-CRC, and the American College of Radiology announced the inclusion of non-invasive, stool-based DNA screening technology in the updated national colorectal cancer screening guidelines as a screening option for the detection of colorectal cancer in average risk, asymptomatic individuals age 50 and above. These new guidelines now divide colorectal cancer screening into two groups, one including non-invasive methods for the early detection of colorectal cancer and the other including invasive techniques for the prevention and early detection of colorectal cancer. Non-invasive technologies include fecal occult blood testing and stool-based DNA screening for individuals unwilling or unable to use invasive screening procedures. Invasive procedures include colonoscopy, flexible sigmoidoscopy, CT colonography, and double contrast barium enema, which, according to the new guidelines, are designed to detect both early cancer and adenomatous polyps and should be encouraged if resources are available and patients are willing to undergo an

Table of Contents

invasive test. While we view inclusion of our stool-based DNA technology in the ACS and MSTF-CRC guidelines as a critical first step toward building sufficient demand for any stool-based DNA screening test for colorectal cancer, we believe that FDA approval or clearance of our technologies, as well as reimbursement from CMS and other third-party payors will be necessary to achieve any significant increase in demand for our technologies. In addition, the ACS and MSTF-CRC guidelines indicated that new technologies and new technical versions of approved technologies need to detect a majority of colorectal cancers in a screening population to meet guidelines criteria. Neither we nor LabCorp have performed a stand-alone colorectal cancer screening study of LabCorp's ColoSure test and there can be no assurance that the guidelines groups will agree that existing studies using our Version 2 technologies, and any related data supporting ColoSure, will meet the requirements set forth in the current ACS and MSTF-CRC guidelines for inclusion of such technologies in future guidelines of such organizations. If the guidelines groups indicate a lack of acceptance for these more advanced technologies, such action could have a materially adverse impact on our business.

Regulatory Update

In April 2008, we began to focus our regulatory efforts on pursuing FDA clearance for Version 2 of our technology and we submitted a pre-Investigational Device Exemption, or pre-IDE, request to the FDA. The objective of the pre-IDE process was to seek informal guidance from the FDA that a 510(k) submission followed by a *de novo* classification request is an appropriate regulatory path for our Version 2 technology and that the clinical and other studies proposed in our Version 2 pre-IDE submission would likely support such a *de novo* regulatory path. In July 2008, we received feedback from the FDA as to the clinical performance characteristics and the minimum number of average-risk colorectal cancer samples that would be required for validation of our two-marker Version 2 stool-based DNA technology for colorectal cancer screening. In addition, based on our discussions with the FDA, we believe that the *de novo* pathway would be the appropriate regulatory path for our Version 2 technology. In July 2008, we reduced our cost structure by suspending the clinical validation study and other studies for our Version 2 technology and eliminating eight positions within the company.

Following the closing of our strategic transaction with Genzyme in January 2009, we have been exploring efforts to develop a product for sale to commercial laboratories that would enable the buyers to offer a stool-based DNA colorectal cancer screening testing service, which may include a Version 3 technology currently in prototype stage. Development of this product and obtaining FDA clearance or approval will require the support of clinical study data. A large clinical study will require substantial funds to complete. Developing and validating new versions of our technology will also require significant resources. Because we do not currently have sufficient funds to complete all of the development, validation, and FDA studies necessary to support an FDA submission of any version of our technology, we will need to gain access to additional capital through a strategic transaction, a debt or equity financing, a merger or sale of the Company, or third-party collaboration, if any, and/or some combination of any of the foregoing in order to fund these efforts. There can be no assurance that we will be successful in securing or gaining access to any additional capital to pursue these activities. If we are unable to finance the requisite development and clinical efforts, we will not be able to complete and submit our application to seek FDA approval or clearance of our stool-based DNA technology.

Table of Contents

Also, in July 2008, LabCorp began offering a new single marker in-house laboratory-developed test called ColoSure, which is based on certain of our Version 2 intellectual property and that does not use the Effipure component. There can be no assurance that LabCorp's offering of ColoSure falls within the category of in-house developed laboratory tests, or LDT, over which the FDA has historically exercised enforcement discretion. If the FDA deems ColoSure a medical device that requires FDA clearance or approval prior to marketing, LabCorp or we may receive another FDA warning letter or be the subject of other enforcement action, and LabCorp may be required to discontinue offering ColoSure and, under such circumstances, our business would likely be materially adversely affected.

Financial Overview

Our revenue is comprised of the amortization of up-front license fees for the licensing of certain patent rights to LabCorp under our strategic license agreement and product royalty fees on tests sold by LabCorp utilizing our technology, which has historically been based on PreGen-Plus sales but will now be based on ColoSure sales. We expect that product royalty fees for the full year 2009 will be higher than amounts recorded in 2008 as a result of the recording in 2007 and 2008 of nearly the full potential third-party royalty obligations in connection with our amended license agreement with LabCorp. While we expect license fee revenue resulting from the amortization of the up-front license payment from LabCorp in 2009 to be consistent with amounts recorded in 2008, we expect that total license fee revenue for 2009 will be higher than amounts recorded in 2008 as a result of the Genzyme transaction.

Factors Affecting Potential Revenue Growth

We believe that substantial funds and managerial attention will likely need to be invested in sales and marketing efforts over the next several years for our stool-based DNA screening technologies to be commercially successful. We do not have, and we cannot assure you that LabCorp will devote, the funds or management resources that we believe are likely necessary to build sufficient demand for ColoSure. Despite the inclusion of stool-based DNA screening in colorectal cancer screening guidelines and the state insurance mandates discussed above, we do not expect material revenue growth from LabCorp's sales of ColoSure or from any of our potential future sales of a product that we may develop until such time as FDA clearance or approval is obtained and such product is launched by us, if ever, and reimbursement is provided by CMS and other third-party payors at an acceptable level. In addition, we believe our success will also depend upon a number of additional factors that are largely out of our control, including the following:

- the impact that the inclusion of stool-based DNA screening in guidelines will have on prescribing physicians, third-party payors, including CMS, and health care consumers;
- any regulatory restrictions placed upon ColoSure;
- any regulatory restrictions placed upon any product or testing service that we or others may offer based on our intellectual property;
- success in educating third-party payors, including CMS, managed care organizations, and technology assessment groups regarding stool-based DNA screening;
- effective negotiation and contracting with CMS and other third-party payors for coverage at acceptable levels of reimbursement for stool-based DNA screening;
- patient awareness and acceptance of stool-based DNA screening, including its novel sample collection process;
- the absence of competing technologies that offer equal or better attributes than stool-based DNA screening;

Table of Contents

stool-based DNA screening becoming a standard of care among prescribing physicians; and

the quality and service of the LabCorp testing process.

Our Cost Structure

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, which we refer to as the 2008 Sublease Agreement, with QTEROS, Inc., or QTEROS, to sublease to QTEROS the majority of the remaining space at our corporate headquarters.

In addition to the 2008 Restructuring, in July 2007 and October 2006, we initiated cost reduction plans and reduced our workforce and other operating expenses, which we refer to as the 2007 Restructuring and the 2006 Restructuring, respectively, 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. The 2006 Restructuring eliminated 21 positions, or 48% of our staff at that time, across all departments.

Research and development expenses include costs related to scientific and laboratory personnel, research and clinical studies and reagents and supplies used in the development of our technologies and, effective as of January 1, 2006, non-cash stock-based compensation recorded pursuant to SFAS No. 123 (revised 2004), *Share-Based Payment*, or SFAS No. 123(R). The completion of an FDA-approved in vitro diagnostic test will require extensive additional development work and evaluation. We intend to further examine the marker combinations and platform requirements necessary for optimal performance based on market need. In this regard, we intend to either hire new regulatory and development personnel or collaborate with third parties, or some combination of both, in order to achieve these goals. The costs to complete development of an FDA-approved in vitro diagnostic test will be material, and the development will be time intensive. We do not have, and can make no assurance that we can raise or otherwise secure, the capital necessary to complete the development and commercialization of an FDA-approved in vitro diagnostic test, which will require development efforts and investment, a clinical validation study to be executed in an average risk, asymptomatic screening population, a subsequent submission to the FDA for clearance or approval of an in vitro diagnostic test, and sales and marketing efforts required to successfully commercialize an FDA-approved in vitro diagnostic test. As a result of the activities anticipated in support of our objectives toward developing an FDA-approved in vitro diagnostic test, we expect research and development costs in 2009 to be higher than 2008 levels.

General and administrative expenses have consisted primarily of non-research personnel salaries, office expenses, professional fees and, as of January 1, 2006, non-cash stock-based compensation recorded pursuant to SFAS No. 123(R). As a result of the 2007 Restructuring, in which we eliminated our sales and marketing functions effective August 31, 2007, we did not incur any sales and marketing expenses in 2008 and do not expect to incur material sales and marketing operating expenses in 2009. We expect general and administrative expenses in 2009 to be higher than 2008 levels, primarily as a result of professional fees in connection with the Genzyme Transaction and the transition of our senior management team as described above, including payment of severance to our officers relating to their separation from the company in March 2009.

Significant Accounting Policies

This management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance

Table of Contents

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, or the Second Amendment, 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 amortize the remaining deferred revenue balance at the time of the Second Amendment ($4.7 million) on a straight-line basis over the remaining exclusive license period, which ends in December 2010.

Product royalty fees We have licensed certain of our technologies, including improvements to such technologies, to LabCorp on an exclusive basis through December 2010. LabCorp developed and commercially offered PreGen-Plus, a non-invasive stool-based DNA colorectal cancer screening service for the average-risk population based on our Version 1 technology, from August 2003 through June 2008. Effective June 1, 2008, LabCorp stopped offering PreGen-Plus and, on July 14, 2008, LabCorp began to commercially offer ColoSure, its next generation non-invasive, stool-based DNA testing service for the detection of colorectal cancer in the average-risk population, which is based on certain of our Version 2 technology. We will be entitled to the same royalty and milestone structure on any sales of ColoSure as we were entitled to on sales of PreGen-Plus.

Prior to the effective date of the Second Amendment, our product royalty fees were based on a specified contractual percentage of LabCorp's cash receipts from performing PreGen-Plus tests. Accordingly, we recorded product royalty fees based on this specified percentage of LabCorp's cash receipts, as reported to us each month by LabCorp. Subsequent to the effective date of the Second Amendment, our product royalty fees are based on a specified contractual percentage of LabCorp's net revenues from sales of PreGen-Plus through June 1, 2008, when LabCorp stopped offering PreGen-Plus and from sales of ColoSure from and after July 2008. Accordingly, subsequent to the effective date of the Second Amendment, we record product royalty fees based on the specified contractual percentage of LabCorp's net revenues from its sales of such colorectal cancer screening tests, as reported to us each month by LabCorp. The current royalty rate is 15%, subject to an increase to 17% in the event that LabCorp achieves a specified significant threshold of annual net revenues from the sales of such colorectal cancer screening tests.

Additionally, pursuant to the Second Amendment, we will potentially be obligated to reimburse LabCorp for certain third-party royalty payments, as described in Note 4 to the consolidated financial statements located elsewhere in this annual report on Form 10-K. To the

Table of Contents

extent we incur liabilities in connection with this provision of the Second Amendment, the accretion of such liabilities will be recorded as a reduction in the product royalty fee line item in our consolidated statements of operations.

Product revenue Product revenue from the sale of certain components of our Effipure technology to LabCorp was recognized upon transfer of the components provided that title passed, the price was fixed or determinable and collection of the receivable was probable. Effipure is not used as a component in LabCorp's ColoSure offering and we therefore do not expect to record product revenue in connection with Effipure sales in future periods.

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

Patent Costs. Patent costs are capitalized as incurred and are amortized beginning when patents are issued over an estimated useful life of five years. Capitalized patent costs are expensed upon disallowance of the patent, upon a decision by us to no longer pursue the patent, or when the related intellectual property is deemed to be no longer of value to us.

We apply SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets and for Long-Lived Assets*, or SFAS No. 144, which requires that we continually evaluate whether events or circumstances have occurred that indicate that the estimated remaining useful life of long-lived assets and certain identifiable intangibles and goodwill may warrant revision or that the carrying value of these assets may be impaired.

During the quarters ended June 30 and December 31, 2008, we evaluated certain events which indicated that the remaining useful life or the carrying value of our patent portfolio might have been impaired. After performing the requisite impairment analyses, we wrote off approximately $253,000 in capitalized patents during the quarter ended June 30, 2008 related specifically to one of the components of our Version 2 technology that is not used in LabCorp's current ColoSure testing service, and wrote off an additional $112,000 in capitalized patents during the quarter ended December 31, 2008 due to uncertainty around the near term recoverability of those capitalized patent costs. As of December 31, 2008, the majority of the recorded value of the patent portfolio related to intellectual property sold to Genzyme in January 2009. See description of the Genzyme transaction above.

Stock-Based Compensation. We adopted SFAS No. 123(R) effective January 1, 2006 using the modified prospective transition method. SFAS No. 123(R) requires 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), to be recognized in the financial statements based on their fair values. SFAS No. 123(R) did not change the accounting guidance for share-based payment transactions with parties other than employees provided in SFAS No. 123, as originally issued and EITF 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. Prior to January 1, 2006, we accounted for stock-based compensation under the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*.

We believe that full consideration has been given to all relevant circumstances that we may be subject to, and the financial statements accurately reflect our best estimate of the results of operations, financial position and cash flows for the periods presented.

Critical Accounting Estimate Third-Party Royalty Obligation

Pursuant to the terms of the Second Amendment, we will potentially be obligated to reimburse LabCorp for certain third-party royalty payments if LabCorp's third-party royalty rate is greater than a

Table of Contents

specified royalty rate during the measuring period, as outlined in the table below. Our obligation to pay LabCorp pursuant to this provision of the Second Amendment is based on LabCorp's sales volumes of colorectal cancer screening tests using our technology during three separate measurement periods, as defined below. A significant increase in such sales volumes during any measurement period, as compared to historical PreGen-Plus sales volumes, could reduce our potential obligation during any measurement period, while test volumes consistent with historical PreGen-Plus sales levels could result in aggregate payments to LabCorp totaling up to $3.5 million during the measurement periods. Until LabCorp's sales of colorectal cancer screening tests using our technology increase to a level that would reduce this potential maximum obligation, if ever, we intend to record our estimated obligation under this provision of the Second Amendment as a reduction in the product royalty fee line item in its consolidated statements of operations, in accordance with EITF No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*, or EITF 01-9. Based on sales volumes of PreGen-Plus through June 1, 2008 and anticipated sales volumes of ColoSure, as of December 31, 2008, we had accrued a total of $3.45 million of the total potential $3.5 million obligation to LabCorp. We recorded charges of $2.25 million and $1.2 million, respectively, during the years ended December 31, 2008 and 2007 in connection with this third-party royalty obligation. These charges were recorded under the caption "Product royalty fees" in our consolidated statements of operations. This obligation is recorded in our consolidated balance sheets under the caption "Third- party royalty obligation." 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. Amounts included in the table are in thousands.

Measurement period Start Date	Measurement period End Date	Payment Due Date for Measurement Period	Potential Minimum Third Party Royalty Obligation During Measurement Period	Potential Maximum Third Party Royalty Obligation During Measurement Period
June 28, 2007	December 31, 2008	January 30, 2009	$	$ 1,500
January 1, 2009	December 31, 2009	January 30, 2010		1,000
January 1, 2010	December 31, 2010	January 30, 2011		1,000
			$	$ 3,500

Recent Accounting Pronouncements

In November 2007, the FABS issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements,* or EITF 07-1, which defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties, including the appropriate income statement presentation and classification of, and the required disclosures related to, these arrangements. EITF 07-1 is effective January 1, 2009, to be applied retrospectively for collaborative arrangements existing as of the effective date. We do not anticipate that EITF 07-1 will have a material impact on our financial statements.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, or SFAS 162. SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the U. S. SFAS 162 is effective 60 days following the SEC approval of Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. We do not anticipate that SFAS 162 will have a material impact on our financial statements.

Table of Contents

Results of Operations

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. Total revenue during these periods is composed of the amortization of up-front technology license fees associated with our amended license agreement with LabCorp that are being amortized on a straight-line basis over the exclusive license period, which ends in December 2010, royalties on LabCorp's sales of PreGen-Plus and ColoSure and sales of Effipure units to LabCorp as well as provisions added for our third-party royalty reimbursement obligation to LabCorp which are recorded as reductions to revenue under EITF 01-9. Effective June 1, 2008, LabCorp stopped offering PreGen-Plus and indicated that it had discontinued its use of Effipure.

The decrease in total revenue for the year ended December 31, 2008 when compared to the same period of 2007 was primarily the result of a decrease of approximately $1.5 million in license fee revenue resulting from the Second Amendment, which extended 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 ($4.7 million at the time of the Second Amendment) are now being recognized over a longer period of time, resulting in lower non-cash license fee amortization as compared to prior periods.

In addition, product royalty fees were approximately $1.1 million lower for the year ended December 31, 2008 when compared to the year ended December 31, 2007 due 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. During the year ended December 31, 2007, we recorded $1.2 million in charges 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 were recorded pursuant to the Second Amendment and resulted in negative product royalty revenue for the years ended December 31, 2008 and 2007.

In June 2008, LabCorp stopped offering PreGen-Plus, the version of the stool-based DNA technology that utilizes Effipure and has been the subject of FDA inquiry over the past several years. In July 2008, LabCorp began offering ColoSure, a new stool-based DNA test that is different from our Version 2 technology and is based solely on the Vimentin gene, a methylated DNA marker that in published studies was shown to be associated with colorectal cancer. Pursuant to our license agreement with LabCorp, we are entitled to the same royalty and milestone structure on sales of ColoSure as we were entitled to on sales of PreGen-Plus.

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 as described under the heading "Our Cost Structure" above. The decrease in research and development expenses for the year ended December 31, 2008, as compared to the year ended December 31, 2007, 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 compensation charges resulting primarily from the June 2007 issuance of 100,000 shares of our common stock to Oncomethylome Sciences S.A., or OMS, on June 14, 2007 pursuant to the terms of a Manufacturing and Supply Agreement with OMS.

