EXACT SCIENCES CORP
Form 10-K
March 17, 2008

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended: December 31, 2007

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, as of the last business day of the Registrant's most recently completed second fiscal quarter was approximately $73,273,910 (based on the closing price of the Registrant's Common Stock on June 29, 2007 of $2.89 per share).

The number of shares outstanding of the Registrant's $.01 par value Common Stock as of March 13, 2008 was 27,146,241.

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, 2007. Portions of such proxy statement are incorporated by reference into Part III of this Form 10-K.

EXACT SCIENCES CORPORATION
ANNUAL REPORT ON FORM 10-K
YEAR ENDED DECEMBER 31, 2007

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PART I

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange 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 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 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 is an applied genomics company that develops proprietary DNA-based technologies for use in the detection of cancer. We have selected colorectal cancer as the first application of our technologies. We have licensed certain of our technologies, on an exclusive basis through December 2010, to Laboratory Corporation of America® Holdings ("LabCorp®") in connection with a commercial testing service that is marketed in the United States under the name "PreGen-Plus ." PreGen-Plus, which is based on our Version 1 technology, is LabCorp's non-invasive stool-based DNA testing service for the detection of colorectal cancer in the average-risk population. Royalties from LabCorp's sales of PreGen-Plus, and other license fees from LabCorp, represent our primary source of revenue.

Colorectal cancer is the second leading cause of cancer death in the U.S. 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 colorectal cancer screening is recommended, it is estimated that less than one-half have ever been screened, and 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 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 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. PreGen-Plus is therefore

now the first DNA-based, non-invasive colorectal cancer screening test to be included in the colorectal cancer screening guidelines of the ACS and MSTF-CRC in the United States for the average risk population.

PreGen-Plus is currently offered commercially by LabCorp, the second largest commercial laboratory in the United States with more than 35 primary laboratories and over 1,600 patient service centers. LabCorp is the exclusive licensee, in the United States and Canada, of certain of our technologies utilized in PreGen-Plus through December 2010, followed by a non-exclusive license for the life of the licensed patents. LabCorp currently does not offer PreGen-Plus in Canada. LabCorp performs the PreGen-Plus testing service in a single specialized centralized laboratory and, by the terms of the license, pays us a royalty based on its net revenues from sales of PreGen-Plus. 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 our technology to select third-party organizations and commercial service laboratories, subject to LabCorp's preferential pricing terms. LabCorp maintains sole responsibility, at its expense, for all commercial activities including marketing, sales, and reimbursement related to PreGen-Plus under the agreement. LabCorp may terminate the license agreement if, among other things, the failure to commercially launch our Version 2 technology is attributable to a failure on our part or Version 2 does not attain certain sensitivity and specificity thresholds in connection with technical validation.

In addition to our Version 1 technology underlying the PreGen-Plus testing service offered by LabCorp, we have also developed a Version 2 colorectal cancer screening technology that we believe has greater sensitivity and is more cost effective than Version 1. In a recent 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 has the exclusive right through December 2010 to our Version 2 technology, subject to certain rights that we maintain to offer our technology commercially. As of the date of this Annual Report on Form 10-K, we are in discussions with LabCorp, the exclusive licensee to our Version 2 technology, regarding the potential future commercialization of Version 2.

Background

Colorectal cancer is the third most common malignant disease and the second most frequent cause of cancer-related death in the United States, with more than 148,000 new cases and more than 49,000 deaths anticipated 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 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

*
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 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*. Based on this study data, our bead-based stool-based DNA detection technology demonstrated sensitivity four times greater than the leading FOBT, Hemoccult II®, currently 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 PreGen-Plus stool-based DNA testing service that was developed by LabCorp and that

LabCorp is commercially offering today incorporates technical improvements over the test that was used in the multi-center study, which we believe result in higher assay sensitivity than that seen in our multi-center study. In addition, 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.

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 and diagnostic 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 post-market survey of patients whom have used PreGen-Plus 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 technologies 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 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.

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 technologies are used to promote the reproducible isolation and amplification of the human DNA found in stool.

Cancer Detection Methods. Many of the specialized methods for detecting and identifying genomic markers associated with colorectal cancer can be performed on existing instruments commonly available in clinical laboratories conducting molecular testing.

Commercial Focus

Our goal has been 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:

Obtain regulatory clearance for stool-based DNA screening. In October 2007, we were notified in a warning letter from the U.S. Food and Drug Administration, or FDA, that PreGen-Plus is a Class III medical device that cannot be commercially distributed without an appropriate pre-market approval or clearance from the FDA. Accordingly, among our primary business objectives is to obtain FDA approval or clearance for our technologies and, as of the date of this Annual Report on Form 10-K, we have met with the FDA on two separate occasions to specifically address the matters raised in the warning letter. Based on these discussions, we are currently focusing our efforts on concluding our pre-IDE, or pre-Investigational Device Exemption, discussions with the FDA to determine the appropriate premarket submission requirement. We believe, based on our most recent discussion with the FDA in February 2008 and the proposed intended use of the test, that a *de novo* 510(k) application for our test incorporating Version 1 technology may likely be the filing route that is available to us in satisfying the FDA's requirements. As described in the section "Government Regulation" below, obtaining FDA clearance or approval could require additional lengthy clinical or other studies to validate our technologies, the costs of which are likely to be material. We may not have sufficient funds to complete any FDA clearance or approval process for our technologies or we may delay any such process to preserve funds. Moreover, we will require the support of third parties to assist us in the achievement of objectives relating to FDA clearance of our technologies, which may be costly. Additionally, as a result of the warning letter, LabCorp may decide to halt commercial sales of PreGen-Plus until it is cleared or approved by the FDA, which could materially harm our business and revenue prospects. Alternatively, LabCorp may decide to discontinue the use of PreGen-Plus, which was the basis for the FDA's warning letter, and instead seek to begin commercializing our Version 2 stool-based DNA screening technology for colorectal cancer. Such conversion could result in an interruption in service and a lengthy delay during which no version of the test utilizing our technologies remains on the market. Further, the FDA may not approve of certain sales, marketing or promotional initiatives of EXACT or LabCorp, which could negatively affect our ability to build awareness around stool-based DNA testing, regardless of which version of the test remains on the market.