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 when comparing the year ended December 31, 2008 with the year ended December 31,

Table of Contents

2007 as well as a decrease of $0.9 million in salary, benefit and other costs due to lower general and administrative headcount during the year ended December 31, 2008, as compared to the same period of 2007. 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 from $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 "Our Cost Structure" above.

2008 Restructuring. In connection with the 2008 Restructuring, we recorded restructuring charges of approximately $0.5 million during the three months ended September 30, 2008, including $0.2 million in one-time termination benefits arising under retention and severance agreements with each of the terminated employees and $0.3 million resulting from the write-off of leasehold improvements abandoned by us in connection with the reduction in force. Our decision to eliminate 67% of our workforce as part of the 2008 Restructuring was deemed to be an impairment indicator under SFAS No. 144. As a result of performing the impairment evaluations, non-cash asset impairment charges of $0.3 million were recorded to adjust the carrying value of the related leasehold improvements to their net realizable value.

In addition, in connection with the 2008 Restructuring, our board of directors accelerated the vesting of 15,523 shares under terminated employees' previously unvested stock options, with a weighted average exercise price of $2.65 per share, and extended the expiration date of all the terminated employees' outstanding options as of their date of termination, covering an aggregate of 181,828 shares with a weighted average exercise price of $4.50, through August 1, 2009. Pursuant to the measurement provisions of SFAS No. 123(R), we recorded one-time non-cash stock- based compensation charges of approximately $3,000 in the "Restructuring" line item of our consolidated statements of operations during the quarter ended September 30, 2008.

During the fourth quarter of 2008, we entered into a sublease agreement, which we refer to as the 2008 Sublease Agreement, with QTEROS, Inc., or QTEROS, to sublease to QTEROS approximately 25,537 square feet of rentable area in our corporate headquarters. The term of the 2008 Sublease Agreement, which commenced on December 9, 2008, is 20 months with a base rent of $625,657 per year. Pursuant to the 2008 Sublease Agreement, QTEROS has no rights to renew or extend the 2008 Sublease Agreement. Under the terms of the 2008 Sublease Agreement, QTEROS will be required to pay its pro rata share of any increases in building operating expenses and real estate taxes and to provide a security deposit in the form of an irrevocable, standby letter of credit from a national commercial bank reasonably acceptable to us in the amount of approximately $52,000 naming us as beneficiary. The 2008 Sublease Agreement provides for our employees to continue to occupy approximately 1,100 square feet in the premises subleased to QTEROS. We believe that such 1,100 square feet are adequate to meet our space requirements with respect to administrative needs. We believe that the development of an FDA-approved product for colorectal cancer screening will require that we lease additional space. In this regard, we are currently exploring additional space in Madison, Wisconsin.

In connection with the 2008 Sublease Agreement, we also recorded the following restructuring charges during the fourth quarter of 2008 (included opposite the caption "Facility consolidation costs"

Table of Contents

in the table below): approximately $0.1 million in future cash payments related to the difference between our committed lease payments and the estimated sublease rental income under the 2008 Sublease Agreement; approximately $0.1 million in one time real estate transaction and laboratory decommissioning fees; and approximately $0.1 million of non-cash charges related to the write-off of leasehold improvements abandoned by us in connection with the 2008 Sublease Agreement. These charges were offset by cash receipts of approximately $0.3 million received in connection with sales of fully depreciated fixed assets upon commencement of the 2008 Sublease Agreement.

Amounts remaining in the 2008 Restructuring accrual at December 31, 2008, which are expected to be paid out in cash through July 2010, are recorded under the caption "Accrued expenses" in our condensed consolidated balance sheets. The following table summarizes changes made to the restructuring accrual during the year ended December 31, 2008 relating to the 2008 Restructuring. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2007	Charges	Cash Payments	Non-cash Write-offs	Balance, December 31, 2008
Employee separation costs	$	$ 266	$ (247)	$ (3)	$ 16
Facility consolidation costs		343	(112)	(66)(1)	165
Total	$	$ 609	$ (359)	$ (69)	$ 181

(1) Amount is net of approximately $274,000 in cash received from sales of fully depreciated assets in connection with the Company's exit of certain space in its Marlborough, Massachusetts facility.

2007 Restructuring. 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 each of the 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. The term of the 2007 Sublease Agreement, which commenced on December 15, 2007, is 32 months with a base rent of $266,265 per year. Pursuant to the 2007 Sublease Agreement, INTRINSIX has no rights to renew or extend the 2007 Sublease Agreement. Under the terms of the 2007 Sublease Agreement, INTRINSIX was required to provide a security deposit of $35,000 and will be required to pay its pro rata share of any building operating expenses and real estate taxes.

In connection with the 2007 Sublease Agreement, we recorded restructuring charges of approximately $0.4 million during the fourth quarter of 2007 (included opposite the caption "Facility consolidation costs" in the table below), which consist of approximately $0.3 million in future cash payments related to the difference between our committed lease payments and the estimated sublease rental income under the 2007 Sublease Agreement and approximately $0.1 million of non-cash charges related to the write-off of leasehold improvements abandoned by us in connection with the 2007 Sublease Agreement. Our decision to enter into the 2007 Sublease Agreement was deemed to be an impairment indicator under SFAS No. 144. As a result of performing the impairment evaluations, asset impairment charges of $0.1 million were recorded to adjust the carrying value of the related leasehold improvements to their net realizable value. Facility consolidation costs also include one time real estate transaction fees in connection with the Sublease Agreement.

Table of Contents

Amounts remaining in the 2007 Restructuring accrual at December 31, 2008, 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, 2008. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2007	Charges	Cash Payments	Non-cash Write-offs	Balance, December 31, 2008
Employee separation costs	$ 224	$ (7)	$ (217)	$	$
Facility consolidation costs	268		(107)		161
Total	$ 492	$ (7)	$ (324)	$	$ 161

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.

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.

Comparison of the years ended December 31, 2007 and 2006

Revenue. Total revenue decreased to $1.8 million for the year ended December 31, 2007, from $4.8 million for the year ended December 31, 2006. Total revenue is primarily composed of the amortization of up-front technology license fees associated with our amended license agreement with LabCorp that are being amortized on a straight-line basis over the exclusive license period, which ends in December 2010 and, to a lesser extent, royalties on LabCorp's sales of PreGen-Plus, and sales of Effipure units to LabCorp. Effective June 1, 2008, LabCorp stopped offering PreGen-Plus and indicated that it had discontinued its use of Effipure.

The decrease in total revenue for the year ended December 31, 2007 when compared to the year ended December 31, 2006, was primarily the result of a decrease of approximately $1.5 million in non-cash license fee amortization revenue resulting from the Second Amendment, which extended 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 ($4.7 million at the time of the Second Amendment) are now being recognized over a longer period of time, resulting in lower non-cash license fee amortization as compared to prior periods.

In addition, product royalty revenues were $1.3 million lower for the year ended December 31, 2007, when compared to the year ended December 31, 2006, due to charges of $1.2 million recorded in the product royalty revenue line item of our consolidated statements of operations in the year ended December 31, 2007 in connection with a certain third-party royalty reimbursement obligation to LabCorp. These charges to product royalty revenue were recorded pursuant to the Second Amendment and resulted in negative product royalty revenue for the year ended December 31, 2007. Our obligation to pay LabCorp under this provision of our amended license agreement is based on LabCorp's sales volumes of PreGen-Plus during three measurement periods over the exclusive license period, which ends in December 2010. A significant increase in PreGen-Plus test sales volumes during any of the measurement periods described under the heading "Critical Accounting Estimate Third-Party Royalty Obligation" above could reduce our obligation related to that period, while test volumes consistent with historical PreGen-Plus sales levels could result in aggregate payments to LabCorp of up to $3.5 million over the remaining exclusive license period. Based on sales volumes that we anticipated in light of the current regulatory and reimbursement status of our technology, as of December 31, 2007, we accrued

Table of Contents

$1.2 million of the total potential $1.5 million obligation related to the first measurement period, which ended in December 2008. 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.

Cost of revenue. Total cost of revenue decreased to $49,000 for the year ended December 31, 2007 from $0.8 million for the year ended December 31, 2006. Total cost of revenue includes both the cost of Effipure components sold to LabCorp as well as the cost of product royalty revenue owed to third parties for technology currently incorporated into PreGen-Plus. During 2006, we recorded charges to cost of revenue of approximately $0.7 million as a result of LabCorp's decision to discontinue use of Effipure in the processing of PreGen-Plus tests. These write-offs resulted in the decrease in cost of revenue when comparing the year ended December 31, 2007 to December 31, 2006.

As of December 31, 2007 and 2006, the carrying value of our Effipure inventory was $0. Under the terms of the Second Amendment, we may be obligated to pay LabCorp up to a maximum of $0.3 million in connection with certain costs related to Effipure, $45,000 of which was charged to cost of sales in our consolidated statements of operations for the three months ended September 30, 2007.

Research and development expenses. Research and development expenses decreased to $4.9 million for the year ended December 31, 2007 from $6.7 million for the year ended December 31, 2006. This decrease was primarily the result of the cost reduction plan undertaken in connection with the 2006 Restructuring. Pursuant to the 2006 Restructuring, we took actions to reduce our headcount across all departments in order to lower our overall cost structure and focused our research and development organization on the optimization and validation of our Version 2 technology. Included in the decrease in research and development expenses for the year ended December 31, 2007, as compared to the year ended December 31, 2006, were decreases of $0.9 million in personnel-related expenses, $0.7 million in laboratory operating costs, $0.5 million in laboratory supplies, $0.4 million in non-cash stock-based compensation charges related to employee option awards, and $0.2 million in clinical study expenses, all of which resulted from the restructuring activities discussed above. These decreases in operating expenses were partially offset by an increase in licensing costs of $0.9 million, related primarily to licenses for our Version 2 technology. This increase included approximately $0.3 million in non-cash stock-based compensation recorded in connection with the issuance of 100,000 shares of our common stock to OMS on June 14, 2007.

Sales and marketing expenses. Sales and marketing expenses decreased to $1.0 million for the year ended December 31, 2007 from $3.8 million for the year ended December 31, 2006. This decrease was the result of the elimination of our sales and marketing functions effective August 31, 2007, as described under the heading "2007 Restructuring" above.

General and administrative expenses. General and administrative expenses increased to $7.5 million for the year ended December 31, 2007, compared to $6.9 million for the year ended December 31, 2006. The increase was primarily the result of an increase of $0.5 million in non-cash stock-based compensation expense due to the acceleration of the vesting of 216,251 shares of previously unvested stock options, with a weighted average exercise price of $2.94 per share, held by Don M. Hardison, our former President and Chief Executive Officer, as well as the extension of the expiration date of all of Mr. Hardison's outstanding options, covering an aggregate of 1,025,560 shares, through August 31, 2009. Mr. Hardison resigned from the Company effective August 31, 2007, and, pursuant to a separation agreement between us and Mr. Hardison, Mr. Hardison is prohibited from selling, prior to August 31, 2009, any of the shares of common stock obtained upon the exercise of any accelerated stock options. In connection with these stock option modifications, we recorded one-time stock-based compensation charges of approximately $0.7 million in the quarter ended September 30, 2007 in accordance with the provisions of SFAS No. 123(R). Also contributing to the increase in general and administrative expenses was an increase in professional fees of $0.3 million in connection with our

Table of Contents

ongoing regulatory efforts. These increases were partially offset by a decrease of $0.2 million in salary, benefit and other costs due to a reduction in general and administrative headcount during the year ended December 31, 2007, as compared to the year ended December 31, 2006.

2007 Restructuring. In connection with the 2007 Restructuring, we recorded restructuring charges of approximately $0.8 million during the three months ended September 30, 2007 primarily related to one-time termination benefits arising under retention and severance agreements with each of the terminated employees. See "2007 Restructuring" above.

2006 Restructuring. The 2006 Restructuring was implemented to reduce employee related costs, as well as our overall research and development and sales and marketing costs, in order to preserve existing cash and cash equivalents.

Pursuant to the 2006 Restructuring, we accrued charges of $0.7 million in the quarter ended December 31, 2006 in connection with one-time employee termination benefits, including severance and outplacement services. All amounts owed pursuant to the 2006 Restructuring were paid out through September 2007 and were recorded under the caption "Accrued expenses" in the condensed consolidated balance sheets at December 31, 2006.

Interest income. Interest income decreased to $0.9 million for the year ended December 31, 2007 from $1.3 million for the year ended December 31, 2006. The decrease in interest income was due primarily to lower average cash, cash equivalents and marketable securities balances held during the year ended December 31, 2007 as compared to the year ended December 31, 2006.

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 transaction described above. As of December 31, 2008, we had approximately $4.9 million in unrestricted cash and cash equivalents and $0.6 million in restricted cash, which has been pledged as collateral for an outstanding letter of credit in connection with the lease for our Marlborough, Massachusetts facility. In addition, we received gross proceeds of $22.65 million in unrestricted cash in January 2009 upon closing of the Genzyme transaction.

All of our investments in marketable securities are comprised of fixed income investments and all are deemed available-for-sale. The objectives of this portfolio are to provide liquidity and safety of principal while striving to achieve the highest rate of return, consistent with these two objectives. Our investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer.

Net cash used in operating activities was $7.9 million, $8.8 million, and $12.2 million for the years ended December 31, 2008, 2007 and 2006, respectively. The principal use of cash in operating activities for each of the years ended December 31, 2008, 2007 and 2006 was to fund our net loss. The decrease in net cash used in operating activities for the year ended December 31, 2008 as compared to the year ended December 31, 2007, as well as for the year ended December 31, 2007 as compared to the year ended December 31, 2006, 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, 2007 and 2006, which are discussed elsewhere in this report. 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 provided by investing activities was $8.2 million, $8.0 million and $4.5 million for the years ended December 31, 2008, 2007 and 2006, respectively. Excluding the impact of purchases and

Table of Contents

maturities of marketable securities, net cash provided by investing activities was $0.2 million for the year ended December 31, 2008, compared to net cash used in investing activities of $0.1 million and $0.4 million for the years ended December 31, 2007 and 2006, respectively. 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.

Purchases of property and equipment of approximately $4,000 during the year ended December 31, 2008 were significantly lower than purchases of property and equipment for the years ended December 31, 2007 and 2006 as a result of the cost reduction efforts undertaken in 2008 discussed elsewhere in this report. As a result of the cash received in January 2009 in connection with the Genzyme Transaction and based on our plans for further development of our stool-based DNA technology for colorectal cancer detection, we expect that purchases of property and equipment during 2009 will be higher than amounts invested in 2008. Amounts invested in our patent portfolio in 2008 were materially consistent with amounts invested during 2007 and 2006. We expect that investments made in our patent portfolio during 2009 will be materially consistent with amounts invested during 2008.

Net cash provided by financing activities was $0.1 million, $0.4 million and $0.5 million for the years ended December 31, 2008, 2007 and 2006, respectively, and was the result of decreases in restricted cash in connection with the lease for our corporate headquarters and proceeds received from the issuance of common stock under our employee stock option and purchase plans.

We expect that cash and cash equivalents on hand at December 31, 2008, together with the receipt of $22.65 million in January 2009 in connection with the Genzyme transaction, will be sufficient to fund our current operations for at least the next twelve months, based on current operating plans. The projection is based on our currently anticipated cost structure and operating assumptions, which include allocations related to collection of stool samples for study purposes which would likely be used to support an FDA submission for clearance or approval of our stool-based DNA technology for colorectal cancer screening. Such allocations do not provide for the full funding of the commercial development of our stool-based DNA technology and related FDA submission and commercialization efforts or other programs and initiatives. 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. Since we have no current sources of material ongoing revenue, we believe that we will need to raise additional capital to complete the development, FDA submission for clearance or approval, and commercialization of our technologies, including an FDA-approved in vitro diagnostic test for stool-based DNA colorectal cancer screening . If we are unable to obtain sufficient additional funds to enable us to fund our operations through the completion of the development of such a test, the submission to the FDA for clearance or approval of the test, and commercialization of the test, our results of operations and financial condition would be materially adversely affected and we may be required to delay such efforts and otherwise scale back our operations. 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.

Table of Contents

The table below reflects our estimated fixed obligations and commitments as of December 31, 2008:

		Payments Due by Period			
Description	**Total**	**Less Than One Year**	**1 - 3 Years**	**3 - 5 Years**	**More Than 5 Years**
		(in Thousands)			
Obligations under license and collaborative agreements	$5,832	$ 1,806	$ 2,292	$ 342	$ 1,392
Operating lease obligations	1,618	1,016	602		
Severance obligations	15	15			
Purchase obligations	192	192			
Total	$7,657	$ 3,029	$ 2,894	$ 342	$ 1,392

Obligations under license and collaboration agreements represent on-going commitments under various research collaborations and licensing agreements. This category includes a potential obligation to reimburse LabCorp for a certain third-party royalty, up to an aggregate maximum of $3.5 million, during three defined measurement periods between June 28, 2007 and December 31, 2010. Although payment of this potential obligation is dependent upon LabCorp's sales levels of PreGen-Plus and ColoSure during the measurement periods, the total potential $3.5 million obligation has been included in the table above based on historical sales levels of PreGen-Plus and current sales levels of ColoSure as of December 31, 2008. 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. Purchase obligations primarily represent a potential obligation to reimburse LabCorp for certain costs related to Effipure as well as commitments associated with our operating activities.

Severance obligations represent remaining commitments to personnel terminated in connection with the 2008 Restructuring. The table above excludes approximately $0.9 million of severance commitments which were triggered in March 2009 in connection with the departure of Mr. Luber, our President and Chief Executive Officer, effective April 2, 2009 and Mr. Carelli, our Chief Financial Officer, effective April 2, 2009, as described elsewhere in this report.

We do not have any special purpose entities or any other off-balance sheet financing arrangements.

Our anticipated future capital requirements include, but are not limited to, continued funding of our development efforts, including product development and FDA submissions, clinical and other studies required for such FDA submissions and resubmission of our CMS application for approval of our technologies, and continued investment in our intellectual property estate. Our future capital requirements may depend on many factors, including the following:

- the regulatory requirements for ColoSure, or other stool-based DNA testing services utilizing our technologies, and the timing of any required regulatory approval process;
- our ability to attract third parties to support the development of an FDA-cleared or approved product based on our technologies;
- acceptance, endorsement and formal policy approval of stool-based DNA screening for reimbursement by Medicare and other third-party payors;
- our ability to achieve milestones under our strategic agreement with LabCorp;
- a determination that additional studies surrounding our technologies are needed;

a sustained level of interest and commitment by LabCorp in the commercialization of our technologies;

Table of Contents

stool-based DNA screening becoming a standard of care among prescribing physicians;

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

opportunities to license additional third-party intellectual property;

threats posed by competing technologies;

new out-licensing arrangements relating to our technologies; and

the successful commercialization and sales growth of ColoSure, or other stool-based DNA testing services utilizing our technologies.

Additionally, LabCorp could decide, or be required, to stop offering ColoSure, or could decide to stop offering ColoSure until it has been approved or cleared by the FDA, if ever. Either of these situations will limit our revenue and materially adversely affect our business and cash reserves.

Net Operating Loss Carryforwards

As of December 31, 2008, we had net operating loss carryforwards of approximately $146.5 million and tax credit carryforwards of approximately $3.3 million. The net operating loss and tax credit carryforwards will expire at various dates through 2028, if not utilized. The Internal Revenue Code and applicable state laws impose substantial restrictions on a corporation's utilization of net operating loss and tax credit carryforwards if an ownership change is deemed to have occurred.

A valuation allowance is provided for deferred tax assets if it is more likely than not these items will either expire before we are able to realize their benefit, or that future deductibility is uncertain. In general, companies that have a history of operating losses are faced with a difficult burden of proof on their ability to generate sufficient future income within the next two years 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, 2008, we had no off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk is principally confined to our cash, cash equivalents and marketable securities. We invest our cash, cash equivalents and marketable securities in securities of the U.S. governments and its agencies and in investment-grade, highly liquid investments consisting of commercial paper, bank certificates of deposit and corporate bonds, all of which are currently invested in the United States and, as of December 31, 2007, 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.

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

Table of Contents

Item 8. Financial Statements and Supplementary Data

EXACT SCIENCES CORPORATION

Index to Financial Statements

Table of Contents

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of EXACT Sciences Corporation:

We have audited the accompanying consolidated balance sheets of EXACT Sciences Corporation as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three 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 2007, and the consolidated results of its operations and its cash flows for each of the three 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

Table of Contents

EXACT SCIENCES CORPORATION

Consolidated Balance Sheets

(Amounts in thousands, except share data)

	December 31, 2008	December 31, 2007
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 4,937	$ 4,486
Marketable securities		8,101
Prepaid expenses and other current assets	190	275
Total current assets	5,127	12,862
Property and Equipment, at cost:		
Laboratory equipment	174	3,730
Office and computer equipment	13	1,420
Leasehold improvements		1,161
Furniture and fixtures		299
	187	6,610
Less Accumulated depreciation and amortization	(111)	(6,009)
	76	601
Patent costs, net of accumulated amortization of $2,820 and $3,019 at December 31, 2008 and 2007, respectively	95	432
Restricted cash	600	700
	$ 5,898	$ 14,595
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current Liabilities:		
Accounts payable	$ 683	$ 245
Accrued expenses	1,498	2,811
Third party royalty obligation, current portion	1,500	
Deferred license fees, current portion	1,350	1,350
Total current liabilities	5,031	4,406
Third party royalty obligation, less current portion	1,950	1,200
Deferred license fees, less current portion	1,350	2,701
Commitments and contingencies		
Stockholders' (Deficit) Equity:		
Preferred stock, $0.01 par value		
Authorized 5,000,000 shares		
Issued and outstanding 0 shares at December 31, 2008 and 2007		
Common stock, $0.01 par value		
Authorized 100,000,000 shares		
Issued and outstanding 27,522,931 and 27,225,541 shares at December 31, 2008 and December 31, 2007, respectively	275	273
Additional paid-in capital	169,854	168,813
Treasury stock, at cost, 85,550 shares	(97)	(97)
Other comprehensive income		23

Accumulated deficit	(172,465)	(162,724)
Total stockholders' (deficit) equity	(2,433)	6,288
	$ 5,898	$ 14,595

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

Table of Contents

EXACT SCIENCES CORPORATION

Consolidated Statements of Operations

(Amounts in Thousands, except per share data)

	Year Ended December 31,		
	2008	**2007**	**2006**
Revenue:			
Product royalty fees	$ (2,234)	$ (1,137)	$ 179
License fees	1,351	2,857	4,363
Product	16	78	208
	(867)	1,798	4,750
Cost of revenue:			
Product royalty fees	1	4	12
Product		45	797
	1	49	809
Gross (loss) profit	(868)	1,749	3,941
Operating expenses:			
Research and development(1)	2,034	4,887	6,735
General and administrative(1)	6,469	7,541	6,910
Sales and marketing(1)		991	3,792
Restructuring(1)	602	1,177	671
	9,105	14,596	18,108
Loss from operations	(9,973)	(12,847)	(14,167)
Interest income	232	888	1,252
Net loss	$ (9,741)	$ (11,959)	$ (12,915)
Net loss per share basic and diluted	$ (0.36)	$ (0.44)	$ (0.49)
Weighted average common shares outstanding basic and diluted	27,212	26,945	26,509

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

Research and development	$ 89	$ 541	$ 653
General and administrative	918	1,889	1,397
Sales and marketing		202	956
Restructuring	3	174	

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

64

Table of Contents

EXACT SCIENCES CORPORATION
Consolidated Statements of Stockholders' (Deficit) Equity
(Amounts in thousands, except per 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, 2006	26,436,498	$ 264	$ 162,349	85,550	$ (97)	$ (45)	$ (137,850)	$ 24,621	
Issuance of shares under stock purchase plan	46,520	1	90					91	$
Exercise of common stock options	247,500	2	160					162	
Issuance of common stock to fund the Company's 2005 401(k) match	85,800	1	183					184	
Compensation expense related to issuance of stock options and restricted stock awards	47,045	1	2,763					2,764	
Net loss							(12,915)	(12,915)	(12,915)
Other comprehensive income						51		51	51
Comprehensive loss									$ (12,864)
Balance, December 31, 2006	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 8)			852					852	
Net loss							(11,959)	(11,959)	(11,959)
Other comprehensive income						17		17	17
Comprehensive loss									$ (11,942)
Balance, December 31, 2007	27,225,541	$ 273	$ 168,813	85,550	$ (97)	$ 23	$ (162,724)	$ 6,288	
Exercise of common stock options	5,979		7					7	
Issuance of common stock to fund the Company's 2007 401(k) match	27,660		59					59	
Compensation expense related to issuance of stock options and restricted stock awards	263,751	2	972					974	
Compensation expense related to stock option modifications (Note 8)			3					3	
Net loss							(9,741)	(9,741)	(9,741)
Other comprehensive loss						(23)		(23)	(23)
Comprehensive loss									$ (9,764)
Balance, December 31, 2008	27,522,931	$ 275	$ 169,854	85,550	$ (97)	$	$ (172,465)	$ (2,433)	

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

65

Table of Contents

EXACT SCIENCES CORPORATION

Consolidated Statements of Cash Flows

(Amounts in thousands)

	Year Ended December 31,		
	2008	**2007**	**2006**
Cash flows from operating activities:			
Net loss	$ (9,741)	$(11,959)	$(12,915)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and write-offs of fixed assets	189	228	454
Restructuring	66	85	
Amortization and write-offs of patents	437	385	901
Stock-based compensation	1,010	2,806	3,006
Amortization of deferred license fees	(1,351)	(2,857)	(4,363)
Changes in assets and liabilities:			
Prepaid expenses and other current assets	85	111	772
Accounts payable	438	87	(310)
Accrued expenses	(1,287)	1,147	301
Third party royalty obligation	2,250	1,200	
Net cash used in operating activities	(7,904)	(8,767)	(12,154)
Cash flows from investing activities:			
Purchases of marketable securities	(3,458)	(20,686)	(31,381)
Maturities of marketable securities	11,536	28,846	36,300
Purchases of property and equipment	(4)	(78)	(149)
Proceeds from sales of fixed assets	274	8	
Increase in patent costs and other assets	(100)	(54)	(245)
Net cash provided by investing activities	8,248	8,036	4,525
Cash flows from financing activities:			
Proceeds from exercise of common stock options and stock purchase plan	7	286	253
Decrease in restricted cash	100	100	220
Net cash provided by financing activities	107	386	473
Net increase (decrease) in cash and cash equivalents	451	(345)	(7,156)
Cash and cash equivalents, beginning of period	4,486	4,831	11,987
Cash and cash equivalents, end of period	$ 4,937	$ 4,486	$ 4,831
Supplemental disclosure of non-cash investing and financing activities:			
Issuance of 27,660 shares of common stock to fund the Company's 401(k) matching contribution for 2007	$ 59	$	$
Issuance of 34,030 shares of common stock to fund the Company's 401(k) matching contribution for 2006	$	$ 102	$
	$	$ 466	$

Issuance of 156,675 shares of restricted common stock to collaborators in lieu of cash payments			
Issuance of 85,800 shares of common stock to fund the Company's 401(k) matching contribution for 2005	$	$	$ 184

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

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008

(Amounts in thousands, except share and per share data)

(1) ORGANIZATION AND BASIS OF PRESENTATION

Organization

EXACT Sciences Corporation (the "Company") was incorporated in February 1995. The Company has developed proprietary DNA-based technologies for use in the detection of cancer. The Company has selected colorectal cancer as the first application of its technologies. The Company has licensed certain of its technologies, including improvements to such technologies, on an exclusive basis through December 2010 to Laboratory Corporation of America® Holdings ("LabCorp®") for use in a commercial testing service for the detection of colorectal cancer developed by LabCorp. LabCorp's first generation testing service, "PreGen-Plus ," was a non-invasive stool-based DNA testing service for the detection of colorectal cancer in the average-risk population and was marketed by LabCorp from August 2003 through June 1, 2008. In July 2008, LabCorp began offering "ColoSure ", its new non-invasive laboratory developed stool- based DNA testing service for the detection of colorectal cancer in the average-risk population, which is based on the Vimentin gene, a methylated DNA marker that in published studies was shown to be associated with colorectal cancer. The Company has devoted the majority of its efforts to date on research and development and commercialization support of its colorectal cancer detection technologies.

As fully described in Note 15 below, the Company entered into a strategic transaction with Genzyme Corporation (the "Genzyme Strategic Transaction") on January 27, 2009, pursuant to which Genzyme acquired certain intellectual property assets related to the fields of prenatal and reproductive health and licensed certain intellectual property outside the fields of colorectal cancer screening and stool-based DNA detection. Genzyme also purchased 3.0 million shares of the Company's common stock. Pursuant to the strategic transaction, EXACT retained worldwide rights to its colorectal cancer screening and stool-based DNA testing intellectual property, and will receive a share of Genzyme's sublicensing income derived from the purchased intellectual property outside the fields of prenatal and reproductive health.

The Genzyme Strategic Transaction provides for the Company to receive up to $24.5 million in cash in total. On January 27, 2009, the Company received $16.65 million, with an additional $1.85 million to be received over the next 18 months, contingent upon the non-occurrence of certain events, in exchange for the sale and license of certain of the Company's intellectual property assets, including those relating to reproductive and prenatal health. In addition, at closing, Genzyme purchased 3.0 million shares of EXACT common stock at $2.00 per share for an aggregate purchase price of $6.0 million.

The Company expects that cash and cash equivalents on hand at December 31, 2008, together with the receipt of $22.65 million in January 2009 in connection with the Genzyme transaction, will be sufficient to fund its current operations for at least the next twelve months, based on current operating plans. The projection is based on the Company's currently anticipated cost structure and operating assumptions, which include allocations related to collection of stool samples for study purposes which would likely be used to support an FDA submission for clearance or approval of the Company's stool-based DNA technology for colorectal cancer screening. Such allocations do not provide for the full funding of the commercial development of the Company's stool-based DNA technology and related FDA submission and commercialization efforts or other programs and initiatives. We do not expect that product royalty payments or milestone payments from LabCorp will materially supplement the Company's liquidity position in the next twelve months, if at all. Since the Company has no current

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(1) ORGANIZATION AND BASIS OF PRESENTATION (Continued)

sources of material ongoing revenue, it believes that it will need to raise additional capital to complete the development, FDA submission for clearance or approval, and commercialization of its technologies, including an FDA-approved in vitro diagnostic test for stool-based DNA colorectal cancer screening. If the Company is unable to obtain sufficient additional funds to enable us to fund its operations through the completion of the development of such a test, the submission to the FDA for clearance or approval of the test, and commercialization of the test, the Company's results of operations and financial condition would be materially adversely affected and it may be required to delay such efforts and otherwise scale back operations. Even if the Company successfully raises sufficient funds to continue our operations to fund the development, FDA submission, and commercialization of its technology, including an FDA-approved in vitro diagnostic test for stool-based DNA colorectal cancer screening, the Company cannot assure you that its business will ever generate sufficient cash flow from operations to become profitable.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The consolidated financial statements include the accounts of the Company's wholly-owned subsidiary, EXACT Sciences Securities Corporation, a Massachusetts securities corporation. All significant intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly-liquid investments with maturities of 90 days or less at the time of acquisition to be cash equivalents. Cash equivalents primarily consist of money market funds.

Restricted Cash

At December 31, 2008 and 2007, approximately $0.6 million and $0.7 million, respectively, of the Company's cash has been pledged as collateral for an outstanding letter of credit in connection with the lease for the Company's corporate headquarters.

Marketable Securities

The Company accounts for its investments in marketable securities in accordance with Statement of Financial Accounting Standards ("SFAS") No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. Management determines the appropriate classification of debt securities at the time of purchase and re-evaluates such designation as of each balance sheet date. Debt securities are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

maturity. Marketable equity securities and debt securities not classified as held-to-maturity are classified as available-for-sale. Available-for-sale securities are carried at fair value, with the unrealized gains and losses, net of tax, reported in other comprehensive income. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity computed under the effective interest method. Such amortization is included in investment income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in investment income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in investment income.

All of the Company's investments 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. The Company's investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer. There were no realized gains or losses on the sales of available-for sale securities during the years ended December 31, 2008, 2007 or 2006.

The Company held no marketable securities as of December 31, 2008. Marketable securities consisted of the following at December 31, 2007. Amounts included in the table are in thousands.

	Amortized Cost			Gross Unrealized		
	Due Under One Year	Due After One Year	Amortized Cost	Gains	Losses	Aggregate Fair Value
2007						
Corporate debt securities	$ 8,078	$	$ 8,078	$ 23	$	$ 8,101
Total	$ 8,078	$	$ 8,078	$ 23	$	$ 8,101

Property and Equipment

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

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

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Patent Costs

Patent costs, which have historically consisted of related legal fees, are capitalized as incurred and are amortized beginning when patents are approved over an estimated useful life of five years. Capitalized patent costs are expensed upon disapproval, upon a decision by the Company to no longer pursue the patent or when the related intellectual property is deemed to be no longer of value to the Company.

The following table summarizes activity with respect to the Company's capitalized patents for the years ended December 31, 2008, 2007 and 2006. Amounts included in the table are in thousands.

Balance, January 1, 2006	$1,419
Patent costs capitalized	245
Amortization of patents	(591)
Write-offs of patents	(310)
Balance, December 31, 2006	763
Patent costs capitalized	54
Amortization of patents	(148)
Write-offs of patents	(237)
Balance, December 31, 2007	432
Patent costs capitalized	100
Amortization of patents	(72)
Write-offs of patents	(365)
Balance, December 31, 2008	$ 95

The Company does not expect material amortization expense related to issued patents beyond December 31, 2008 as a result of the sale of intellectual property to Genzyme in January 2009.

The Company applies SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets and for Long-Lived Assets* ("SFAS No. 144"), which requires the Company to continually evaluate whether events or circumstances have occurred that indicate that the estimated remaining useful life of long-lived assets and certain identifiable intangibles and goodwill may warrant revision or that the carrying value of these assets may be impaired.

During the quarters ended June 30 and December 31, 2008, the Company evaluated certain events which indicated that the remaining useful life or the carrying value of the Company's patent portfolio might have been impaired. After performing the requisite impairment analyses, the Company wrote off approximately $253,000 in capitalized patents during the quarter ended June 30, 2008 related specifically to one of the components of its Version 2 technology that is not used in LabCorp's current ColoSure testing service, and wrote off an additional $112,000 in capitalized patents during the quarter ended December 31, 2008 due to uncertainty around the near term recoverability of those capitalized patent costs.

70

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

The majority of the remaining net book value of the patent portfolio at December 31, 2008 related to intellectual property sold to Genzyme in January 2009 as part of the Genzyme Strategic Transaction. See Note 15 for description of the Genzyme Strategic Transaction.

Net Loss Per Share

Basic and diluted net loss per share is presented in conformity with SFAS No. 128, *Earnings per Share* ("SFAS No. 128"), for all periods presented. In accordance with SFAS No. 128, basic net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted average common shares outstanding during the period, less shares subject to repurchase. Basic and diluted net loss per share are the same because all outstanding common stock equivalents have been excluded, as they are anti-dilutive.

The following potentially issuable common shares were not included in the computation of diluted net loss per share for the following years ended December 31 because they had an antidilutive effect due to net losses for such periods:

	2008	2007	2006
Shares issuable upon exercise of stock options	3,703,899	3,996,688	4,125,940
Shares issuable upon exercise of outstanding warrants		1,000,000	1,000,000
	3,703,899	4,996,688	5,125,940

Accounting for Stock-Based Compensation

The Company adopted SFAS No. 123 (revised 2004), *Share-Based Payment,* ("SFAS No. 123(R)") effective January 1, 2006 using the modified prospective transition method. SFAS No. 123(R) requires 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), to be recognized in the financial statements based on their fair values. SFAS No. 123(R) did not change the accounting guidance for share-based payment transactions with parties other than employees provided in SFAS No. 123, as originally issued, and EITF 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. Prior to January 1, 2006, the Company accounted for its stock-based compensation plans under the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*.