Obtain formal acceptance of stool-based DNA screening for reimbursement by Medicare and other third-party payors. Between the commercial launch of PreGen-Plus in August 2003 and December 31, 2007, LabCorp has received over 14,300 patient samples for testing from across the country, billed insurers and received payment from numerous third-party payors, including more than 350 health plans. None of these third-party payors have yet issued formal policy approval for PreGen-Plus. Our reimbursement strategy consists primarily of leveraging LabCorp's ability to educate large managed care organizations and large self-insured employers about the clinical benefits and cost-effectiveness of using stool-based DNA screening for colorectal cancer. An important component of our reimbursement strategy is to obtain a National Coverage Determination, or NCD, from the Centers for Medicare and Medicaid Services, or CMS, for inclusion of our stool-based DNA screening technologies for colorectal cancer in the Medicare program. In December 2004, we submitted our application for a NCD on our Version 1

technology, which was accepted by CMS on August 1, 2007. Following acceptance of our application to CMS, we received the warning letter from the FDA in October 2007. Based, in part, on the FDA's determination as set forth in the warning letter that PreGen-Plus required premarket clearance or approval, CMS issued a proposed decision memorandum regarding our application on January 30, 2008, which proposed not to provide coverage for our Version 1 technology. The proposed decision memo indicated that CMS would reconsider our application for coverage following any such FDA clearance or approval of our stool-based DNA screening technology. Accordingly, we intend to submit our NCD application for reconsideration following any such FDA clearance or approval of our technology. While we believe that the publication of our multi-center study results in the *New England Journal of Medicine* in December 2004 and patient preference and compliance study results regarding stool-based DNA screening will aid in our long-term efforts to gain reimbursement for our technologies, we also believe that additional performance data and patient compliance and preference data may likely be required before we submit to CMS with our request for reconsideration of our NCD application.

Pursue commercial introduction of next-generation stool-based DNA screening technology. In a recent research study that we designed to test the efficacy of technological advances to enhance colorectal cancer detection in stool, our Version 2 technology demonstrated sensitivity of 83 percent and specificity of 82 percent for the detection of colorectal cancer. The Version 2 research study involved the blinded analysis of post-colonoscopy collected stool samples from individuals whose colonoscopy results were positive for colorectal cancer. Although the specificity result in the Version 2 study was lower than our previous studies, we believe that the significant improvement in sensitivity compared to studies of Version 1 of our technology, including the multi-center study, will provide the basis to pursue the future commercial introduction of Version 2. Pursuant to our license agreement with LabCorp, LabCorp has exclusive rights through December 2010 to our Version 2 technology, subject to certain rights that we maintain to offer our technology commercially as well. As of the date of this Annual Report on Form 10-K, we are in discussions with LabCorp regarding their potential future commercialization of Version 2. We currently intend to pursue FDA clearance or approval for our Version 2 technology, which may require additional lengthy studies, the costs of which are likely to be material.

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 responsibility for all sales and marketing activities related to PreGen-Plus to LabCorp. LabCorp is the second largest commercial laboratory in the country and processes over 370,000 patient specimens daily through its system of more than 35 primary laboratories and over 1,600 patient service centers across the United States. LabCorp's large sales force of more than 1,100 people is devoted to selling a wide range of diagnostic tests to physicians across all specialties. We currently intend to leverage LabCorp's relationships and infrastructure to build market demand for PreGen-Plus and Version 2 of our stool-based DNA technology.

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 be one of the key prerequisites for any future CMS approval of our NCD application which we believe will, in turn, be 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, we do not expect that third-party payors will issue formal policy approval for PreGen-Plus or Version 2 prior to any FDA approval of our technologies, and, absent any such formal policy approval, it is unlikely that PreGen-Plus or Version 2 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 of tissue and 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 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 that is currently the most widely used non-invasive colorectal cancer screening test. 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 the study 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 recent 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 subset of samples from 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 prior to colonoscopy from an asymptomatic population.

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%
Mount Sinai School of Medicine	2005/2007	40	23	Effipure(4)	Yes	73%	89%
Version 2 Study							
Mount Sinai School of Medicine	2005/2007	40	2	Effipure(4)	Yes	88%	82%

(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 without cancer. 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 has been utilized in LabCorp's commercial testing service, PreGen-Plus, designed to increase human DNA yield

(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 the commercial test on the market today.

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, a common first-line FOBT colorectal cancer screening option. 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 neoplasia and has offered 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 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

At December 31, 2007, our research and development efforts are primarily focused on supporting regulatory submissions required by the FDA for clearance or approval of our technologies, and may be focused on supporting any commercial launch of Version 2 of our DNA screening technology. Addressing the FDA compliance matters relating to our technologies and the future commercialization of our Version 2 technology could require additional lengthy studies and, accordingly, the timing and costs of any FDA clearances 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 Version 2 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 our prior Version 2 study results. Our research and development expenses were $4.9 million, $6.7 million and $8.0 million for the years ended December 31, 2007, 2006 and 2005, respectively.

Sales and Marketing

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 are, therefore, materially dependent on LabCorp's sales efforts in building market demand for PreGen-Plus and Version 2 of our stool-based DNA technology. LabCorp's large sales force of more than 1,100 people calls on primary care physicians and promotes numerous products. Our efforts with respect to building awareness of stool-based DNA screening for colorectal cancer 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 in order to gain formal policy-level reimbursement for stool-based DNA testing.

Advocacy Development. We seek to work with influential advocacy groups to promote their awareness of stool-based DNA testing and its potential 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.

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

Reimbursement

We are continuing to work to obtain national coverage and reimbursement approval for our stool-based DNA colorectal cancer screening technologies from Medicare and, primarily through our relationship with LabCorp, major national and regional managed care organizations and insurance carriers, and self-insured employer groups. We support LabCorp in these efforts, from time to time, as circumstances warrant. Our reimbursement strategy consists primarily of leveraging our relationship with LabCorp toward the education of large managed care organizations, large self-insured employers and large physician groups about the clinical benefits and cost-effectiveness of stool-based DNA screening. We seek to complement these efforts through targeted, focused initiatives that benefit from direct relationships maintained by one or more of our employees.

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 a NCD on our Version 1 technology, which was accepted by CMS on August 1, 2007. Our Version 1 technology patents are the basis for LabCorp's PreGen-Plus testing service. Following acceptance of our application to CMS, we received the warning letter from the FDA in October 2007. Based in part on the FDA's determination as set forth in the warning letter that PreGen-Plus required premarket clearance, CMS issued a proposed decision memorandum regarding our application on January 30, 2008, which proposed not to provide coverage for our Version 1 technology. The proposed decision memo indicated that CMS would reconsider our application for coverage following any such 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 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. Accordingly, our future plans will likely include working to accumulate additional performance data, and patient compliance and preference data to submit to CMS 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 a positive coverage decision from CMS at acceptable reimbursement levels. 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 those payors may defer reimbursement policy decisions with respect to our technology until we obtain FDA clearance for our technologies, if ever. Finally, certain members of the MSTF-CRC may separately fail to support the position of the MSTF-CRC, which could have a detrimental effect on our commercial and reimbursement efforts.

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.

FDA Background

Laboratories that make and perform certain types of laboratory-developed tests, known in the industry as "homebrew" testing services, 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 has said it would exercise enforcement discretion, which allowed laboratories to develop their own clinical diagnostic test without obtaining FDA approval or clearance by following the regulations of the Clinical Laboratory Improvement Amendments of 1988, or CLIA.