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, the Company entered into an amendment to its exclusive license agreement with LabCorp (the "Second Amendment") that, among other modifications to the terms of the license, extended the exclusive license period from August 2008 to December 2010, subject to carve-outs for certain named organizations. See Note 4. Accordingly, the Company amortizes the remaining deferred revenue balance resulting from its license agreement with LabCorp at the time of the Second Amendment ($4.7 million) on a straight-line basis over the remaining exclusive license period, which ends in December 2010.

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Product royalty fees The Company has licensed certain of its technologies, including improvements to such technologies, on an exclusive basis through December 2010 to LabCorp. LabCorp developed and commercially offered PreGen-Plus, a non-invasive stool-based DNA colorectal cancer screening service for the average-risk population based on the Company's Version 1 technology, from August 2003 through June 2008. In June 2008, LabCorp stopped offering PreGen-Plus and, on July 14, 2008, LabCorp began to commercially offer ColoSure, its next generation non-invasive, stool-based DNA testing service for the detection of colorectal cancer in the average-risk population, which is based on certain of the Company's intellectual property. The Company will be entitled to the same royalty and milestone structure on any sales of ColoSure as it was entitled to on sales of PreGen-Plus.

Prior to the effective date of the Second Amendment, the Company's product royalty fees were based on a specified contractual percentage of LabCorp's cash receipts from performing PreGen-Plus tests. Accordingly, the Company recorded product royalty fees based on this specified percentage of LabCorp's cash receipts, as reported to the Company each month by LabCorp. Subsequent to the effective date of the Second Amendment, the Company's product royalty fees are based on a specified contractual percentage of LabCorp's net revenues from sales of PreGen-Plus through June 1, 2008, when LabCorp stopped offering PreGen-Plus, and from sales of ColoSure from and after July 2008. Accordingly, subsequent to the effective date of the Second Amendment, the Company records product royalty fees based on the specified contractual percentage of LabCorp's net revenues from its sales of such colorectal cancer screening tests, as reported to the Company each month by LabCorp. The current royalty rate is 15%, subject to an increase to 17% in the event that LabCorp achieves a specified significant threshold of annual net revenues from the sales of such colorectal cancer screening tests.

Additionally, pursuant to the Second Amendment, the Company will potentially be obligated to reimburse LabCorp for certain third-party royalty payments, as described in Note 4 below. To the extent the Company incurs liabilities in connection with this provision of the Second Amendment, the accretion of such liabilities will be recorded as a reduction in the product royalty fee line item in the Company's consolidated statements of operations.

Product revenue Product revenue from the sale of certain components of the Company's Effipure technology to LabCorp was recognized upon transfer of the components provided that title passed, the price was fixed or determinable and collection of the receivable was probable. LabCorp has indicated that Effipure is not used as a component in LabCorp's ColoSure offering and the Company therefore does not expect to record product revenue in connection with Effipure sales in future periods.

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

Advertising Costs

The Company expenses the costs of media advertising at the time the advertising takes place. The Company expensed approximately $0, $0.1 million, and $0.1 million of media advertising during the years ended December 31, 2008, 2007 and 2006, respectively.

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Comprehensive Income

SFAS No. 130, *Reporting Comprehensive Income*, establishes presentation and disclosure requirements for comprehensive income (loss). For the Company, comprehensive loss consists of net loss and the change in unrealized gains and losses on marketable securities.

Segment Information

SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*, requires companies to report selected information about operating segments, as well as enterprise-wide disclosures about products, services, geographic areas and major customers. Operating segments are determined based on the way management organizes its business for making operating decisions and assessing performance. The Company has determined that it conducts its operations in one business segment. The Company conducts its business in the United States. As a result, the financial information disclosed herein represents all of the material financial information related to the Company's principal operating segment.

Fair Value of Financial Instruments

SFAS No. 107, *Disclosures about Fair Value of Financial Instruments*, requires disclosures about fair value of financial instruments. Financial instruments consist of cash, cash equivalents, marketable securities and accounts payable. Marketable securities are carried at fair value. The estimated fair value of all other financial instruments approximates their carrying values due to their short-term maturity.

Fair Value Measurements

In September 2006, the FASB issued Statement No. 157, *Accounting for Fair Value Measurements* ("SFAS No. 157"). SFAS No. 157 clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements are separately disclosed by level within the fair value hierarchy. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company adopted SFAS No. 157 on January 1, 2008 and it did not have any impact on its consolidated results of operations, financial position or cash flows.

SFAS No. 157 establishes a fair value hierarchy that prioritizes the inputs used to measure fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs. Observable inputs are inputs that reflect the assumptions that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances.

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

The three levels of the fair value hierarchy established by SFAS No. 157 in order of priority are as follows:

Level 1 Quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access as of the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

Level 2 Pricing inputs other than quoted prices in active markets included in Level 1, which are either directly or indirectly observable as of the reporting date. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3 Unobservable inputs that reflect the Company's assumptions about the assumptions that market participants would use in pricing the asset or liability. Unobservable inputs shall be used to measure fair value to the extent that observable inputs are not available.

As of December 31, 2008, the Company's balance sheet contained no assets or liabilities requiring fair value measurement disclosures pursuant to the provisions of SFAS No. 157. Cash and cash equivalents are recorded at cost, which approximates fair value. Cash equivalents at December 31, 2008 consist of money market funds and short term commercial paper.

Concentration of Credit Risk

SFAS No. 105, *Disclosure of Information about Financial Instruments with Off-Balance-Sheet Risk and Financial Instruments with Concentrations of Credit Risk*, requires disclosure of any significant off-balance-sheet risk and credit risk concentration. The Company has no significant off-balance-sheet risk, such as foreign exchange contracts or other hedging arrangements. Financial instruments that subject the Company to credit risk consist of cash, cash equivalents and marketable securities. The Company maintains its cash equivalents with financial institutions with high credit ratings.

During 2008, 2007, and 2006 all of the Company's revenues were derived from its license agreement with LabCorp.

Recent Accounting Pronouncements

In November 2007, the FABS issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements* ("EITF 07-1"), which defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties, including the appropriate income statement presentation and classification of, and the required disclosures related to, these arrangements. EITF 07-1 is effective January 1, 2009, to be applied retrospectively for collaborative arrangements existing as of the effective date. The Company does not anticipate that EITF 07-1 will have a material impact on our financial statements.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* ("SFAS 162"). SFAS 162 identifies the sources of accounting principles and the framework

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the U. S. SFAS 162 is effective 60 days following the SEC approval of Public Company Accounting Oversight Board ("PCAOB") amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. The Company does not anticipate that SFAS 162 will have a material impact on the Company's financial statements.

Reclassifications

Certain prior year expenses previously included in the "sales and marketing" line item in the Company's consolidated statements of operations have been reclassified as "general and administrative" expenses to conform to the current year presentation. This change had no impact on the Company's net loss or net loss per share as previously reported.

(3) COLORECTAL CANCER SCREENING GUIDELINES

Professional colorectal cancer screening guidelines in the United States, including those of the American Cancer Society ("ACS"), the American College of Gastroenterology and the American Gastroenterological Association, recommend regular screening by a variety of methods. Historically, such recommendations consisted of colonoscopy, flexible sigmoidoscopy, double contrast barium enema and fecal occult blood testing (FOBT), as well as combinations of some of these methods. On March 5, 2008, the ACS, the U.S. Multi-Society Task Force on Colorectal Cancer, a consortium of several organizations including 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 (the "MSTF-CRC"), and the American College of Radiology announced that non-invasive, stool-based DNA screening technology has been 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 above, a population of approximately 89 million Americans. These new guidelines now divide colorectal cancer screening into two groups, one including non-invasive methods for the early detection of colorectal cancer and the other including invasive techniques for the prevention and early detection of colorectal cancer. Non-invasive technologies include fecal occult blood testing and stool-based DNA screening for individuals unwilling or unable to use invasive screening procedures. Invasive procedures include colonoscopy, flexible sigmoidoscopy, CT colonography, and double contrast barium enema and, according to the new guidelines, are designed to detect both early cancer and adenomatous polyps and should be encouraged if resources are available and patients are willing to undergo an invasive test. While the Company views inclusion of its stool-based DNA technology in the ACS and MSTF-CRC guidelines as a critical first step toward building sufficient demand for any stool-based DNA screening test for colorectal cancer, the Company believes that FDA clearance for its technologies, and reimbursement from the Centers for Medicare and Medicaid Services and other third-party payors will be necessary to achieve any significant increase in demand for its technologies. In addition, the ACS and MSTF-CRC guidelines indicated that new technologies and new technical versions of approved technologies need only detect a majority of colorectal cancers in a screening population to meet guidelines criteria. The Company has not performed a stand-alone colorectal cancer screening study of LabCorp's ColoSure test and there can be no assurance that the guidelines groups will agree that

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(3) COLORECTAL CANCER SCREENING GUIDELINES (Continued)

existing studies using the Company's Version 2 technologies, and any related data supporting ColoSure, will meet the requirements set forth in the current ACS and MSTF-CRC guidelines for inclusion of such technologies in future guidelines of such organizations. If the guidelines groups indicate a lack of acceptance for these more advanced technologies, such action could have a materially adverse impact on the Company's business.

(4) STRATEGIC ALLIANCE AGREEMENT

On June 26, 2002, the Company entered into a license agreement (subsequently amended on January 19, 2004, June 27, 2007, August 31, 2007, and March 17, 2008) with LabCorp for an exclusive, strategic alliance between the parties to commercialize LabCorp's proprietary, non-invasive DNA-based technologies for the early detection of colorectal cancer in the average-risk population. Pursuant to the amended agreement, the Company exclusively licensed to LabCorp all U.S. and Canadian patents and patent applications owned by the Company relating to its stool-based colorectal cancer screening technology initially through August 2008, followed by a non-exclusive license for the life of the patents. In return for the license, LabCorp agreed to pay the Company certain up-front, milestone and performance-based payments, and a per-test royalty fee. LabCorp made an initial payment of $15 million upon the signing of the agreement, and a second payment of $15 million was made in August 2003 upon the commercial launch of PreGen-Plus. In addition to certain royalty fees, under the amended license agreement, the Company may also be eligible for certain milestone payments from LabCorp as described below.

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

At the time of issuance, the LabCorp Warrant had an expiration date of June 26, 2005. On June 24, 2005, the Company entered into an amendment to the LabCorp Warrant to extend the expiration date of the LabCorp Warrant to August 13, 2008, which was the expiration date of the exclusive period at the time of the extension. All other terms of the LabCorp Warrant were unaffected. The Company assigned a value to the LabCorp Warrant extension of $0.6 million using the Black-Scholes option pricing model. In accordance with Emerging Issues Task Force Issue No. 01-09, *Accounting for Consideration Given by a Vendor to a Customer* ("EITF No. 01-09"), the Company recorded the cost of the LabCorp Warrant extension as a one-time, non-cash reduction in license fee revenue of $0.6 million in the quarter ended June 30, 2005 The LabCorp Warrant expired unexercised on August 13, 2008.

Second Amendment to LabCorp License Agreement On June 27, 2007, the Company entered into the Second Amendment with LabCorp. The Second Amendment modified LabCorp's exclusive rights to the Company's DNA technology for colorectal cancer screening to permit the Company to license its technology to select third-party organizations and commercial service laboratories, subject to LabCorp's preferential pricing terms, and to extend LabCorp's modified exclusive period under the Second

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(4) STRATEGIC ALLIANCE AGREEMENT (Continued)

Amendment until December 31, 2010. Additionally, the Second Amendment clarifies the rights and obligations with respect to the Company's second-generation stool-based DNA screening technology for colorectal cancer screening ("Version 2").

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

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

Pursuant to the terms of the Second Amendment, the Company will potentially be obligated to reimburse LabCorp for certain third-party royalty payments if LabCorp's third-party royalty rate is greater than a specified royalty rate during the measuring period, as outlined in the table below. The Company's obligation to pay LabCorp pursuant to this provision of the Second Amendment is based on LabCorp's sales volumes of colorectal cancer screening tests using the Company's technology during three separate measurement periods, as defined below. A significant increase in such sales volumes during any measurement period, as compared to historical PreGen-Plus sales volumes, could reduce the Company's potential obligation during any measurement period, while test volumes consistent with historical PreGen-Plus sales levels could result in aggregate payments to LabCorp totaling up to $3.5 million during the measurement periods. Until LabCorp's sales of colorectal cancer screening tests using the Company's technology increase to a level that would reduce this potential maximum obligation, if ever, the Company intends to record its estimated obligation under this provision of the Second Amendment as a reduction in the product royalty fee line item in its consolidated statements of operations, in accordance with EITF No. 01-09. Based on sales volumes of PreGen-Plus through June 1, 2008 (when LabCorp ceased selling this service) and anticipated sales volumes of ColoSure, as of December 31, 2008, the Company had accrued a total of $3.45 million related to the total potential $3.5 million obligation to LabCorp. The Company recorded charges of $2.25 million and $1.2 million during the years ended December 31, 2008 and 2007, respectively, in connection with this third-party royalty obligation. These charges were recorded under the caption "Product royalty fees" in the Company's consolidated statements of operations. Future increases in this obligation, to the extent

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(4) STRATEGIC ALLIANCE AGREEMENT (Continued)

necessary, will continue to be recorded as charges to the product royalty revenue line item of the Company's consolidated statements of operations. Amounts included in the table are in thousands.

Measurement period Start Date	Measurement period End Date	Payment Due Date for Measurement Period	Potential Minimum Third Party Royalty Obligation During Measurement Period	Potential Maximum Third Party Royalty Obligation During Measurement Period
June 28, 2007	December 31, 2008	January 30, 2009	$	$ 1,500
January 1, 2009	December 31, 2009	January 30, 2010		1,000
January 1, 2010	December 31, 2010	January 30, 2011		1,000
			$	$ 3,500

In addition, as a result of extending the exclusive license period from August 2008 to December 2010, the amortization of the remaining deferred revenue as of the date of the Second Amendment ($4.7 million) related to up-front technology license fees received from LabCorp is amortized on a straight line basis over the extended exclusive license period beginning in the quarter ended September 30, 2007. Additionally, pursuant to the Second Amendment, the Company could be obligated to reimburse LabCorp for certain costs related to Effipure, up to a maximum of $0.3 million during the term of the exclusive period. The Company recorded a liability of $45,000 pursuant to this provision of the Second Amendment during the year ended December 31, 2007 under the caption "Cost of product revenue" in its consolidated statements of operations.

The Second Amendment also provided LabCorp with termination rights if stool-based colorectal cancer screening is not accepted as standard of care in the near term (i.e. included in screening guidelines of the American Cancer Society or the American Gastroenterological Association), if the Company's Version 2 technology is not commercially launched in the near term, or if the Company's Version 2 technology does not attain certain sensitivity and specificity thresholds during technology validation.

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

Fourth Amendment to LabCorp License Agreement On March 17, 2008, the Company entered into the fourth amendment (the "Fourth Amendment") to its exclusive license agreement with LabCorp. Among other things, the Fourth Amendment further clarified certain license rights of the parties, amended LabCorp's termination rights relating to the failure to launch the Company's Version 2 technology and restricted certain of the Company's termination rights in the event the FDA limits

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(4) STRATEGIC ALLIANCE AGREEMENT (Continued)

LabCorp's ability to market products that incorporate technology licensed to LabCorp under the amended license agreement. In addition, the Fourth Amendment eliminated certain of the Company's termination rights for a specified period of time during which LabCorp is not marketing any stool-based DNA test for colorectal cancer as a result of preparing for a commercial launch of a stool-based DNA test for colorectal cancer based on the Company's Version 2 technology.

(5) RESTRUCTURING

The Company accounts for its restructuring charges in accordance with SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* ("SFAS No. 146"). SFAS No. 146 requires that a liability for a cost associated with an exit or disposal activity be recognized and measured initially at its fair value in the period in which the liability is incurred, except for one-time termination benefits that meet specified requirements.

2006 Restructuring In October 2006, the Company initiated a plan to reduce its cost structure by eliminating 21 positions, or 48% of its staff at that time, across all departments (the "2006 Restructuring"). This workforce reduction was intended to reduce the Company's expenses and help preserve its existing cash and cash equivalents

Pursuant to the 2006 Restructuring, the Company accrued charges of $0.7 million in the quarter ended December 31, 2006 in connection with one-time employee termination benefits, including severance and outplacement services. The Company recorded changes in estimates to the restructuring accrual as outlined in the table below during the year ended December 31, 2007 in connection with adjustments to estimates of one-time employee termination benefits.

As of December 31, 2007, all liabilities related to the 2006 Restructuring had been paid. The following table summarizes the restructuring activities during the year ended December 31, 2007. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2006	Charges	Cash Payments	Non-cash Write-offs	Balance, December 31, 2007
Employee separation costs	$ 283	$ 26	$ (309)	$	$
Total	$ 283	$ 26	$ (309)	$	$

2007 Restructuring During the third quarter of 2007, in connection with the Third Amendment to the LabCorp agreement, the Company notified six employees of their termination from the Company (the "2007 Restructuring"). The 2007 Restructuring was principally designed to eliminate the Company's sales and marketing functions to reduce costs and help preserve the Company's cash resources. In connection with the 2007 Restructuring, the Company recorded restructuring charges of approximately $0.8 million during the three months ended September 30, 2007, primarily related to one-time termination benefits arising under retention and severance agreements with each of the terminated employees.

Restructuring charges recorded during the third quarter of 2007 of $0.8 million included $0.6 million in severance and related benefit costs which were paid in cash through May 2008, and

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(5) RESTRUCTURING (Continued)

$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. See Note 8 for a description of stock option modifications which occurred in the year ended December 31, 2007.

During the fourth quarter of 2007, the Company entered into a sublease agreement (the "2007 Sublease Agreement") with INTRINSIX Corporation to sublease to the INTRINSIX approximately 11,834 square feet of rentable area in the Company's corporate headquarters. The term of the 2007 Sublease Agreement, which commenced on December 15, 2007, is 32 months with a base rent of $266,265 per year. Pursuant to the 2007 Sublease Agreement, INTRINSIX has no rights to renew or extend the 2007 Sublease Agreement. Under the terms of the 2007 Sublease Agreement, INTRINSIX was required to provide a security deposit of $35,000 and will be required to pay its pro rata share of any building operating expenses and real estate taxes.