We had believed, since LabCorp's commercial launch of PreGen-Plus in 2003, that PreGen-Plus met the requirements to qualify for regulation under CLIA as a homebrew test 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.

Since the commercial launch of PreGen-Plus in August 2003, LabCorp has validated and offered the PreGen-Plus testing service as an in-house developed laboratory test, or homebrew. 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 component used in processing 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 pre-market 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 has continued to market and process the PreGen-Plus test as a homebrew testing service. LabCorp's supply of Effipure includes components that have a finite useful life the duration of which, we believe, may be nearly exhausted. If LabCorp is unable to extend the useful life of these components, then LabCorp may be unable to continue to process PreGen-Plus tests in the near term. We further believe that certain finite resources required for the ongoing processing of the Version 1 test may also be nearly exhausted, which may result in an interruption in the PreGen-Plus testing service.

On October 11, 2007 the FDA sent the warning letter to us with respect to the PreGen-Plus testing service, 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 FDA. We are currently in communication with the FDA to specifically address the matters raised in the warning letter and to determine the appropriate premarket submission requirements and regulatory submission pathway in order to resolve the matters raised in the warning letter. As of the date of this Annual Report on Form 10-K, we have met with the FDA on two separate occasions to specifically address the matters raised in the warning letter. Based on these discussions, we are currently concluding our pre-IDE request discussions with the FDA and we believe, based on our most recent discussion with the FDA in February 2008, that the filing of a *de novo* 510(k) application with the FDA relating to Version 1 of our technology is the probable premarket submission pathway, which, if it results in clearance or approval, will, we believe, satisfy the FDA with respect to the matters raised in the warning letter.

EXACT's Interactions with the FDA

On November 2, 2007, in response to the FDA warning letter, we submitted to the FDA a pre-IDE request that described our intended premarket submission filing approach, including the reproducibility studies that we proposed to perform in connection therewith. The FDA responded by letter to our pre-IDE submission in December 2007, and, in an in-person meeting with the FDA in February 2008, we learned that the likely regulatory path forward with respect to our Version 1 technology would be a *de novo* 510(k) application, which would likely include a single-site reproducibility study, the details of which still need to be confirmed by the FDA. We do not have final confirmation or assurance from the FDA that the regulatory path forward will in fact be a *de novo* 510(k) or that a single site study along the dimensions we described to FDA will be acceptable. There also can be no assurance that the FDA will not instead require a PMA or regulatory filing approach that is different from the approach described here and certain other smaller technical studies.

The FDA has not yet indicated definitively whether the submission with respect to Version 1 of our technology would be a *de novo* 510(k). Moreover, the FDA may determine that a pre-market approval application, or PMA, is the appropriate path forward for us with respect to Version 1 of our stool-based DNA technology. The FDA may also determine that additional clinical studies, which could be costly and time-intensive, are required in connection with our submission, or that our proposal is

otherwise inadequate. Accordingly, the costs of any such studies could require that we seek additional capital in the near term, which could have an adverse and material impact on our financial position. There can be no assurance that the filing of a *de novo* 510(k) for our Version 1 technology will bring us into compliance with the matters raised by the FDA in the warning letter, or that the FDA will not issue a similar letter to LabCorp or otherwise require LabCorp to stop offering its PreGen-Plus testing service during the regulatory clearance process. The clearance or approval process for any version of our DNA-based technologies may require, among other things, successfully completing additional clinical and other studies, may require a PMA (rather than a 510(k) or *de novo* 510(k)) and may also necessitate our submitting PMAs with the FDA for multiple versions of our technology simultaneously or in sequence, all of which could take substantial time and resources including investment by us of substantial additional funds.

There can be no assurance that any version of our stool-based DNA technology will be cleared or approved by the FDA, that our proposed *de novo* 510(k) approach will satisfy the FDA's regulatory requirements for our Version 1 technology or any subsequent version of our technology, or that such FDA clearance or approval process can be completed without significant delays or material additional expense resulting from additional FDA required clinical or other studies. We may not have sufficient funds to complete any FDA regulatory clearance or approval process for our DNA-based technologies. In addition, we may delay any such process to preserve funds for on-going operations or otherwise. Moreover, we will require the support of third parties to assist us in the achievement of objectives relating to FDA clearance of our technologies, which may be costly. Ongoing compliance with FDA regulations will also increase the cost of conducting our business, subject us and LabCorp to inspection by FDA and to the requirements of FDA and penalties for failure to comply with these requirements.

Moreover, we cannot assure you that the commercial sales of PreGen-Plus will not be delayed, halted or prevented during the regulatory approval process, or that the FDA will not initiate enforcement action, which could involve criminal or civil penalties and cause material harm to our business. Additionally, LabCorp could decide to stop offering the current version of PreGen-Plus, could decide not to launch the Version 2 technology, or could decide to defer any potential future launch of the Version 2 technology until that version has been approved or cleared by the FDA, if ever, any of which would materially increase our costs, limit our revenue and cause material harm to our business and result in impairments of our fixed assets or capitalized patent portfolio ($0.4 million at December 31, 2007) or other personnel or facility related restructuring charges.

In addition, any stool-based DNA *in vitro* diagnostic test kit that we may develop in the future that would require FDA clearance or approval would be distinct from LabCorp's PreGen-Plus testing service, which remains on the market today as a homebrew testing service.

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 LabCorp fails to meet any applicable requirements of CLIA or state law, it could further delay acceptance of our CMS application, prevent its approval entirely, and/or interrupt the commercial sale of PreGen-Plus and otherwise cause us to incur significant expense.

In addition, the specimen containers that are used in connection with the PreGen-Plus test may also be deemed to be medical devices regulated by the FDA. Once a physician orders a test, the patient will need to receive a specimen container to collect the patient's stool. Specimen transport and storage containers generally have been exempted by regulation from the FDA's premarket clearance or

approval requirement and much of the Quality System Regulation. We believe that the specimen container falls within an applicable exemption, but we cannot be sure that the FDA will not assert that the container is not exempt and seek to impose a premarket clearance or approval requirement on the container itself.

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 near term markets for stool-based DNA testing.

As of December 31, 2007, we had 37 patents issued and 22 pending patent applications in the United States and, in foreign jurisdictions, 76 patents issued and 39 pending patent applications. Our success depends to a significant degree upon our ability to protect our technologies through patent coverage.

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 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 the United States, Japan, Europe and Canada.

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 provide LabCorp with the ability to manufacture and use the Acrydite technology in the PreGen-Plus test. The Acrydite technology is useful in connection with the proprietary electrophoretic DNA gel capture technology used in the isolation of 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 Johns Hopkins University, or JHU, certain patents owned by JHU that relate to digital amplification of DNA. 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 screening technologies. In exchange for the license, we have agreed to pay JHU certain royalties on revenues received by us relating to our or our sublicensees' sales of products and service.

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 provides us and our sublicensee, LabCorp, with the ability to use SBE in the PreGen-Plus test.

In June 2007, we licensed, 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.

In June 2007, we licensed, 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 PreGen-Plus testing service. We and LabCorp will also need to secure additional third-party intellectual property prior to any commercial introduction of the Version 2 technology.

Competition

To our knowledge, none of the large genomics or diagnostics companies are developing tests to conduct stool-based DNA testing 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 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. 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;

cost-effectiveness; and

patent protection.

Employees

As of December 31, 2007, we had fourteen employees, two of whom have a Ph.D. and one of whom has an M.D. We currently have eight employees engaged in research and development and six employees in general and administration. None of our employees are represented by a labor union. We consider our relationship with our employees to be good.

Available Information

We were incorporated in the State of Delaware on February 10, 1995. Our executive offices are located at 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 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.

Our independent auditors have expressed substantial doubt about our ability to continue as a going concern, and we may be unable to raise additional capital on acceptable terms in the future.

We have incurred substantial losses to date and we expect to incur substantial losses for the foreseeable future. As of December 31, 2007, we had an accumulated deficit of approximately $162.7 million. We have received a report from Ernst & Young LLP, our independent registered public accounting firm, regarding our consolidated financial statements for the fiscal year ended December 31, 2007, which included an explanatory paragraph stating that the financial statements were prepared assuming we will continue as a going concern. The report also stated that our recurring operating losses and need for additional financing have raised substantial doubt about our ability to continue as a going concern. We believe that our existing cash, cash equivalents and investment balances will be sufficient to meet our anticipated cash requirements through 2008, based on our current cost structure and current assumptions regarding the clinical and other studies and other requirements that we believe may be necessary to obtain U.S. Food and Drug Administration, or FDA, clearance of Version 1 of our DNA-based colorectal cancer screening technology. We have not yet reached final agreement with the FDA regarding any studies that would be necessary for the FDA clearance of Version 1 of our DNA-based technology, however, and the costs of any such studies could require us to obtain

additional funding before previously expected. Our future liquidity and capital requirements will depend upon numerous factors, including the following:

- the regulatory requirements for PreGen-Plus, or other stool-based DNA testing services utilizing our technologies, and the timing of 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 Laboratory Corporation of America Holdings, or 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;
- stool-based DNA screening becoming a standard of care among prescribing physicians;
- the scope of and progress made in our research and development activities; and
- the successful commercialization and sales growth of PreGen-Plus, or other stool-based DNA testing services utilizing our technologies.

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 will have to raise additional monies during 2008 through the sale of debt or equity securities, strategic collaborations with third parties and other strategic opportunities, if any, to continue our business operations beyond the end of our 2008 fiscal year. We cannot assure you that any of these alternatives will be successful, or even available, or that our actual cash requirements will not be greater than anticipated. In addition, the going concern explanatory paragraph included in our auditor's report on our consolidated financial statements could inhibit our ability to enter into license agreements or other collaborations or our ability to raise additional financing. If we are unable to obtain the required funds to enable us to fund our operations through the completion of any financing or other strategic opportunities that may become available to us, we will be required to further reduce the scale of our operations and our business, our results of operation and financial condition would be materially adversely affected and we may be required to seek bankruptcy protection.

Additionally, even if we do raise sufficient capital and generate revenues to support our operating expenses beyond fiscal 2008, there can be no assurances that the revenue will be sufficient to enable us to develop our business to a level where it will generate profits and cash flows from 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.

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, 2007, we have accumulated a total deficit of approximately $162.7 million. We expect that our losses will continue for at least the next several years and, depending upon our strategic direction, we may need to invest significant additional funds toward other

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areas in the oncology testing business. The FDA approval path for our colorectal cancer screening technology is likely to involve significant time as well as research and development 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 these investments and there can be no assurance that LabCorp will invest sufficient amounts in sales and marketing activities for PreGen-Plus or other future testing services based on our technologies. In addition, while we believe we are permitted, from a regulatory standpoint, to promote stool-based DNA testing services generically, our inability to market the brand "PreGen-Plus" under current FDA regulations may limit our return on amounts that we have invested or may invest in sales and marketing activities. 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, in large part, upon whether PreGen-Plus or other testing services offered by LabCorp based on our technologies 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 PreGen-Plus or Version 2, and the timing of any required regulatory filing and approval process;
- our ability to continue to fund our operations;
- whether LabCorp continues to offer PreGen-Plus or Version 2 commercially;
- 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 PreGen-Plus;
- 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;
- effective LabCorp sales and sales management personnel and processes to educate physician staffs regarding PreGen-Plus 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 technology;
- patient acceptance of PreGen-Plus, 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 PreGen-Plus or other stool-based DNA testing services utilizing our technologies.

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.

Since the commercial launch of PreGen-Plus, LabCorp has offered its testing service as an in-house developed laboratory test, or "homebrew" testing service. On October 11, 2007 the FDA sent a warning letter to us, which we refer to as the Warning Letter, with respect to the PreGen-Plus testing service, 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 FDA. We are currently in communication with the FDA to specifically address the matters raised in the Warning Letter and to determine the appropriate regulatory approval process to resolve the matters raised in the Warning Letter.

On November 2, 2007, in response to the FDA Warning Letter, we submitted to the FDA a pre-IDE, or pre-Investigational Device Exemption, request that described the specifics of our intended 510(k) filing approach, including the reproducibility studies that we proposed to perform in connection therewith. The FDA responded by letter to our pre-IDE submission in December 2007, and, in an in-person meeting with the FDA in February 2008, we learned that the most likely regulatory path forward with respect to our Version 1 technology would be a *de novo* 510(k) application, which would likely include a single-site reproducibility study.

The FDA has not yet indicated definitively whether the submission with respect to Version 1 of our technology would be a *de novo* 510(k). Moreover, the FDA may determine that a pre-market approval application, or PMA, is the appropriate path forward for us with respect to Version 1 of our stool-based DNA technology. The FDA may also determine that additional clinical studies, which could be costly and time-intensive, are required in connection with our submission, or that our proposal is otherwise inadequate. Accordingly, the costs of any such studies could require that we seek additional capital in the near term, which could have an adverse and material impact on our financial position. There can be no assurance that the filing of a *de novo* 510(k) for our Version 1 technology will bring us into compliance with the matters raised by the FDA in the Warning Letter, or that the FDA will not issue a similar letter to LabCorp or otherwise require LabCorp to stop offering its PreGen-Plus testing service during the regulatory clearance process. The clearance or approval process for any version of our DNA-based technologies may require, among other things, successfully completing additional clinical and other studies, may require a PMA (rather than a 510(k) or *de novo* 510(k)) and may also necessitate our submitting PMAs with the FDA for multiple versions of our technology simultaneously or in sequence, all of which could take substantial time and resources including investment by us of substantial additional funds.