In connection with the 2007 Sublease Agreement, the Company recorded restructuring charges of approximately $0.4 million during the fourth quarter of 2007 (included opposite the caption "Facility consolidation costs" in the table below), which consist of approximately $0.3 million in future cash payments related to the difference between the Company's committed lease payments and the estimated sublease rental income under the 2007 Sublease Agreement and approximately $0.1 million of non-cash charges related to the write-off of leasehold improvements abandoned by the Company in connection with the Sublease Agreement. The Company's decision to enter into the 2007 Sublease Agreement was deemed to be an impairment indicator under SFAS No. 144. As a result of performing the impairment evaluations, asset impairment charges of $0.1 million were recorded to adjust the carrying value of the related leasehold improvements to their net realizable value. Facility consolidation costs also include one time real estate transaction fees in connection with the Sublease Agreement.

Amounts remaining in the 2007 Restructuring accrual at December 31, 2008, which are expected to be paid out through July, 2010, are recorded under the caption "Accrued expenses" in the Company's condensed consolidated balance sheets. The following table summarizes the 2007 Restructuring activities during the year ended December 31, 2008. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2007	Charges	Cash Payments	Non-cash Write-offs	Balance, December 31, 2008
Employee separation costs	$ 224	$ (7)	$ (217)	$	$
Facility consolidation costs	268		(107)		161
Total	$ 492	$ (7)	$ (324)	$	$ 161

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.

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

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(5) RESTRUCTURING (Continued)

In connection with the 2008 Restructuring the Company recorded restructuring charges of approximately $0.5 million during the three months ended September 30, 2008, including $0.3 million in one-time termination benefits arising under retention and severance agreements with each of the terminated employees and $0.3 million resulting from the write-off of leasehold improvements abandoned by the Company in connection with the reduction in force. The Company's decision to eliminate 67% of its workforce was deemed to be an impairment indicator under SFAS No. 144. As a result of performing the impairment evaluations, non-cash asset impairment charges of $0.3 million were recorded to adjust the carrying value of the related leasehold improvements to their net realizable value.

In addition, in connection with the 2008 Restructuring, the Company accelerated the vesting of 15,523 shares under terminated employees' previously unvested stock options, with a weighted average exercise price of $2.65 per share, and extended the expiration date of all the terminated employees' outstanding options as of their date of termination, covering an aggregate of 181,828 shares with a weighted average exercise price of $4.50, through August 1, 2009. Pursuant to the measurement provisions of SFAS No. 123(R), the Company recorded one-time non-cash stock-based compensation charges of approximately $3,000 in the "Restructuring" line item of the Company's condensed consolidated statements of operations during the quarter ended September 30, 2008.

During the fourth quarter of 2008, the Company entered into a sublease agreement (the "2008 Sublease Agreement") with QTEROS, Inc. ("QTEROS") to sublease to QTEROS approximately 25,537 square feet of rentable area in the Company's corporate headquarters. The term of the 2008 Sublease Agreement, which commenced on December 9, 2008, is 20 months with a base rent of $625,657 per year. Pursuant to the 2008 Sublease Agreement, QTEROS has no rights to renew or extend the 2008 Sublease Agreement. Under the terms of the 2008 Sublease Agreement, QTEROS will be required to pay its pro rata share of any increases in building operating expenses and real estate taxes and to provide a security deposit in the form of an irrevocable, standby letter of credit from a national commercial bank reasonably acceptable to the Company in the amount of approximately $52,000 naming the Company as beneficiary. The 2008 Sublease Agreement provides for the Company's employees to continue to occupy approximately 1,100 square feet in the premises subleased to QTEROS. The Company believes that such 1,100 square feet are adequate to meet our space requirements with respect to administrative needs. The Company believes that the development of an FDA-approved product for colorectal cancer screening will require that it lease additional space. In this regard, the Company is currently exploring additional space in Madison, Wisconsin.

In connection with the 2008 Sublease Agreement, the Company also recorded the following restructuring charges during the fourth quarter of 2008 (included opposite the caption "Facility consolidation costs" in the table below): approximately $0.1 million in future cash payments related to the difference between the Company's committed lease payments and the estimated sublease rental income under the 2008 Sublease Agreement; approximately $0.1 million in one time real estate transaction and laboratory decommissioning fees; and approximately $0.1 million of non-cash charges related to the write-off of leasehold improvements abandoned by the Company in connection with the 2008 Sublease Agreement. These charges were offset by cash receipts of approximately $0.3 million received in connection with sales of fully depreciated fixed assets upon commencement of the 2008 Sublease Agreement.

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(5) RESTRUCTURING (Continued)

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

Type of Liability	Balance, December 31, 2007	Charges	Cash Payments	Non-cash Write-offs	Balance, December 31, 2008
Employee separation costs	$	$ 266	$ (247)	$ (3)	$ 16
Facility consolidation costs		343	(112)	(66)(1)	165
Total	$	$ 609	$ (359)	$ (69)	$ 181

(1) Amount is net of approximately $274,000 in cash received from sales of fully depreciated assets in connection with the Company's exit of certain space in its Marlborough, Massachusetts facility.

(6) EMPLOYMENT ARRANGEMENTS

In June 2006, the Company entered into an Employment Agreement with Don M. Hardison, the Company's President and Chief Executive Officer at that time. Under the Employment Agreement, Mr. Hardison was paid an annual salary of $0.36 million and was eligible to earn an annual performance bonus on the basis of the achievement of certain Company and personal objectives. Additionally, Mr. Hardison was eligible to earn an annual retention bonus in the amount of $0.2 million, payable on each of January 1, 2007 and January 1, 2008, provided Mr. Hardison continued to be employed by the Company. The Employment Agreement provided that upon the occurrence of certain triggering events, such as a change of control or termination without cause, Mr. Hardison would have been entitled to receive any unpaid retention bonus, and severance payments for a period of twelve months at a rate equal to his base salary at the time of termination of employment. The agreement provided a term of 24 months, subject to automatic twelve month renewals unless either Mr. Hardison or the Company provided sixty days prior written notice to the other of such party's election not to extend the term of the Employment Agreement.

In July 2007, Mr. Hardison announced his resignation from the Company effective August 31, 2007. Pursuant to terms of Mr. Hardison's employment agreement with the Company, Mr. Hardison received a retention bonus payment of $0.2 million in January 2007 and the Company had accrued a proportional amount of the remaining $0.2 million retention bonus which would have been payable on January 1, 2008, if he had continued employment with the Company. As a result of Mr. Hardison's resignation from the Company in July 2007, the remaining potential retention bonus of $0.2 million was not paid out and the expense previously accrued in connection with Mr. Hardison's remaining retention bonus (approximately $0.1 million as of June 30, 2007) was reversed in the statement of operations for the three and six month periods ended June 30, 2007.

On April 18, 2008, the Company entered into amended and restated employee retention agreements (the "Agreements") with certain employees, including Jeffrey R. Luber, the Company's President and Chief Executive Officer, and Charles R. Carelli, Jr., the Company's Senior Vice

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(6) EMPLOYMENT ARRANGEMENTS (Continued)

President, Chief Financial Officer, Treasurer and Secretary. The Agreements supersede and replace the prior employee retention agreements entered into between the Company and Messrs. Luber and Carelli on October 23, 2006.

As described in Note 15 below, and in connection with the hiring of Kevin T. Conroy and Maneesh Arora as President and Chief Executive Officer and Chief Financial Officer, respectively, Jeffrey R. Luber agreed to resign as the Company's President and Chief Executive Officer and as a director on the Company's Board of Directors, in each case effective April 2, 2009. In addition, Charles R. Carelli, Jr. agreed to resign as our Chief Financial Officer, effective April 2, 2009. Messrs. Conroy and Arora will be employed by the Company as Vice Presidents until April 2, 2009, when Messrs. Luber and Carelli's departures become effective. Note 15 below includes a description of the employment agreements between the Company and Messrs. Conroy and Arora.

In connection with their departure from the Company, Messrs. Luber and Carelli were entitled to receive severance benefits pursuant to their previously disclosed retention agreements, including salary continuation of $472,500 and $287,500, which is equal to eighteen months and fifteen months, respectively, of their base salaries as of the date of termination. On March 31, 2009, the Company entered into release agreements with Messrs. Luber and Carelli that provided, in exchange for a general release in favor of the Company, for the accelerated payment of the salary continuation obligations on March 31, 2009. In addition, the release agreements also provided for the repurchase by the Company of options held by Messrs. Luber and Carelli for an aggregate of 895,000 shares of common stock, in lieu of accelerated vesting and an extension of the option exercise period arising from the prior retention agreements. The Company paid Messrs. Luber and Carelli approximately $39,000 and $11,000, respectively, to repurchase Mr. Luber's options to purchase 620,000 shares and Mr. Carelli's options to purchase 275,000 shares. The purchase price of the outstanding options represented a 75 percent discount from the estimated fair value of the vested options as of March 31, 2009. Messrs. Luber and Carelli retained the balance of their existing options, which will remain exercisable for two years following, and will be subject to nine months acceleration of vesting upon, the termination of their respective employment with the Company. The Company expects to record in its first quarter financial results the charges associated with the acceleration of the severance payments to Messrs. Luber and Carelli and the redemption and modification of their options.

(7) ISSUANCES OF COMMON STOCK

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

On March 22, 2007, pursuant to the March 19, 2007 Amendment to the license agreement between the Company and JHU, the Company issued to JHU 56,675 unregistered shares of the Company's common stock, $.01 par value per share (the "Common Stock") as payment for the

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(7) ISSUANCES OF COMMON STOCK (Continued)

minimum license fee obligation due for the six month period ended December 31, 2006. The Company recorded a non-recurring non-cash stock-based compensation charge of approximately $0.2 million in its consolidated statements of operations during the quarter ended December 31, 2006 in connection with the Common Stock issuance.

On June 14, 2007, pursuant to the terms of a Manufacturing and Supply Agreement by and between Oncomethylome Sciences S.A. ("OMS") and the Company dated June 8, 2007, the Company issued to OMS 100,000 shares of the Company's Common Stock. The Company recorded a non-recurring non-cash stock-based compensation charge of approximately $0.3 million in its consolidated statements of operations during the quarter ended June 30, 2007 in connection with the Common Stock issuance.

(8) STOCK-BASED COMPENSATION

Stock-Based Compensation Plans

1995 Stock Option Plan Under the 1995 stock option plan (the "1995 Option Plan"), the Company's board of directors could grant incentive and non-qualified stock options to purchase an aggregate of up to 3,987,500 shares of common stock to employees, directors and consultants of the Company. The exercise price of each option is determined by the board of directors. Incentive stock options may not be less than the fair market value of the stock on the date of grant, as defined by the board of directors. Options granted under the 1995 Option Plan vest over a three to five year period and expire 10 years from the grant date.

The 1995 Option Plan was terminated on January 31, 2001, the effective date of the Company's registration statement in connection with its initial public offering. Options granted prior to the date of termination remain outstanding and may be exercised in accordance with their terms. At December 31, 2008, options to purchase 346,722 shares were outstanding under the 1995 Option Plan.

2000 Stock Option Plan The Company adopted the 2000 Stock Option and Incentive Plan (the "2000 Option Plan") on October 17, 2000. At December 31, 2008, a total of 7,039,858 shares of common stock have been authorized and reserved for issuance under the 2000 Option Plan. The 2000 Option Plan provides that the number of shares authorized for issuance will automatically increase on each January 1 by (i) the greater of 5% of the outstanding number of shares of common stock on the preceding December 31, or that number of shares underlying option awards issued during the one-year period prior to such January 1, or (ii) such lesser number as may be approved by the board of directors. Under the terms of the 2000 Option Plan, the Company is authorized to grant incentive stock options, as defined under the Internal Revenue Code, non-qualified options, restricted stock awards and other stock awards to employees, officers, directors, consultants and advisors. Options granted under the 2000 Option Plan expire ten years from the date of grant. Grants made from the 2000 Option Plan generally vest monthly over a period of three to four years.

The 2000 Option Plan is administered by the compensation committee of the Company's board of directors, which selects the individuals to whom equity-based awards will be granted and determines the option exercise price and other terms of each award, subject to the provisions of the 2000 Option Plan. The 2000 Option Plan provides that upon an acquisition of the Company, all options to purchase common stock will accelerate by a period of one year. In addition, upon the termination of an

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(8) STOCK-BASED COMPENSATION (Continued)

employee without cause or for good reason prior to the first anniversary of the completion of the acquisition, all options then outstanding under the 2000 Option Plan held by that employee will immediately become exercisable. At December 31, 2008, options to purchase 3,357,177 shares were outstanding under the 2000 Option Plan and 3,258,855 shares were available for future grant under the 2000 Option Plan.

2000 Employee Stock Purchase Plan The 2000 Employee Stock Purchase Plan (the "2000 Purchase Plan") was initially adopted by the Company in October 2000, and subsequently amended and restated. The 2000 Purchase Plan provides participating employees the right to purchase common stock at a discount through a series of offering periods. The 2000 Purchase Plan provides that the number of shares authorized for issuance will automatically increase on each February 1 by (i) the greater of 0.75% of the outstanding number of shares of common stock on the immediately preceding December 31, or that number of shares issued during the one-year period prior to such February 1, or (ii) such lesser number as may be approved by the Company's board of directors. At December 31, 2008, the 2000 Purchase Plan had available an aggregate of 720,780 shares of common stock for purchase by participating employees.

The compensation committee of the Company's board of directors administers the 2000 Purchase Plan. Generally, all employees whose customary employment is more than 20 hours per week and for more than five months in any calendar year are eligible to participate in the 2000 Purchase Plan. Participating employees authorize an amount, between 1% and 15% of the employee's compensation, to be deducted from the employee's pay during the offering period. On the last day of the offering period, the employee is deemed to have exercised the option, at the option exercise price, to the extent of accumulated payroll deductions. Under the terms of the 2000 Purchase Plan, the option exercise price is an amount equal to 85% of the fair market value, as defined under the 2000 Purchase Plan and no employee can purchase more than $25,000 of the Company common stock under the 2000 Purchase Plan in any calendar year. Rights granted under the 2000 Purchase Plan terminate upon an employee's voluntary withdrawal from the 2000 Purchase Plan at any time or upon termination of employment. The Company issued the following shares of common stock under the 2000 Purchase Plan for the years ended December 31 2006 and 2007. No shares were issued under the 2000 Purchase Plan in 2008.

Offering period ended	Number of Shares	Price per Share
January 31, 2006	23,531	$ 2.22
July 31, 2006	22,989	$ 1.66
January 31, 2007	9,055	$ 1.61
July 31, 2007	7,932	$ 1.61

Adoption of SFAS No. 123(R)

The Company adopted SFAS No. 123(R) effective January 1, 2006, using the modified prospective transition method. SFAS No. 123(R) requires 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), to be recognized in the financial statements based on their fair values. SFAS No. 123(R) did not change the accounting guidance for share-based payment transactions with parties

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(8) STOCK-BASED COMPENSATION (Continued)

other than employees provided in SFAS No. 123, as originally issued and EITF 96-18. Prior to January 1, 2006, the Company accounted for its stock-based compensation plans under the provisions of Accounting Principles Board Opinion No. 25.

Stock-Based Compensation Expense

The Company recorded approximately $1.0 million in stock-based compensation during the year ended December 31, 2008 in connection with the amortization of awards of common stock, restricted common stock and stock options granted to employees, non-employee directors and non-employee consultants, the Company's 2008 401(k) match, which will be made in Company common stock in May 2009, as well as certain stock option modifications discussed below.

The Company recorded approximately $2.8 million in stock-based compensation during the year ended December 31, 2007 in connection with the amortization of awards of common stock, restricted common stock and stock options granted to employees, non-employee directors and non-employee consultants, as well as restricted common stock issued to collaborators, certain stock option modifications discussed below, and stock-based compensation expense related to the Company's 2007 401(k) match, which was made in Company common stock in May 2008.

The Company recorded stock-based compensation of $3.0 million during the year ended December 31, 2006 in connection with common stock issued to a collaborator, stock options and restricted stock awards granted to non-employee consultants and directors as well as stock-based compensation expense related to the Company's 2006 401(k) match.

The Company's annual employee grant of stock options generally occurs in February of each year, subject to board approval. The fair value of stock-based awards for the years ended December 31, 2008, 2007 and 2006 was determined as outlined below.

Determining Fair Value

Valuation and Amortization Method The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model based on the assumptions in the table below. The estimated fair value of employee stock options is amortized to expense using the straight-line method over the vesting period.

Expected Term The Company uses the simplified calculation of expected life, described in the SEC's Staff Accounting Bulletin 107, as the Company does not currently have sufficient historical exercise data on which to base an estimate of expected term. This method allows the Company to estimate the expected life 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 volatility from the time of its initial public offering in January 2001 through the measurement date of the awards.

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

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(8) STOCK-BASED COMPENSATION (Continued)

Forfeitures As required by SFAS No. 123(R), the Company records share-based compensation expense only for those awards that are expected to vest. The Company does not need to estimate forfeitures because all share based awards vest monthly.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model based on the assumptions in the following table.

	December 31,		
	2008	**2007**	**2006**
Option Plan Shares			
Risk-free interest rates	2.80% - 3.02%	4.04% - 4.60%	4.59% - 5.03%
Expected term (in years)	6	6	6
Expected volatility	70% - 75%	70%	70%
Dividend yield	0%	0%	0%
Weighted average fair value per share of options granted during the period	$1.08	$1.87	$1.67
ESPP Shares			
Risk-free interest rates	(1)	5.10% - 5.17%	4.57% - 5.22%
Expected term (in years)	(1)	0.5 - 2	0.5 - 2
Expected volatility	(1)	70%	70%
Dividend yield	(1)	0%	0%
Weighted average fair value per share of stock purchase rights granted during the period	(1)	$1.08	$0.94

(1) The Company did not issue stock purchase rights under its 2000 Purchase Plan during the period indicated.