There can be no assurance that any version of our stool-based DNA technology will be cleared or approved by the FDA, that our proposed *de novo* 510(k) approach will satisfy the FDA's regulatory requirements for our Version 1 technology or any subsequent version of our technology, or that such FDA clearance or approval process can be completed without significant delays or material additional expense resulting from additional FDA required clinical or other studies. We may not have sufficient funds to complete any FDA regulatory clearance or approval process for our DNA-based technologies. In addition, we may delay any such activities and process to preserve funds for on-going operations or otherwise. Moreover, we will require the support of third parties to assist us in the achievement of objectives relating to FDA clearance of our technologies, which may be costly. Ongoing compliance with FDA regulations will also increase the cost of conducting our business, subject us and LabCorp to inspection by FDA and to the requirements of FDA and penalties for failure to comply with these requirements.

Moreover, we cannot assure you that the commercial sales of PreGen-Plus will not be delayed, halted or prevented during the regulatory approval process, or that the FDA will not initiate enforcement action, which could involve criminal or civil penalties and cause material harm to our business. Additionally, LabCorp could decide to stop offering the current version of PreGen-Plus, could decide not to launch the Version 2 technology, or could decide to defer any potential future launch of

the Version 2 technology until that version has been approved or cleared by the FDA, if ever, any of which would materially increase our costs, limit our revenue and cause material harm to our business and result in impairments of our fixed assets or capitalized patent portfolio ($0.4 million at December 31, 2007).

Our ability to generate revenue depends on LabCorp's commercial sales of PreGen-Plus and future generations of our technologies.

All of our current operating revenue is dependent upon LabCorp's commercial sales of PreGen-Plus. We cannot assure you that LabCorp will ever achieve sufficient sales of PreGen-Plus or future generations of PreGen-Plus, such as Version 2, for us to become profitable. Moreover, in light of recent FDA regulatory action, we cannot assure you that LabCorp will keep PreGen-Plus on the market or commercially launch Version 2 while we seek FDA clearance for our technologies, if at all.

If LabCorp is unsuccessful in increasing sales of PreGen-Plus or commercializing Version 2, 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 PreGen-Plus or Version 2 under our strategic agreement, or whether it will elect to pursue the development or commercialization of Version 2. Any failure of the LabCorp sales force to give continued and sustained focus to PreGen-Plus or Version 2 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 or us could also negatively impact our ability to successfully commercialize PreGen-Plus or Version 2.

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 PreGen-Plus or Version 2 tests on an accurate and timely basis or has difficulty obtaining reimbursement, our revenue could be materially and adversely affected. Future demand for the PreGen-Plus test may require LabCorp to further optimize operational and quality assurance processes 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.

Our business is substantially dependent on the success of our strategic agreement with LabCorp.

We have a strategic alliance with LabCorp, under which we licensed to LabCorp certain of our technologies, including improvements to such technologies, that are required for the commercialization of PreGen-Plus. If LabCorp were to terminate the agreement, fail to meet its obligations under the agreement, decide to stop processing PreGen-Plus commercially, or otherwise decrease its commitment to PreGen-Plus, our revenues would be materially adversely affected, the commercialization of PreGen-Plus would 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 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 the continued commercialization of PreGen-Plus by LabCorp 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 we are unsuccessful in managing our strategic relationship with LabCorp, we would be required to enter into other strategic relationships for the commercialization of PreGen-Plus or attempt to commercialize the testing service 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.

If Medicare and other third-party payors, including managed care organizations, do not issue positive policy decisions approving reimbursement for PreGen-Plus, the commercial success of PreGen-Plus would be compromised.

Many physicians may decide not to order colorectal cancer screening tests using our technologies unless the tests are 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 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. Currently, no third-party payors have issued broad formal policy approving payment for stool-based DNA testing. Furthermore, following the August 1, 2007 acceptance by Centers for Medicare and Medicaid Services, or CMS, of our application for a National Coverage Determination, or NCD, on January 30, 2008, CMS issued a Proposed Decision Memo for Screening DNA Stool Test for Colorectal Cancer (CAG-00144N) that proposed not to provide coverage for our Version 1 technology because the FDA has determined that our Version 1 technology required FDA premarket clearance. The proposed decision memo stated that CMS would reconsider providing coverage for our technologies; however, such reconsideration will 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 have a similar impact on private third-party payors in that those payors may defer reimbursement policy decisions with respect to our technology until we obtain FDA clearance for our technologies, if ever.

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 2008 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 could potentially 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 recently released ACS guidelines, 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 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 sDNA 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. Such exclusion could materially limit our ability to secure third-party reimbursement and as a result, materially limit our revenues.

Neither we nor LabCorp has secured any broad-based policy-level reimbursement approval from Medicare or third-party payors to ensure the long-term commercial success of PreGen-Plus. 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 PreGen-Plus, the commercial success of PreGen-Plus would be compromised and our revenues would be significantly limited.

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 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 recommendations for each of the other six other colorectal cancer screening modalities included in such guidelines. Lack of a definitive screening interval recommendation by the ACS and the MSTF-CRC 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. Moreover, the lack of a screening interval recommendation may also lead to a 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.

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 PreGen-Plus requires access to certain technologies and supplies of raw materials, including elements relating to the Effipure microtiter plates, for which licensing and supply agreements are required. Although LabCorp indicated to the FDA that it is working on changes to PreGen-Plus that could eliminate the use of Effipure in processing PreGen-Plus tests, we cannot assure that it will be able to replace Effipure or that any substitute technology will have comparable performance. There also can be no assurance that existing inventory levels of materials necessary to process the PreGen-Plus test will be sufficient to support ongoing processing of

such tests for the period of time necessary for LabCorp to replace Effipure in commercial use or for the period of time necessary for LabCorp to transition to Version 2 of the stool-based DNA screening technology, either of which could result in an interruption in the testing service. Moreover, LabCorp's supply of certain materials and other components relating to its Version 1 PreGen-Plus testing service, including Effipure (which has a finite useful life) are nearly exhausted. If LabCorp is unable or unwilling to acquire new materials for the PreGen-Plus Version 1 test, and if LabCorp is unwilling or unable to extend the useful life of components with a finite shelf-life, then LabCorp may be unable to continue to process PreGen-Plus tests in the near term. Failure to transition to a new and effective DNA capture technology or to Version 2 of the test in the near term, could have a material adverse affect on the processing of PreGen-Plus and on our business. In the event LabCorp is able to identify a new DNA capture technology for use in connection with PreGen-Plus, any such technology may require us or LabCorp to pay additional royalties or other fees to third parties, which would have an adverse affect on our revenues or gross margin. Similarly, the commercialization of our Version 2 stool-based DNA screening technology will still 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 DNA capture component 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 PreGen-Plus or Version 2, or necessary to our realization of material revenues. Any failure to obtain necessary technologies or raw materials could require PreGen-Plus or Version 2 to be re-configured which could interrupt the testing service entirely, negatively impact its commercial sale and increase the costs associated with PreGen-Plus or Version 2, 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 PreGen-Plus.

If the results of our research and clinical studies do not convince third-party payors, physicians and thought leaders of the clinical value of our stool-based DNA technologies, we and LabCorp may never successfully commercialize such testing services 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 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 the PreGen-Plus testing service.

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 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, including the results of our recent study of Version 2, 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 PreGen-Plus and the successful commercialization of Version 2.

We expect to rely on third parties to conduct any future studies of our technologies that may be required by the FDA, and those third parties may not perform satisfactorily.

We do not have the ability to independently conduct clinical or other studies that may be required to obtain clearance for our DNA-based colorectal screening technology with the FDA. Accordingly, we expect to rely on third parties such as contract research organizations, medical institutions and clinical investigators to conduct any such studies. Our reliance on these third parties for clinical development activities will reduce our control over these activities. Accordingly, these third-party contractors may not complete activities on schedule, or may not conduct studies in accordance with regulatory requirements or our study design. Our reliance on third parties that we do not control does not relieve us of our requirement to prepare, and ensure our compliance with, various procedures required under good clinical practices, even though third-party contract research organizations have prepared and are complying with their own, comparable procedures. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our studies may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our technologies.

If PreGen-Plus cannot be effectively sold at a price acceptable to the market, the successful commercialization of PreGen-Plus would be materially harmed.

The success of PreGen-Plus and future versions of PreGen-Plus or other testing services based on our technologies depends, in material part, on the ability of LabCorp 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 endorse stool-based DNA screening for guidelines inclusion. In order to make PreGen-Plus less costly and more commercially attractive to consumers, physicians and third party payors, LabCorp will need to reduce the costs of tests using our technologies through significant automation of key operational processes or other cost savings procedures. There can be no assurance that such parties, including Medicare, will pay for PreGen-Plus at levels that will enable LabCorp or us to earn a profit, if at all, regardless of the performance of the technology. If LabCorp fails to create and improve technologies that sufficiently reduce costs, LabCorp's sales of PreGen-Plus and, as a result, our revenues may be limited. Moreover, if LabCorp is 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 our or LabCorp's technological advancements do not increase the performance of PreGen-Plus in a cost effective manner, the demand for PreGen-Plus may be negatively impacted.

We continue to work to improve the performance characteristics of stool-based DNA testing through research on technical innovations, such as our Version 2 technology. However, there can be no assurance that Version 2, or the commercial version of the PreGen-Plus test currently offered by LabCorp will have sufficient sensitivity and specificity or performance to be commercially successful. There also can be no assurance that the sample handling protocols employed by LabCorp for PreGen-Plus are adequate to prevent DNA degradation and resulting negative impacts on test performance. If the current commercial version or future generations of the PreGen-Plus test 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 PreGen-Plus, 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 PreGen-Plus for their patients which would limit our revenues and materially adversely affect our business.

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 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 PreGen-Plus, 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, 2007 we have 37 issued patents and 22 pending patent applications in the United States and we also have 76 issued foreign patents and 39 pending foreign patent applications. 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. A third party opposed one of our issued European patents relating to the enumerative analysis of nucleic acids in biological samples. The European Patent Office issued a decision to maintain the patent in force; however, this decision may be appealed by the third-party opponent. 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. A third-party institution is a co-owner of one of our issued patents relating to pooling patient samples in connection with our loss of heterozygosity detection method. 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, a pending U.S. 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 cancers of the lung, pancreas, esophagus, stomach, small intestine, bile duct, naso-oro-pharyngeal airways, liver, and/or gall bladder in stool. As joint owners of these 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.

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.

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. 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 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 PreGen-Plus testing service. Although we have identified suppliers that we believe are capable of supplying these raw materials and components in sufficient quantity today, 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 and components necessary to meet demand will be available in sufficient quantities or on acceptable terms, if at all. If we, or LabCorp, should encounter delays or difficulties in securing the necessary raw materials and components for LabCorp's PreGen-Plus testing service, LabCorp may need to reconfigure its PreGen-Plus 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 PreGen-Plus is 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 PreGen-Plus in certain jurisdictions. Also, conforming the marketing and sale of our technologies to any applicable regulations and guidelines could substantially increase our operating expenses. In addition, LabCorp and any other laboratory that uses PreGen-Plus are 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 PreGen-Plus, 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 PreGen-Plus has been based on existing healthcare policies. Changes in healthcare policy could substantially interrupt the sales of PreGen-Plus, 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 a laboratory developed test, or homebrew, over which the FDA would exercise its enforcement discretion. In October 2007, we then received the Warning Letter 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 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 loss of key members of our senior management team could adversely affect our business.

Our success depends upon the continued services of key members of our senior management team. Although we have in the past entered, and may in the future enter, into retention agreements with members of our management team, each of our executive officers could terminate his relationship with us at any time. For instance, in July 2007, Don M. Hardison resigned his position as our President and Chief Executive Officer. Mr. Hardison has been critical to the pursuit of our business goals and we may experience difficulties developing our technologies and testing processes, and implementing our business strategies. The loss of any member of our current management team could significantly delay or prevent the achievement of our business or development objectives and could materially harm our business. In addition, as part of our restructuring activities to reduce expenditures in 2005, 2006 and 2007, we significantly reduced our headcount. These restructurings could materially harm our ability to attract and retain skilled personnel, including our management.

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 Global Market under the symbol "EXAS." Factors affecting our stock price may include:

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

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

clinical trial results relating to the PreGen-Plus test, 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 PreGen-Plus; 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.

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 PreGen-Plus;

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 PreGen-Plus commercialization efforts, licensing and acquisition initiatives, clinical studies, and internal research and development.

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 Global 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.

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 and research and academic institutions, such as Mayo Clinic, 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, 2007, we occupied approximately 25,537 square feet of space in our headquarters located in Marlborough, Massachusetts under a lease which expires in July 2010. We believe that these facilities will be adequate to meet our space requirements for the foreseeable future.

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 2007.

PART II

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

Our common stock is listed on the NASDAQ Global 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.

	High	Low
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
2006		
First quarter	$4.97	$2.16
Second quarter	3.40	2.05
Third quarter	3.09	1.53
Fourth quarter	3.04	1.71

As of December 31, 2007, there were approximately 27,139,991 shares of our common stock outstanding held by approximately 77 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, 2007, 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.