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(8) STOCK-BASED COMPENSATION (Continued)

Stock Option Activity

A summary of stock option activity under the 1995 Option Plan and the 2000 Option Plan during the years ended 2008, 2007 and 2006 is as follows:

Options and Restricted Stock (Aggregate intrinsic value in thousands)	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value(1)
Outstanding, January 1, 2006	4,499,927	$ 6.10		
Granted	930,921	2.53		
Exercised	(294,545)	0.55		
Cancelled	(1,010,363)	6.09		
Outstanding, December 31, 2006	4,125,940	5.69		
Granted	1,362,000	2.66		
Exercised	(154,486)	1.68		
Cancelled	(1,336,766)	5.48		
Outstanding, December 31, 2007	3,996,688	4.88		
Granted	818,600	1.18		
Exercised	(84,730)	0.08		
Cancelled	(1,026,659)	5.54		
Outstanding, December 31, 2008	3,703,899	$ 3.99	4.9	$ 112
Exercisable, December 31, 2008	2,840,134	$ 4.65	3.7	$ 7
Vested and expected to vest, December 31, 2008	3,432,159	$ 3.79	4.3	$ 112

(1) The aggregate intrinsic value of options outstanding at December 31, 2008 is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for the 221,349 options that had exercise prices that were lower than the $0.57 market price of our common stock at December 31, 2008. The aggregate intrinsic value of options exercisable at December 31, 2008 is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for the 36,349 options that had exercise prices that were lower than the $0.57 market price of our common stock at December 31, 2007. The total intrinsic value of options exercised during the years ended December 31, 2008, 2007 and 2006 was $4,000, $0.1 million, and $0.5 million, respectively, determined as of the date of exercise.

The table above includes outstanding restricted stock awards of 185,000, 18,751 and 0 shares as of December 31, 2008, 2007, and 2006, respectively. The Company granted 245,000, 85,000 and 23,921 restricted stock awards during the years ended December 31, 2008, 2007, and 2006, respectively.

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(8) STOCK-BASED COMPENSATION (Continued)

Restricted common stock awards that vested and were no longer subject to restriction during the years ended December 31, 2008, 2007, and 2006 were 78,751, 66,249, and 47,045, respectively.

As of December 31, 2008, there was approximately $1.0 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under all equity compensation plans. Total unrecognized compensation cost will be adjusted for future changes in forfeitures. The Company expects to recognize that cost over a weighted average period of 1.6 years.

The Company received approximately $7,000, $0.3 million, and $0.2 million from stock option exercises during the years ended December 31, 2008, 2007 and 2006, respectively. During the years ended December 31, 2008, 2007 and 2006, zero, 16,987, and 46,520 shares, respectively, of common stock were issued under the Company's 2000 Purchase Plan resulting in proceeds to the Company of $0, $27,000, and $0.1 million, respectively.

The following table summarizes information relating to currently outstanding and exercisable stock options as of December 31, 2008:

	Outstanding			Exercisable	
Exercise Price	Number of Options	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
$ - $ 1.00	296,349	8.8	$ 0.23	67,594	$ 0.53
$1.01 - $ 2.00	376,882	8.6	$ 1.83	95,837	$ 1.83
$2.01 - $ 2.50	462,247	2.7	$ 2.09	462,247	$ 2.09
$2.51 - $ 3.00	1,274,314	5.8	$ 2.79	928,129	$ 2.76
$3.01 - $ 4.00	254,250	5.0	$ 3.46	248,138	$ 3.47
$4.01 - $ 5.00	241,044	3.1	$ 4.46	239,376	$ 4.46
$5.01 - $ 7.00	134,500	1.0	$ 6.78	134,500	$ 6.78
$7.01 - $ 9.00	387,938	1.9	$ 7.80	387,938	$ 7.80
$9.01 - $14.33	276,375	2.9	$ 13.04	276,375	$ 13.04
	3,703,899	4.9	$ 3.99	2,840,134	$ 4.65

Stock Option Modifications

2006 Modifications In connection with the October 2006 Restructuring (See Note 5), the Company's board of directors approved an extension of the exercise period of 507,148 stock options through December 31, 2007 for the 21 employees terminated as a part of the restructuring. The stock options that were modified represented only those options which were vested as of the employees' termination date (October 20, 2006). The Company did not continue to vest stock options in connection with this modification beyond the employees' termination date and did not accelerate vesting of any options prior to the termination date. Under the provisions of SFAS No. 123(R), these stock option modifications did not result in significant incremental stock-based compensation expense.

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(8) STOCK-BASED COMPENSATION (Continued)

2007 Modifications In August 2007, in connection with the 2007 Restructuring (See Note 5) and the resignation of Don M. Hardison as the Company's President and Chief Executive Officer, the Company's board of directors approved the following stock option modifications:

On August 31, 2007, the effective date of Mr. Hardison's resignation from the Company, the Company accelerated the vesting of 216,251 shares under Mr. Hardison's previously unvested stock options, with a weighted average exercise price of $2.94 per share, and extended the expiration date of all of Mr. Hardison's outstanding options, covering an aggregate of 1,025,560 shares, through August 31, 2009. Prior to August 31, 2009, Mr. Hardison is prohibited from selling any of the shares of common stock obtained upon the exercise of any accelerated stock options. As a result of these modifications, the Company recorded one-time stock-based compensation charges of approximately $0.7 million in the "General and Administrative" line item of the Company's consolidated statements of operations during the quarter ended September 30, 2007 in accordance with the provisions of SFAS No. 123(R).

On August 31, 2007, the Company extended by nine months the expiration date of stock options to purchase 726,052 shares, with a weighted average exercise price of $6.41 per share, held by employees that were terminated as a part of the 2007 Restructuring. Stock options subject to the extension now expire on August 31, 2008. The Company did not continue to vest stock options in connection with this modification beyond the employees' termination date and did not accelerate vesting of any options prior to the termination date. In accordance with the measurement provisions of SFAS No. 123(R), the Company recorded one-time non-cash stock-based compensation charges of $0.2 million in the "Restructuring" line item of the Company's consolidated statements of operations during the quarter ended September 30, 2007 in connection with these modifications.

2008 Modifications In connection with the 2008 Restructuring (See Note 5), the Company accelerated the vesting of 15,523 shares under terminated employees' previously unvested stock options, with a weighted average exercise price of $2.65 per share, and extended the expiration date of all the terminated employees' outstanding options as of their date of termination, covering an aggregate of 181,828 shares with a weighted average exercise price of $4.50, through August 1, 2009. Pursuant to the measurement provisions of SFAS No. 123(R), the Company recorded one-time stock-based compensation charges of approximately $3,000 in the "Restructuring" line item of the Company's condensed consolidated statements of operations during the quarter ended September 30, 2008.

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(8) STOCK-BASED COMPENSATION (Continued)

Shares Reserved for Issuance

The Company has reserved the following shares of its authorized common shares to be issued upon exercise or issuance of shares related to its employee stock purchase and stock option plans, including all outstanding stock option grants noted above at December 31, 2008:

Shares reserved for issuance	
2000 Option Plan	6,962,754
2000 Stock Purchase Plan	720,780
1995 Option Plan	346,722
	8,030,256

(9) COMMITMENTS AND CONTINGENCIES

Operating Leases

The Company conducts its operations in a leased facility under a noncancelable operating lease expiring in July 2010. Future minimum payments under its operating lease as of December 31, 2008 are as follows. Amounts included in the table are in thousands.

Year Ending December 31,	
2009	1,016
2010	602
Total lease obligations	$1,618

Rent expense included in the accompanying consolidated statements of operations was approximately $0.6 million, $1.0 million, and $1.0 million for the years ended December 31, 2008, 2007 and 2006, respectively.

As described in Note 5, during the fourth quarter of 2007, the Company entered into the 2007 Sublease Agreement with INTRINSIX to sublease approximately 11,834 square feet of rentable area in the Company's corporate headquarters. The term of the 2007 Sublease Agreement, which commenced on December 15, 2007, is 32 months. The Company expects to receive approximately $0.7 million in sublease payments over the life of the 2007 Sublease Agreement. Pursuant to the Sublease Agreement, INTRINSIX has no rights to renew or extend the 2007 Sublease Agreement. Under the terms of the 2007 Sublease Agreement, INTRINSIX was required to provide a security deposit of $35,000 and will be required to pay its pro rata share of any increases building operating expenses and real estate taxes.

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(9) COMMITMENTS AND CONTINGENCIES (Continued)

As described in Note 5, during the fourth quarter of 2008, the Company entered into the 2008 Sublease Agreement with QTEROS to sublease to QTEROS approximately 25,537 square feet of rentable area in the Company's corporate headquarters. The term of the 2008 Sublease Agreement, which commenced on December 9, 2008, is 20 months with a base rent of $625,657 per year. The Company expects to receive approximately $1.0 million in sublease payments over the life of the 2008 Sublease Agreement. Pursuant to the 2008 Sublease Agreement, QTEROS has no rights to renew or extend the 2008 Sublease Agreement. Under the terms of the 2008 Sublease Agreement, QTEROS will be required to pay its pro rata share of any increases in building operating expenses and real estate taxes and to provide a security deposit in the form of an irrevocable, standby letter of credit from a national commercial bank reasonably acceptable to the Company in the amount of approximately $52,000 naming the Company as beneficiary. The 2008 Sublease Agreement provides for our employees to continue to occupy approximately 1,100 square feet in the premises subleased to QTEROS. The Company believe that such 1,100 square feet are adequate to meet its space requirements with respect to administrative needs. The Company believes that such 1,100 square feet are adequate to meet our space requirements with respect to administrative needs. The Company believes that the development of an FDA-approved product for colorectal cancer screening will require that it lease additional space. In this regard, the Company is currently exploring additional space in Madison, Wisconsin.

Licensing and Research Agreements

The Company licenses, on a non-exclusive basis, certain technologies that are, or may be, incorporated into its technology under several license agreements. Generally, the license agreements require the Company to pay royalties based on net revenues received using the technologies, and may require minimum royalty amounts or maintenance fees. On March 24, 2003, the Company entered into a license agreement, subsequently amended on November 17, 2004, May 11, 2006, March 19, 2007, October 17, 2008, October 30, 2008, and again on January 27, 2009 with Johns Hopkins University ("JHU") for an exclusive long-term license to certain patents for use in colorectal cancer detection in stool relating to the digital-PCR technology developed by Dr. Bert Vogelstein's laboratory at the Johns Hopkins Kimmel Cancer Center. Pursuant to the terms of this license agreement, and subsequent to the closing of the Genzyme strategic transaction (See Note 15), the Company has agreed to pay JHU a license fee based on a percentage of the Company's net revenues, including an annual minimum license fee of approximately $0.1 million, over the life of the licensed patents, or 2023. The Company has recorded research and development expense associated with license agreements of $(0.2) million, $1.2 million, and $0.3 million, respectively, for the years ended December 31, 2008, 2007 and 2006.

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(9) COMMITMENTS AND CONTINGENCIES (Continued)

Future minimum payments due under the Company's technology licenses as of December 31, 2008 are as follows. Amounts included in the table are in thousands.

Year ending December 31,	
2009	$ 307
2010	171
2011	171
2012	171
2013	171
Thereafter	1,393
	$2,384

The Company has also entered into several clinical research agreements, under which it is obligated to fund certain research activities, primarily related to acquiring stool samples sample for purposes of technology development. As of December 31, 2008, the Company had no outstanding sample collection commitments. The Company has recorded research and development expense associated with clinical research agreements of approximately $20,000, $0.2 million, and $0.5 million, respectively, for the years ended December 31, 2008, 2007 and 2006. As of December 31, 2008, the Company's remaining obligation under these agreements was approximately $0.1 million, which is expected to be paid during 2009.

Third Party Royalty Obligation

Under the terms of the Company's amended license agreement with LabCorp, the Company is potentially liable to reimburse LabCorp for a certain third-party royalty payment made by LabCorp in connection with its sales of PreGen-Plus and ColoSure. The Company's potential liability of $3.5 million is described in Note 4 above. In connection with this obligation, the Company recorded charges of $2.25 million and $1.2 million under the caption "Product royalty fees" in its consolidated statements of operations during the years ended December 31, 2008 and 2007, respectively. This obligation is recorded in the Company's consolidated balance sheets under the caption "Third party royalty obligation".

Employee Severance Commitments

The Company has entered into agreements with certain of its employees, including its executive officers, which provide for the payment of severance benefits upon certain triggering events. These severance commitments are described in Note 6 to these consolidated financial statements.

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(10) ACCRUED EXPENSES

Accrued expenses at December 31, 2008 and 2007 consisted of the following. Amounts included in the table are in thousands.

	December 31,	
	2008	2007
Professional fees	$ 382	$ 481
Restructuring	342	492
Occupancy costs	270	203
Commercial operating expenses	171	198
Licenses	151	663
Research and trial related expenses	80	202
Other	70	120
Compensation	32	452
	$1,498	$2,811

(11) EMPLOYEE BENEFIT PLAN

The Company maintains a qualified 401(k) retirement savings plan (the "401(k) Plan") covering all employees. Under the terms of the 401(k) Plan, participants may elect to defer a portion of their compensation into the 401(k) Plan, subject to certain limitations. Company matching contributions may be made at the discretion of the Board of Directors. There were no discretionary contributions made by the Company to the 401(k) Plan from its inception through December 31, 2004.

The Company's Board of Directors approved 401(k) Plan matching contributions for each of 2008, 2007 and 2006 in the form of Company common stock equal to 50% of each participant's elective deferrals for those years. The Company recorded stock-based compensation expense of approximately $34,000, $0.1 million, and $0.1 million, respectively, in the consolidated statements of operations for the years ended December 31, 2008, 2007 and 2006 in connection with 401(k) Plan matching contributions.

(12) REGULATORY STATUS

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

U.S. Food and Drug Administration

Laboratories that make and perform certain types of laboratory-developed tests, currently known in the industry as LDT's, or historically known as homebrews, have generally *not* been required to submit premarket submissions to the FDA, including performance data on the test, for FDA review and approval or clearance. Instead, the FDA exercised enforcement discretion, which allowed laboratories to commercially market their LDTs without obtaining FDA approval or clearance, although such

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(12) REGULATORY STATUS (Continued)

laboratories were still required to comply with the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and its implementing regulations. The Company had believed, since LabCorp's commercial launch of PreGen-Plus in 2003, that PreGen-Plus met the requirements to qualify for FDA enforcement discretion as an LDT and that in-house testing utilizing certain of the Company's technologies, and using any analyte specific reagent that the Company developed, did not require FDA approval or clearance.

From August 2003 through June 2008 through, LabCorp offered the PreGen-Plus testing service as an LDT. On January 13, 2006, the FDA sent correspondence to the Company's and to LabCorp with respect to the PreGen-Plus testing service, as well as the Effipure DNA-capture devices used in conjunction with the PreGen-Plus tests, which indicated that PreGen-Plus is subject to FDA regulation as a medical device. The FDA also indicated that the device cannot be commercially distributed without an appropriate premarket determination from the FDA. Pursuant to the Company and LabCorp's subsequent discussions with the FDA to clarify the regulatory status of PreGen-Plus, the Company and LabCorp agreed, among other things, to revise promotional activities with respect to LabCorp's PreGen-Plus testing service. In addition, LabCorp offered to eliminate its use of Effipure in processing PreGen-Plus tests. Based on the actions outlined above, LabCorp continued to market and process the PreGen-Plus test as a laboratory developed test service until June 2008.

On October 11, 2007 the FDA sent a warning letter to the Company (the "Warning Letter")with respect to the PreGen-Plus testing service, indicating that PreGen-Plus was a Class III medical device and that it could not be commercially distributed without an appropriate premarket approval or clearance from the FDA. Effective June 1, 2008, LabCorp stopped offering PreGen-Plus and indicated that it had discontinued its use of Effipure.

In July 2008, LabCorp began offering a new single marker in-house laboratory developed test called ColoSure, which is based on certain of our intellectual property and that does not use components supplied by the Company. LabCorp has not obtained FDA clearance or approval, but rather, is marketing ColoSure as an LDT. There can be no assurance that the FDA will not take a similar position with respect to ColoSure as it did for PreGen-Plus, and conclude that ColoSure is a medical device requiring premarket clearance or approval. Similarly, there can be no assurance that LabCorp's offering of ColoSure falls within the category of LDT's over which the FDA has historically exercised enforcement discretion. If the FDA deems ColoSure a medical device that requires FDA clearance or approval prior to marketing, LabCorp may be required to discontinue offering ColoSure and, under such circumstances, the Company's business would likely be materially adversely affected.

In April 2008, we began regulatory efforts toward FDA clearance for Version 2 of our technology, a two-marker version that the Company believes offers greater sensitivity and can be more cost-effective than the Company's earlier, 23 marker Version 1 technology. In this regard, in April 2008, the Company submitted a pre-IDE request to the FDA for its Version 2 technology. The objective of the pre-IDE process was to seek concurrence from the FDA that a 510(k) submission followed by a *de novo* classification request is an appropriate regulatory path for the Company's Version 2 technology and that the clinical and other studies proposed in our Version 2 pre-IDE submission would likely support such a *de novo* regulatory path. In July 2008, the Company received feedback from the FDA as to the clinical performance characteristics and the minimum number of average-risk colorectal cancer samples that likely would be required for validation of our two-marker Version 2 stool-based DNA

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(12) REGULATORY STATUS (Continued)

technology for colorectal cancer screening. In addition, based on our discussions with the FDA, the Company believes that the *de novo* pathway would be the appropriate regulatory path for its Version 2 technology. FDA's feedback in response to a pre-IDE as to the pathway to market and data requirements is not legally binding on the agency, and they are free to alter their position at a later time.

Following the consummation of our strategic transaction with Genzyme in January 2009, the Company has begun resuming its efforts to develop an FDA-approved in vitro diagnostic test for stool-based DNA colorectal cancer screening. As part of its product development efforts and ongoing evaluation of stool-based DNA capabilities and market needs, the Company is exploring the marker combinations and platform requirements necessary for optimal performance of its 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 the Company's technology. The Company may seek to leverage its progress and discussions with the FDA around Version 2 of its technology to assist in determining the likely regulatory path forward for its testing product. The FDA may ultimately determine that a premarket approval application, or PMA, is the appropriate path to market with respect to a testing product containing the Company's stool-based DNA technology instead of a *de novo* pathway. In addition, the Company will need to determine the appropriate number of colorectal cancer samples from patients that would be required by the FDA in support of any regulatory application for clearance or approval a testing product. The Company believes that the studies required in connection with any approval or clearance of our technology, regardless of whether the regulatory pathway is *de novo* classification or a PMA, will be material in cost and time-intensive. There can be no assurance that FDA will ultimately approve any *de novo* classification request or approve any PMA submitted by us in a timely manner or at all.