Equity Compensation Plan Information

We maintain the following three equity compensation plans under which our equity securities are authorized for issuance to our employees and/or directors; the 1995 Stock Option Plan, the 2000 Stock Option and Incentive Plan and the 2000 Employee Stock Purchase Plan. Each of the foregoing equity compensation plans was approved by our stockholders. The following table presents information about these plans as of December 31, 2007.

Plan Category	Number Of Securities To Be Issued Upon Exercise Of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price Of Outstanding Options, Warrants And Rights	Number of Securities Remaining Available For Future Issuance Under Equity Compensation Plans (Excluding Securities Outstanding)
Equity compensation plans approved by security holders	3,996,688	$4.88	3,780,242
Equity compensation plans not approved by security holders	None	None	None
Total	3,996,688	$4.88	3,780,242

No further grants are being made under the 1995 Stock Option Plan.

Item 6. Selected Financial Data

The selected historical financial data set forth below as of December 31, 2007 and 2006 and for the years ended December 31, 2007, 2006 and 2005 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, 2005, 2004 and 2003 and statements of operations data for the years ended December 31, 2004 and 2003 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 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,				
	2007	2006	2005	2004	2003
Statements of Operations Data:					
Revenue:					
Product royalty fees	$ (1,137)	$ 179	$ 206	$ 166	$ 8
License fees	2,857	4,363	3,828	4,514	2,871
Product	78	208	216	255	22
	1,798	4,750	4,250	4,935	2,901
Cost of revenue	49	809	566	487	22
Gross profit	1,749	3,941	3,684	4,448	2,879
Operating expenses:					
Research and development(1)	4,887	6,735	7,956	11,122	17,333
Sales and marketing(1)	991	3,792	5,239	5,202	6,822
General and administrative(1)	7,541	6,910	5,497	7,319	7,562
Restructuring(1)	1,177	671	626		
	14,596	18,108	19,318	23,643	31,717
Loss from operations	(12,847)	(14,167)	(15,634)	(19,195)	(28,838)
Interest income	888	1,252	1,114	672	498
Net loss	$ (11,959)	$ (12,915)	$ (14,520)	$ (18,523)	$ (28,340)
Net loss per share:					
Basic and diluted	$ (0.44)	$ (0.49)	$ (0.55)	$ (0.73)	$ (1.50)
Weighted average common shares outstanding:					
Basic and diluted	26,945	26,509	26,270	25,334	18,911
Balance Sheet Data:					
Cash and cash equivalents	$ 4,486	$ 4,831	$ 11,987	$ 12,077	$ 13,189
Marketable securities	8,101	16,244	21,112	37,188	13,606
Total assets	14,595	23,868	37,845	56,111	34,681
Total liabilities	8,307	8,910	13,224	18,128	22,453
Stockholders' equity	6,288	14,958	24,621	37,983	12,228

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

	2007	2006	2005	2004	2003
Research and development	$ 541	$ 653	$ 113	$ 221	$ 249
Sales and marketing	202	956	152		
General and administrative	1,889	1,397	240	277	869
Restructuring	174				

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 cancer. We have selected colorectal cancer as the first application of our technologies. We have licensed certain of our technologies, including improvements to such technologies, on an exclusive basis through December 2010 to Laboratory Corporation of America® Holdings, or LabCorp®, for use in a commercial testing service developed and sold by LabCorp under the name PreGen-Plus . PreGen-Plus is LabCorp's non-invasive, stool-based DNA testing service for the detection of colorectal cancer in the average-risk population. Our Version 1 technology is the basis for LabCorp's PreGen-Plus test. 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 proprietary technologies to LabCorp and others;
- working to further the adoption of stool-based DNA testing for colorectal cancer, including seeking inclusion of such 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; and
- working with LabCorp on activities in support of the commercialization of PreGen-Plus and Version 2.

We have generated limited operating revenues since our inception and, as of December 31, 2007, we had an accumulated deficit of approximately $162.7 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.

LabCorp launched PreGen-Plus commercially in August 2003. From the date of launch through December 31, 2007, LabCorp had accessioned approximately 14,300 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 addition to our Version 1 technology underlying the PreGen-Plus testing service offered by LabCorp, we have also developed a Version 2 colorectal cancer screening technology that we believe has greater sensitivity and is more cost effective than Version 1. In a recent 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. As of the date of this Annual Report on Form 10-K, we are in discussions with LabCorp, the exclusive licensee to our Version 2 technology, regarding the potential future commercialization of Version 2.

To increase market adoption of our stool-based DNA screening technologies, we have focused our efforts on the achievement of the following corporate goals:

Obtaining FDA clearance for our stool-based DNA screening technologies;

Obtaining formal acceptance of stool-based DNA screening for reimbursement by Medicare and other third-party payors; and

Leveraging LabCorp's large sales force to increase sales and marketing efforts for PreGen-Plus and, if commercialized, Version 2.

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 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 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. PreGen-Plus is therefore now the first DNA-based, non-invasive colorectal cancer screening test to be included in the colorectal cancer screening guidelines of the ACS and MSTF-CRC in the United States for the average risk population. 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 PreGen-Plus, we believe that FDA clearance for our current and future technologies, and reimbursement from CMS and other third-party payors will be necessary in order to achieve significant increases in demand for our technologies.

Government Regulation

On October 11, 2007 the FDA sent a warning letter to us 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 FDA. We have met with the FDA on two separate occasions to specifically address the matters raised in the warning letter. Based on these discussions, we are currently focusing our efforts on concluding the pre-Investigational Device Exemption, or pre-IDE, process with the FDA and potentially filing of a *de novo* 510(k) with the FDA on our Version 1 technology.

There can be no assurance that any version of our stool-based DNA technology will be cleared or approved by the FDA, that our proposed *de novo* 510(k) approach will satisfy the FDA's regulatory requirements for our Version 1 technology or any subsequent version of our technology, or that such FDA clearance or approval process can be completed without significant delays or material additional expense resulting from additional FDA required clinical or other studies. We may not have sufficient funds to complete any FDA regulatory clearance or approval process for our DNA-based technologies. In addition, we may delay any such process to preserve funds for on-going operations or otherwise. Moreover, we will require the support of third parties to assist us in the achievement of objectives relating to FDA clearance of our technologies, which may be costly. Ongoing compliance with FDA regulations will also increase the cost of conducting our business, subject us and LabCorp to inspection by FDA and to the requirements of FDA and penalties for failure to comply with these requirements. Moreover, we cannot assure you that the commercial sales of PreGen-Plus will not be delayed, halted or prevented during the regulatory approval process. Additionally, LabCorp could decide to stop offering the current version of PreGen-Plus, could decide not to launch the Version 2 technology, or could decide to defer any potential future launch of the Version 2 technology until that version has

been approved or cleared by the FDA, if ever, any of which would materially increase our costs, limit our revenue and cause material harm to our business and result in impairments of our fixed assets or capitalized patent portfolio ($0.4 million at December 31, 2007) and result in personnel of facility related restructuring charges.