(13) INCOME TAXES

The Company accounts for income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes* ("SFAS No. 109"). Under SFAS No. 109, deferred tax assets or liabilities are computed based on the differences between the financial statement and income tax bases of assets and liabilities using the enacted tax rates. Deferred income tax expense or benefit represents the change in the deferred tax assets or liabilities from period to period. At December 31, 2008, the Company had net operating loss and research tax credit carryforwards of approximately $146.5 million and $3.3 million respectively, for financial reporting purposes, which may be used to offset future taxable income. The carryforwards expire through 2028 and are subject to review and possible adjustment by the Internal Revenue Service. The net operating loss and research and development tax credit carryforwards may be subject to annual limitations provided in Internal Revenue Code (IRC) sections 382 and 383.

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(13) INCOME TAXES (Continued)

The components of the net deferred tax asset with the approximate income tax effect of each type of carryforward, credit and temporary differences are as follows. Amounts included in the table are in thousands.

	December 31,	
	2008	**2007**
Deferred tax assets:		
Operating loss carryforwards	$ 58,017	$ 53,926
Tax credit carryforwards	3,286	3,231
Deferred revenue	1,070	1,605
Other temporary differences	2,970	2,649
Tax assets before valuation allowance	65,343	61,411
Less Valuation allowance	(65,343)	(61,411)
Net deferred tax asset	$	$

The Company has recorded a full valuation allowance against its net deferred tax asset because, based on the weight of available evidence, the Company believes it is more likely than not that the deferred tax assets will not be realized in the future. The valuation allowance increased by approximately $3.9 million during 2008 primarily as a result of operating losses incurred in the year ended December 31, 2008.

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

	2008	**2007**	**2006**
Federal	34.0%	34.0%	34.0%
State	5.6	5.6	5.6
Research and development tax credit	0.6	0.8	1.9
Revenue reduction recorded in connection with warrant extension			
Stock-based compensation expense	(2.2)	(5.6)	(4.1)
Other adjustments	2.1	4.4	(10.2)
Valuation allowance	(40.1)	(39.2)	(27.2)
Effective tax rate	0.0%	0.0%	0.0%

In June 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109* ("FIN 48"). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements in accordance with SFAS No. 109, *Accounting for Income Taxes*, and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Additionally, FIN 48 provides guidance on subsequent derecognition of tax positions, financial statement classification, recognition of interest and penalties, accounting in interim periods, and disclosure and transition requirements. The Company adopted the provisions of FIN 48 on January 1, 2007. Previously, the Company had accounted for tax contingencies in accordance with

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(13) INCOME TAXES (Continued)

Statement of Financial Accounting Standards 5, *Accounting for Contingencies*. As required by FIN 48, the Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority. At the adoption date, the Company applied FIN 48 to all tax positions for which the statute of limitations remained open. The amount of unrecognized tax benefits as of January 1, 2007 was zero. There have been no changes in unrecognized tax benefits since January 1, 2007, nor are there any tax positions where it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within 12 months of December 31, 2008.

The Company has not, as yet, conducted a study of its research and development credit carryforwards. This study may result in an adjustment to the Company's research and development credit carryforwards, however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position under FIN 48. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the consolidated balance sheet or statement of operations if an adjustment were required.

As of December 31, 2008, due to the carry forward of unutilized net operating losses and research and development credits, the Company is subject to U.S. Federal income tax examinations for the tax years 2003 through 2008, and to state income tax examinations for the tax years 2003 through 2008. The Company recognizes accrued interest related to unrecognized tax benefits in interest expense and penalties in operating expense. No amounts were accrued for the payment of interest and penalties through December 31, 2008. The Company's adoption of FIN 48 did not have a material effect on the Company's financial condition, results of operations or cash flows.

(14) QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)

The following table sets forth unaudited quarterly statement of operations data for each of the eight quarters ended December 31, 2008. In the opinion of management, this information has been prepared on the same basis as the audited financial statements appearing elsewhere in this Form 10-K, and all necessary adjustments, consisting only of normal recurring adjustments, have been included in the amounts stated below to present fairly the unaudited quarterly results of operations. The quarterly

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

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

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

	Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
	(Amounts in thousands, except per share data)			
2008				
Revenue	$ 51	$ (146)	$ (663)	$ (109)
Cost of revenue	1			
Research and development	859	528	577	70
General and administrative	1,835	1,495	1,271	1,868
Restructuring	(2)	(5)	539	70
Loss from operations	(2,642)	(2,164)	(3,050)	(2,117)
Interest income	124	64	36	8
Net loss	$ (2,518)	$ (2,100)	$ (3,014)	$ (2,109)
Net loss per share basic and diluted	$ (0.09)	$ (0.08)	$ (0.11)	$ (0.08)
Weighted average common shares outstanding basic and diluted	27,145	27,175	27,233	27,296
2007				
Revenue	$ 1,170	$ 1,115	$ 113	$ (600)
Cost of revenue	2	1	46	
Research and development	1,277	1,332	1,009	1,269
Sales and marketing	389	400	219	(18)
General and administrative	1,648	1,447	2,456	1,991
Restructuring	33	(2)	788	358
Loss from operations	(2,179)	(2,063)	(4,405)	(4,200)
Interest income	259	238	210	181
Net loss	$ (1,920)	$ (1,825)	$ (4,195)	$ (4,019)
Net loss per share basic and diluted	$ (0.07)	$ (0.07)	$ (0.16)	$ (0.15)
Weighted average common shares outstanding basic and diluted	26,790	26,880	27,017	27,088

99

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

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

Certain expenses reported in the Company's 2007 periodic filings with the Securities and Exchange Commission which were previously included in the "sales and marketing" line item in the Company's consolidated statements of operations have been reclassified as "general and administrative" expenses to conform to the current year presentation. This change had no impact on the Company's net loss or net loss per share as previously reported. The following table provides a reconciliation of previously reported amounts to the current year presentation.

	Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
	(Amounts in thousands, except per share data)			
2007				
Sales and marketing expenses as reported on Form 10-Q	$ 495	$ 510	$ 385	
Less: Amounts reclassified as general and administrative expenses	(106)	(110)	(166)	
Sales and marketing expenses revised	$ 389	$ 400	$ 219	
General and administrative expenses as reported on Form 10-Q	$ 1,542	$ 1,337	$ 2,290	
Add: Amounts reclassified as general and administrative expenses	106	110	166	
General and administrative expenses revised	$ 1,648	$ 1,447	$ 2,456	

(15) SUBSEQUENT EVENTS

Genzyme Strategic Transaction

On January 27, 2009, EXACT Sciences Corporation (the "Company") entered into a Collaboration, License and Purchase Agreement (the "CLP Agreement") with Genzyme Corporation ("Genzyme"). Pursuant to the CLP Agreement, the Company (i) assigned to Genzyme all of its intellectual property applicable to the fields of prenatal and reproductive health (the "Transferred Intellectual Property"), (ii) granted Genzyme an irrevocable, perpetual, exclusive, worldwide, fully-paid, royalty-free license to use and sublicense all of the Company's remaining intellectual property (the "Retained Intellectual Property") in the fields of prenatal and reproductive health (the "Genzyme Core Field"), and (iii) granted Genzyme an irrevocable, perpetual, non-exclusive, worldwide, fully-paid, royalty-free license to use and sublicense the Retained Intellectual Property in all fields other than the Genzyme Core Field and other than colorectal cancer detection and stool-based disease protection (the "Company Field"). Following the Genzyme Transaction, EXACT retains rights in its intellectual property to pursue only the fields of colorectal cancer detection and stool-based detection of any disease or condition. Further, subject to the terms of the JHU Amendment (defined below), the Company assigned to Genzyme its rights under the license agreement between the Company and The Johns Hopkins University ("JHU") dated March 25, 2003, as amended (the "JHU Agreement") (collectively, with the licenses and assignment described herein, the "Sale Transaction"). The CLP Agreement also provides for the formation of a joint advisory committee to assist both parties in the achievement of product development and regulatory goals. The collaboration period under the CLP Agreement may be terminated upon certain events. Additional termination rights concerning the collaboration period arise after five years.

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(15) SUBSEQUENT EVENTS (Continued)

Under the CLP Agreement, the Company retained ownership of intellectual property rights other than the Transferred Intellectual Property. In addition, with respect to the Transferred Intellectual Property, Genzyme granted the Company an irrevocable, perpetual, exclusive, worldwide, fully-paid, royalty-free license to use and sublicense such intellectual property in the Company Field. The parties also granted to each other a perpetual (subject to termination for uncured material breaches), exclusive, worldwide, fully-paid, royalty-free license to use and sublicense any improvements Genzyme or the Company makes to the Transferred Intellectual Property that is applicable to the Company Field (in the case of the Company as licensee) or all fields other than the Company Field (the "Genzyme Field") (in the case of Genzyme as licensee). Further, the parties granted to each other a perpetual (subject to termination for uncured material breaches), exclusive, worldwide, fully-paid, royalty-free license to use and sublicense intellectual property jointly developed pursuant to the collaboration between the parties (the "Joint Technology"). The license to the Joint Technology granted by the Company to Genzyme is exclusive in the Genzyme Field and the license to the Joint Technology granted by Genzyme to the Company is exclusive in the Company Field. The Company also granted to Genzyme an exclusive option to obtain an exclusive license, in the Genzyme Core Field, to certain technology that the Company may develop or acquire that has applicability in the Genzyme Core Field. The CLP Agreement contains representations, warranties and covenants with respect to the Sale Transaction and provides, under certain circumstances, for the Company and Genzyme to indemnify each other for breaches of their respective representations, warranties and covenants.

As part of the Sale Transaction, the Company entered into an Assignment, Sublicense, Consent and Eighth Amendment to License Agreement with Genzyme and JHU (the "JHU Amendment") on January 27, 2009, whereby the Company assigned its rights under the JHU Agreement to Genzyme. Pursuant to the JHU Amendment, Genzyme sublicensed to the Company the intellectual property subject to the JHU Agreement for colorectal cancer detection and stool-based disease detection, including the BEAMing technology for the detection of colorectal cancer. Under the JHU Amendment, the Company and Genzyme will share in the royalty and annual payment obligations to JHU. The JHU Amendment also modified the minimum annual license fee due to JHU under the JHU Agreement. The JHU Agreement terminates upon the later of 20 years from the effective date of the JHU Agreement and the expiration of the last to expire of the patents for the licensed technology, or upon certain uncured defaults of JHU or Genzyme. Pursuant to the JHU Amendment, the sublicense to the Company terminates upon certain uncured defaults of the Company. The JHU Amendment also provides that, in the event the JHU Agreement terminates upon an uncured default of Genzyme, if the Company is in good standing under the JHU Agreement at such time, the sublicense to the Company will become a direct license from JHU to the Company.

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

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(15) SUBSEQUENT EVENTS (Continued)

that incorporate the licensed technology, as well as certain minimum royalties, milestone payments and maintenance fees.

Pursuant to the Sale Transaction, Genzyme agreed to pay an aggregate of $18.5 million to the Company, of which $16.65 million was paid at closing and $1.85 million (the "Holdback Amount") is subject to a holdback by Genzyme to satisfy certain potential indemnification obligations of the Company. Subject to the terms and conditions of the CLP Agreement, one-half of the Holdback Amount will be released to the Company in 12 months and one-half will be released in 18 months. Genzyme also agreed to pay a double-digit royalty to the Company on income received by Genzyme as a result of any licenses or sublicenses to third parties of the Transferred Intellectual Property or the Retained Intellectual Property in any field other than the Genzyme Core Field or the Company Field.

In addition, the Company entered into a Common Stock Subscription Agreement with Genzyme (the "Purchase Agreement") on January 27, 2009, which provided for the private issuance and sale to Genzyme of 3,000,000 shares (the "Shares") of the Company's common stock, $0.01 par value per share ("Common Stock"), at a per share price of $2.00, for an aggregate purchase price of $6.0 million. The Company expects to pay approximately $1.0 million in professional fees in connection with the CLP Agreement and the Purchase Agreement.

Pursuant to the Purchase Agreement, Genzyme has the right until December 31, 2010 to participate in certain future private offerings of equity securities by the Company up to the amount necessary to maintain Genzyme's pro-rata percentage ownership of the Company, at a price per share equal to the greater of $2.00 or the closing price of the Common Stock on the Company's trading market on the day prior to the date that the Company notifies Genzyme of its right to purchase additional shares. This right is subject to certain customary exclusions, including issuances to employees pursuant to a stock plan, issuances in connection with a change of control transaction and issuances in connection with strategic partnerships. Under the Purchase Agreement, Genzyme also has the right to include the Shares on a registration statement filed by the Company or, under certain circumstances, cause the Company to file a registration statement covering the resale of the Shares by Genzyme with the Securities and Exchange Commission.

On January 27, 2009, upon, and as a result of, the consummation of the transactions with Genzyme, the Company's Board of Directors awarded bonuses to certain of the Company's employees pursuant to the terms of their respective Employee Retention Agreements with the Company, each dated April 18, 2008 (the "Transaction Bonuses"). The Transaction Bonuses included cash bonuses of $315,000 to Mr. Luber, the Company's current President and Chief Executive Officer, and $230,000 to Charles R. Carelli, Jr., the Company's Senior Vice President, Chief Financial Officer, Treasurer and Secretary. The Transaction Bonuses were awarded in lieu of the Company's annual bonus program.

New Chief Executive Officer and Chief Financial Officer

As described fully in Note 6 above, on March 18, 2009, Jeffrey R. Luber agreed to resign as the Company's President and Chief Executive Officer and as a director of the Company's Board of Directors, in each case effective April 2, 2009. In addition, on March 18, 2009, Charles R. Carelli, Jr. agreed to resign as Chief Financial Officer of the Company, effective April 2, 2009.

In connection with their departure from the Company, Messrs. Luber and Carelli were entitled to receive severance benefits pursuant to their previously disclosed retention agreements, including salary

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(15) SUBSEQUENT EVENTS (Continued)

continuation of $472,500 and $287,500, which is equal to eighteen months and fifteen months, respectively, of their base salaries as of the date of termination. On March 31, 2009, the Company entered into release agreements with Messrs. Luber and Carelli that provided, in exchange for a general release in favor of the Company, for the accelerated payment of the salary continuation obligations on March 31, 2009. In addition, the release agreements also provided for the repurchase by the Company of options held by Messrs. Luber and Carelli for an aggregate of 895,000 shares of common stock, in lieu of accelerated vesting and an extension of the option exercise period arising from the prior retention agreements. The Company paid Messrs. Luber and Carelli approximately $39,000 and $11,000, respectively, to repurchase Mr. Luber's options to purchase 620,000 shares Mr. Carelli's options to purchase 275,000 shares. The purchase price of the outstanding options represented a 75 percent discount from the estimated fair value of the vested options as of March 31, 2009. Messrs. Luber and Carelli retained the balance of their existing options, which will remain exercisable for two years following, and will be subject to nine months acceleration of vesting upon, the termination of respective employment with the Company. The Company expects to record in its first quarter financial results the charges associated with the acceleration of the severance payments to Messrs. Luber and Carelli and the redemption and modification of their options.

On March 18, 2009, the Company's Board of Directors appointed Kevin T. Conroy as President and Chief Executive Officer of the Company, effective April 2, 2009. Also on March 18, 2009, based on the recommendation of the Corporate Governance and Nominating Committee, the Board of Directors elected Mr. Conroy to the Board. In connection with his appointment, Mr. Conroy entered into an employment agreement with the Company on March 18, 2009 (the "Conroy Agreement"). Under the terms of the Conroy Agreement, Mr. Conroy will serve as President and Chief Executive Officer of the Company, receive a base salary of $340,000 and is eligible to earn up to 50% of his base salary in annual bonuses, with the exact amount of any such bonus to be determined by the Compensation Committee. Pursuant to the Conroy Agreement, Mr. Conroy will be granted options to purchase 2.5 million shares of the common stock of the Company, par value $0.01 per share (the "Common Stock"), at a price equal to the closing price of the Common Stock on the NASDAQ Capital Market on March 18, 2009. Twenty-five percent (25%) of the shares underlying the stock options will become exercisable on the one-year anniversary of the date of grant, with the remainder vesting quarterly over the subsequent three years.

Mr. Conroy's employment with the Company continues until terminated in accordance with the Conroy Agreement. Mr. Conroy may terminate his employment with the Company without "good reason" (as defined in the Conroy Agreement) upon 30 business days' written notice to the Company and with good reason at any time within ninety (90) days after the occurrence of an event constituting good reason. The Company may terminate Mr. Conroy's employment, with or without "cause" (as defined in the Conroy Agreement), upon written notice to Mr. Conroy. In the event of termination by the Company without cause or by Mr. Conroy for good reason, then Mr. Conroy will receive (i) salary continuation for a period of eighteen (18) months at his then-current base salary, (ii) any accrued but unpaid base salary as of the termination date, (iii) any accrued but unpaid bonus (including any performance-based bonus), (iv) twelve months' accelerated vesting of any unvested equity awards, and (v) the right to exercise any vested equity awards until the earlier of two (2) years from the date of termination or the date such equity award expires.

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(15) SUBSEQUENT EVENTS (Continued)

In the event of termination by the Company without cause or by Mr. Conroy for good reason, within twelve (12) months before, or if Mr. Conroy remains employed with the Company on the effective date of, a "Change of Control" (as defined in the Conroy Agreement), Mr. Conroy will receive a lump-sum payment equal to twenty-four (24) months (which period will be reduced under certain circumstances) of his then-current base salary. Upon a Change of Control and subject to Mr. Conroy's agreement to remain employed by the Company (or any successor), if requested, for a period of at least six (6) months following such Change of Control at his then current base salary, all of Mr. Conroy's outstanding stock options would become fully vested and exercisable. The foregoing change of control payments shall be subject to increase to cover any excise tax imposed by Section 4999 of the Internal Revenue Code of 1986, as amended. The Conroy Agreement also provides that Mr. Conroy will participate in a long-term incentive plan to be developed by the Company pursuant to which he will be eligible for a cash payment upon certain changes of control of the Company.

The Conroy Agreement prohibits Mr. Conroy from engaging in certain activities involving competition with the Company for an 18-month period following termination of his employment with the Company.

On March 18, 2009, the Company's Board of Directors appointed Maneesh Arora as Senior Vice President and Chief Financial Officer of the Company, effective April 2, 2009. In connection with his appointment, Mr. Arora entered into an employment agreement with the Company on March 18, 2009 (the "Arora Agreement"). Under the terms of the Arora Agreement, Mr. Arora will serve as Senior Vice President and Chief Financial Officer of the Company, receive a base salary of $240,000 and is eligible to earn up to 40% of his base salary in annual bonuses, with the exact amount of any such bonus to be determined by the Compensation Committee. Pursuant to the Arora Agreement, Mr. Arora will be granted options to purchase 1.25 million shares of Common Stock, at a price equal to the closing price of the Common Stock on the NASDAQ Capital Market on March 18, 2009. Twenty-five percent (25%) of the shares underlying the stock options will become exercisable on the one-year anniversary of the date of grant, with the remainder vesting quarterly over the subsequent three years.

Mr. Arora's employment with the Company continues until terminated in accordance with the Arora Agreement. Mr. Arora may terminate his employment with the Company without "good reason" (as defined in the Arora Agreement) upon 30 business days' written notice to the Company and with good reason at any time within ninety (90) days after the occurrence of an event constituting good reason. The Company may terminate Mr. Arora's employment, with or without "cause" (as defined in the Arora Agreement), upon written notice to Mr. Arora. In the event of termination by the Company without cause or by Mr. Arora for good reason, then Mr. Arora will receive (i) salary continuation for a period of fifteen (15) months at his then-current base salary, (ii) any accrued but unpaid base salary as of the termination date, (iii) any accrued but unpaid bonus (including any performance-based bonus), (iv) twelve months' accelerated vesting of any unvested equity awards, and (v) the right to exercise any vested equity awards until the earlier of two (2) years from the date of termination or the date such equity award expires.

In the event of termination by the Company without cause or by Mr. Arora for good reason, within twelve (12) months before, or if Mr. Arora remains employed with the Company on the effective date of, a "Change of Control" (as defined in the Arora Agreement), Mr. Arora will receive a

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2008 (Continued)

(Amounts in thousands, except share and per share data)

(15) SUBSEQUENT EVENTS (Continued)

lump-sum payment equal to eighteen (18) months (which period will be reduced under certain circumstances) of his then-current base salary. Upon a Change of Control and subject to Mr. Arora's agreement to remain employed by the Company (or any successor), if requested, for a period of at least six (6) months following such Change of Control at his then current base salary, all of Mr. Arora's outstanding stock options would become fully vested and exercisable. The Arora Agreement also provides that Mr. Arora will participate in a long-term incentive plan to be developed by the Company pursuant to which he will be eligible for a cash payment upon certain changes of control of the Company.

The Arora Agreement prohibits Mr. Arora from engaging in certain activities involving competition with the Company for an 18-month period following termination of his employment with the Company.

Compliance with NASDAQ Listing Requirements

On July 10, 2008, the Company received notice from The NASDAQ Stock Market LLC ("NASDAQ") that it was not in compliance with NASDAQ Marketplace Rule 4450(b)(1)(A), which requires an issuer to maintain a minimum $50 million market value of its listed securities for continued listing on The NASDAQ Global Market. The Company requested a hearing before the NASDAQ Listing Qualifications Panel, which was held on October 2, 2008, and on November 26, 2008, the NASDAQ Listing Qualifications Panel determined to list the Company's securities on The NASDAQ Capital Market on a conditional basis, pending its review of additional information regarding the Company's plan to evidence compliance with the requirements for continued listing on that market. On January 29, 2009, the Company received a determination from NASDAQ indicating that the Company had evidenced full compliance with all requirements for continued listing on The NASDAQ Capital Market.

On March 6, 2009, the Company received notice from NASDAQ that it was not in compliance with NASDAQ Marketplace Rule 4310(c)(3) (the "Rule"), which requires an issuer to maintain a minimum $35 million market value of its listed securities for continued listing on The NASDAQ Capital Market. NASDAQ also noted that the Company was not in compliance with either of the other alternatives for compliance with the Rule, which require minimum stockholders' equity of $2,500,000 or net income from continuing operations of $500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years, respectively. This notification has no effect on the listing of the Company's common stock at this time. The Company was provided a period of 90 calendar days, or until June 4, 2009, to regain compliance with the Rule. If at any time before June 4, 2009, the market value of the Company's listed securities is $35 million or more for a minimum of 10 consecutive business days, the NASDAQ staff will determine if the Company complies with the Rule. If the Company does not regain compliance with the Rule by June 4, 2009, NASDAQ will provide the Company with written notification that its common stock will be delisted from the NASDAQ Capital Market. At that time, the Company may appeal the delisting determination to a NASDAQ Listings Qualifications Panel pursuant to applicable NASDAQ rules. The Company is currently evaluating its alternatives to resolve the listing deficiency.

Table of Contents

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

There have been no disagreements with accountants on accounting or financial disclosure matters during our two most recent fiscal years.

Item 9A(T). Controls and Procedures

Evaluation of Disclosure Controls and Procedures. The Company maintains controls and procedures designed to ensure that it is able to collect the information it is required to disclose in the reports it files with the SEC, and to process, summarize and disclose this information within the time periods specified in the rules of the SEC. Based on an evaluation of the Company's disclosure controls and procedures as of the end of the period covered by this report conducted by the Company's management, with the participation of the Chief Executive Officer and Chief Financial Officer, the Chief Executive Officer and Chief Financial Officer concluded that these disclosure controls and procedures are effective to enable the Company to record, process, summarize and report the information it is required to disclose in the reports it files with the SEC within the required time periods.

Management's Report on Internal Control over Financial Reporting. Management of the Company is responsible for establishing and maintaining effective internal control over financial reporting as defined in Rules 13a-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance to the Company's management and board of directors regarding the preparation and fair presentation of published financial statements.

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

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2008. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control Integrated Framework.* Based on our assessment, we believe that, as of December 31, 2008, the Company's internal control over financial reporting is effective based on those criteria.

This Annual Report on Form 10-K does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to temporary rules of the SEC that permit the Company to provide only management's report in this Annual Report on Form 10-K.

Item 9B. Other Information

On March 31, 2009, in connection with the planned departure of Jeffrey R. Luber as our President and Chief Executive Officer and of Charles R. Carelli, Jr. as our Senior Vice President, Chief Financial Officer, Treasurer and Secretary, we entered into release agreements with Messrs. Luber and Carelli that provide, in exchange for a general release in our favor, for the accelerated payment of our existing salary continuation obligations owed to Messrs. Luber and Carelli pursuant to their previously disclosed retention agreements. Specifically, the release agreements provide for the payment to Messrs. Luber and Carelli, on March 31, 2009, of a lump sum equal to eighteen months and fifteen months, respectively, of their current base salaries. Under their prior retention agreements, these amounts were to be paid as salary continuation over the applicable period. In addition, the release agreements provide, in lieu of accelerated vesting and an extension of the option exercise period arising from the prior retention agreements, for our repurchase of options held by Messrs. Luber and Carelli to purchase an aggregate of 895,000 shares of common stock. We paid approximately $39,000 and $11,000,

Table of Contents

respectively, to repurchase options covering 620,000 shares held by Mr. Luber and options covering 275,000 shares held by Mr. Carelli as of March 31, 2009. The purchase price of the outstanding options represented a 75 percent discount from the estimated fair value of $154,300 and $42,864, respectively, of the vested options being repurchased as of March 31, 2009 from Messrs. Luber and Carelli. Messrs. Luber and Carelli retained the balance of their existing options, which, in accordance with the terms of their previously disclosed retention agreements, will remain exercisable for two years following, and will be subject to nine months acceleration of vesting upon, the termination of their respective employment with us. Mr. Luber's and Mr. Carelli's noncompetition and nondisclosure obligations continue to survive the termination of their employment with us in accordance with their terms.

The foregoing summary is qualified in its entirety with the terms of the respective release agreements for Messrs. Luber and Carelli, which are filed as Exhibits 10.36 and 10.37, respectively, to this Annual Report on Form 10-K.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2008.

Our policy governing transactions in our securities by directors, officers and employees permits our officers, directors and certain other persons to enter into trading plans complying with Rule 10b5-1 under the Securities Exchange Act of 1934, as amended. We anticipate that, as permitted by Rule 10b5-1 and our policy governing transactions in our securities, some or all of our officers, directors and employees may establish trading plans in the future. We intend to disclose the names of officers and directors who establish a trading plan in compliance with Rule 10b5-1 and the requirements of our policy governing transactions in our securities in our future quarterly and annual reports on Form 10-Q and 10-K filed with the Securities and Exchange Commission. However, we undertake no obligation to update or revise the information provided herein, including for revision or termination of an established trading plan, other than in such quarterly and annual reports.

Item 11. Executive Compensation

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2008.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2008.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2008.

Table of Contents

Item 14. Principal Accounting Fees and Services

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2008.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a)

The following documents are filed as part of this Form 10-K:

(1) Financial Statements (see "Financial Statements and Supplementary Data" at Item 8 and incorporated herein by reference).

(2) Financial Statement Schedules (Schedules to the Financial Statements have been omitted because the information required to be set forth therein is not applicable or is shown in the accompanying Financial Statements or notes thereto).

(3) Exhibits

The following exhibits are filed as part of and incorporated by reference into this Form 10-K:

Exhibit Number	Description
3.1	Sixth Amended and Restated Certificate of Incorporation of the Registrant (previously filed as Exhibit 3.3 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
3.2	Amended and Restated By-Laws of the Registrant (previously filed as Exhibit 3.4 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
4.1	Specimen certificate representing the Registrant's Common Stock (previously filed as Exhibit 4.1 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.1*	1995 Stock Option Plan (previously filed as Exhibit 10.1 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.2+*	2000 Stock Option and Incentive Plan
10.3*	2000 Employee Stock Purchase Plan (previously filed as Exhibit 10.3 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.4*	Sixth Amended and Restated Registration Rights Agreement between the Registrant and the parties named therein dated as of April 7, 2000 (previously filed as Exhibit 10.4 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.5	License Agreement between the Registrant and Genzyme Corporation dated as of March 25,1999 (previously filed as Exhibit 10.6 to our Annual Report on

	Form 10-K for the period ended December 31, 2006, which is incorporated herein by reference)
10.6	Technology License Contract between the Registrant and the Mayo Foundation for Medical Education and Research dated as of July 7, 1998, as amended (previously filed as Exhibit 10.14 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)

Table of Contents

Exhibit Number	Description
10.7	Letter Agreement by and between The Mayo Foundation for Medical Education and Research and the Registrant dated February 4, 1998 (previously filed as Exhibit 10.15 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.8	Form of Consulting Agreement by and between the Registrant and certain members of the scientific advisory board (previously filed as Exhibit 10.16 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.9**	Agreement between the Registrant and Laboratory Corporation of America Holdings, Inc. dated June 26, 2002 (previously filed as Exhibit 10.10 to our Annual Report on Form 10-K for the period ended December 31, 2007, which is incorporated herein by reference)
10.10	Lease Agreement, dated January 23, 2003, between Marlborough Campus Limited Partnership and the Registrant, as amended (previously filed as Exhibit 10.11 to our Annual Report on Form 10-K for the period ended December 31, 2007, which is incorporated herein by reference)
10.11**	Exclusive License Agreement between Matrix Technologies Corporation, d/b/a Apogent Discoveries, and the Registrant dated as of November 26, 2002 (previously filed as Exhibit 10.12 to our Annual Report on Form 10-K for the period ended December 31, 2007, which is incorporated herein by reference)
10.12+**	First Amendment to License Agreement by and between the Registrant and Laboratory Corporation of America Holdings, Inc. dated January 19, 2004
10.13+**	Sublicense Agreement between the Registrant and Beckman Coulter dated July 28, 2003
10.14+*	Form of Incentive Stock Option Agreement
10.15*	Form of Non-Qualified Stock Option Agreement (previously filed as Exhibit 10.1 to our Report on Form 10-Q filed on November 4, 2004, which is incorporated herein by reference)
10.16*	The Registrant's 2000 Employee Stock Purchase Plan (previously filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the period ended March 31, 2005, which is incorporated herein by reference)
10.17*	Amended and Restated Employee Retention Agreement between the Registrant and Jeffrey R. Luber dated April 18, 2008 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on April 22, 2008, which is incorporated herein by reference)
10.18*	Amended and Restated Employee Retention Agreement between the Registrant and Charles R. Carelli, Jr. dated April 18, 2008 (previously filed as Exhibit 10.2 to our Report on Form 8-K filed on April 22, 2008, which is incorporated herein by reference)
10.19**	Second Amendment to Agreement between the Registrant and Laboratory Corporation of America Holdings, dated as of June 27, 2007 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on July 3, 2007, which is incorporated herein by reference)
10.20*	Non-Employee Director Compensation Policy (previously filed as Exhibit 10.2 to our Report on Form 8-K filed on December 15, 2008, which is incorporated herein

by reference)

10.21* Executive Incentive Plan (previously filed as Exhibit 10.2 to our Report on Form 8-K filed on August 15, 2007, which is incorporated herein by reference)

Table of Contents

Exhibit Number	Description
10.22**	Third Amendment to Agreement between the Registrant and Laboratory Corporation of America Holdings, dated as of August 31, 2007 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on September 7, 2007, which is incorporated herein by reference)
10.23	Sublease Agreement between the Registrant and INTRINSIX Corp., dated as of November 20, 2007 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on November 21, 2007, which is incorporated herein by reference)
10.24	Form of Restricted Stock Award Agreement (previously filed as Exhibit 10.29 to our Annual Report on Form 10-K for the period ended December 31, 2007, which is incorporated herein by reference)
10.25**	Fourth Amendment to Agreement between the Registrant and Laboratory Corporation of America Holdings, dated as of March 17, 2008 (previously filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q filed on May 9, 2008, which is incorporated herein by reference)
10.26**	License Agreement between the Registrant and Case Western Reserve University, dated as of July 18, 2005, as amended (previously filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q filed on August 8, 2008, which is incorporated herein by reference)
10.27**	Amended and Restated License Agreement between The Johns Hopkins University and the Registrant, dated as of March 25, 2003, as amended (previously filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q filed on November 7, 2008, which is incorporated herein by reference)
10.28	Sublease Agreement by and between the Registrant and QTEROS, Inc., dated as of December 9, 2008 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on December 15, 2008, which is incorporated herein by reference)
10.29**	Collaboration, License and Purchase Agreement between Genzyme Corporation and the Registrant, dated January 27, 2009 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on January 28, 2009, which is incorporated herein by reference)
10.30**	Assignment, Sublicense, Consent and Eighth Amendment to License Agreement among the Registrant, Genzyme Corporation and The Johns Hopkins University, dated January 27, 2009 (previously filed as Exhibit 10.2 to our Report on Form 8-K filed on January 28, 2009, which is incorporated herein by reference)
10.31**	Amended and Restated License Agreement between Genzyme Corporation and the Registrant, dated January 27, 2009 (previously filed as Exhibit 10.3 to our Report on Form 8-K filed on January 28, 2009, which is incorporated herein by reference)
10.32	Common Stock Subscription Agreement between the Registrant and Genzyme Corporation, dated January 27, 2009 (previously filed as Exhibit 10.4 to our Report on Form 8-K filed on January 28, 2009, which is incorporated herein by reference)
10.33+**	Seventh Amendment to License Agreement between the Registrant and The Johns Hopkins University, dated as of December 15, 2008
10.34*	Employment Agreement by and between Kevin T. Conroy and the Registrant, dated as of March 18, 2009 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on March 18, 2009, which is incorporated herein by reference)

110

Table of Contents

Exhibit Number	Description
10.35*	Employment Agreement by and between Maneesh Arora and the Registrant, dated as of March 18, 2009 (previously filed as Exhibit 10.2 to our Report on Form 8-K filed on March 18, 2009, which is incorporated herein by reference)
10.36+*	Release Agreement between Jeffrey R. Luber and the Registrant, dated as of March 31, 2009
10.37+*	Release Agreement between Charles R. Carelli, Jr. and the Registrant, dated as of March 31, 2009
12.1+	Statement Regarding Computation of Ratios
21.1	Subsidiaries of the Registrant (previously filed as Exhibit 21.1 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
23.1+	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (included on signature page)
31.1+	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934
31.2+	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934
32+	Certification Pursuant to 18 U.S.C Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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

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

\+ Filed herewith.

Table of Contents

SIGNATURES

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

EXACT SCIENCES CORPORATION

By: /s/ JEFFREY R. LUBER

Jeffrey R. Luber
President & Chief Executive Officer

Date: March 31, 2009

POWER OF ATTORNEY AND SIGNATURES

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

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

Name	Title	Date
/s/ JEFFREY R. LUBER Jeffrey R. Luber	President and Chief Executive Officer (Principal Executive Officer)	March 31, 2009
/s/ CHARLES R. CARELLI, JR. Charles R. Carelli, Jr.	Senior Vice President, Chief Financial Officer, Treasurer and Secretary (Principal Financial Officer and Principal Accounting Officer)	March 31, 2009
/s/ PATRICK J. ZENNER Patrick J. Zenner	Chairman of the Board	March 31, 2009
/s/ SALLY W. CRAWFORD Sally W. Crawford	Director	March 31, 2009
/s/ EDWIN M. KANIA, JR. Edwin M. Kania, Jr.	Director	March 31, 2009

Table of Contents

Name	Title	Date
/s/ CONNIE MACK, III Connie Mack, III	Director	March 31, 2009
/s/ LANCE WILLSEY, MD Lance Willsey, MD	Director	March 31, 2009
/s/ MICHAEL E. SINGER Michael E. Singer	Director	March 31, 2009
/s/ KEVIN T. CONROY Kevin T. Conroy	Director	March 31, 2009

Table of Contents

Exhibit Index to Annual Report on Form 10-K

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31.2+	

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Table of Contents

Exhibit Number	Description
32+	Certification Pursuant to 18 U.S.C Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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

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

+
Filed herewith.