Reimbursement

An important component of our reimbursement strategy is to obtain a National Coverage Determination, or NCD, from CMS for inclusion of our stool-based DNA screening technologies for colorectal cancer in the Medicare program. In December 2004, we submitted our application for a NCD on our Version 1 technology, which was accepted by CMS on August 1, 2007. Following acceptance of our application to CMS, we received the warning letter from the FDA. Based in part on the FDA's determination as set forth in the warning letter that our Version 1 technology required premarket clearance or approval, CMS issued a proposed decision memorandum regarding our application on January 30, 2008, which proposed not to provide coverage for our Version 1 technology. The proposed decision memo indicated that CMS would reconsider our application for coverage following any such FDA clearance or approval of our DNA screening technology. Accordingly, we intend to submit our NCD application for reconsideration following any such FDA clearance or approval of our 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 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. Accordingly, we are also working to accumulate additional performance data and patient compliance and preference data to submit to CMS with our request for reconsideration of our NCD application. We could incur significant time and costs to accumulate such additional data to obtain a positive coverage decision from CMS at acceptable reimbursement levels. Additionally, despite the fact that our technology is included in the ACS and MSTF-CRC guidelines, the FDA warning letter may have a similar impact on private third-party payors in that those payors may defer reimbursement policy decisions with respect to our technology until we obtain FDA clearance for our technologies, if ever.

Other 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. 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 PreGen-Plus. Despite the inclusion of stool-based DNA screening in colorectal cancer screening guidelines, we do not expect material revenue growth until such time as FDA clearance or approval is obtained, reimbursement is provided by Medicare and other third party payors at an acceptable level and sufficient funds and managerial time are invested in sales and marketing efforts. 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 PreGen-Plus or any other product based on our technologies;
- whether LabCorp continues to offer PreGen-Plus commercially or commercially launches a testing service based on our Version 2 technology;
- success in educating third-party payors, managed care organizations, and technology assessment groups regarding stool-based DNA screening;
- effective negotiation and contracting by us and LabCorp with Medicare and other third-party payors for coverage at acceptable levels of reimbursement for stool-based DNA screening;

patient 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;

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

the quality and service of the LabCorp testing process.

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, product royalty fees on PreGen-Plus tests sold by LabCorp, and product revenue from the sale to LabCorp of Effipure components, which are used by LabCorp in processing PreGen-Plus tests. We expect that product royalty fees for 2008 will be materially consistent with amounts recorded in 2007 as a result of potential third party royalty obligations in connection with our amended license agreement with LabCorp. In addition, as a result of the amendment to our license agreement with LabCorp, which also extended the exclusive license period under our agreement with LabCorp, we expect that license fee revenue for 2008 will be lower than amounts recorded in 2007 as a result of the extended amortization period over which our remaining deferred revenue will be amortized. See "Amendments to LabCorp License Agreement" below for a discussion of recent modifications to our license agreement with LabCorp.

LabCorp informed the FDA during 2006 that they were working on changes to PreGen-Plus that would eliminate the use of Effipure in PreGen-Plus. We, therefore, do not expect to record material revenues from the sale of Effipure components to LabCorp during 2008. The potential loss of this revenue is not expected to have a material impact on our total revenues. In this regard, LabCorp's supply of Effipure includes components that have a finite useful life the duration of which, we believe, may be nearly exhausted. We also believe that inventory levels at LabCorp relating to other components necessary for the ongoing commercialization of Version 1 of PreGen-Plus may also be nearly exhausted. If LabCorp is unable or unwilling to extend the useful life of these components or acquire new components, then LabCorp may be unable to continue to process PreGen-Plus tests in the near term. Any such interruption in the commercial availability of PreGen-Plus could have a materially adverse affect on our business.

Amendments to LabCorp License Agreement

Second Amendment to LabCorp License Agreement On June 27, 2007, we entered into a second amendment, or Second Amendment, to our license agreement with LabCorp. The Second Amendment modified LabCorp's exclusive rights to our DNA technology for colorectal cancer screening to permit us to license our 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 Amendment until December 31, 2010. Additionally, the Second Amendment clarifies the rights and obligations with respect to our Version 2 technology for colorectal cancer screening.

The Second Amendment also revised certain milestone and royalty obligations of LabCorp. The milestones were revised to eliminate milestone payments aggregating $15 million based upon policy-level reimbursement approval from key payors including Medicare and the inclusion of stool-based DNA screening in clinical practice guidelines. As revised, we may be eligible for up to an aggregate of $40 million in milestone payments, all of which now relate to the achievement of significant sales thresholds. Royalties due to us under the Second Amendment are equal to 15% of LabCorp's net revenues from tests performed using our DNA technology licensed under the Second Amendment, and could increase to 17% if LabCorp achieves a significant annual PreGen-Plus net revenue threshold. LabCorp also retains preferential pricing terms over third-party organizations and commercial service laboratories to which we may license our DNA technology for colorectal cancer screening.

The Second Amendment also eliminated our approximately $3.0 million contingent liability to LabCorp resulting from a certain third-party royalty obligation of LabCorp. Under 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 specified royalty rate during the

measuring period, as outlined in the table below. Our liability to pay LabCorp pursuant to this provision of the Second Amendment is based on LabCorp's sales volumes of PreGen-Plus during three separate measurement periods, as defined below. A significant increase in PreGen-Plus test sales volumes during any measurement period, as compared to historical sales PreGen-Plus sales levels volumes, could reduce our potential obligation to zero 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 over the measurement periods. Until sales of PreGen-Plus increase to a level that would reduce this potential maximum obligation, if ever, we intend to record the estimated obligation under this provision of the Second Amendment as a reduction in the product royalty fee line item in our consolidated statements of operations. Based on low anticipated PreGen-Plus sales volumes prior to any potential FDA approval of our technology, as of December 31, 2007, we have accrued $1.2 million of the total potential $1.5 million obligation related to the first measurement period, which ends in December 2008. This charge was recorded under the caption "Product royalty fees" in our consolidated statements of operations for the year ended December 31, 2007. This obligation is recorded in our consolidated balance sheets under the caption "Third party royalty obligation".

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

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, we 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. We 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 our consolidated statements of operations.

The Second Amendment also provided LabCorp with termination rights if stool-based DNA colorectal cancer screening is not accepted as standard of care in the near term, if our Version 2 technology is not commercially launched in the near term, or if our Version 2 technology does not attain certain sensitivity and specificity thresholds during technology validation.

Third Amendment to LabCorp License Agreement On August 31, 2007, we entered into the third amendment, or Third Amendment, to our exclusive license agreement with LabCorp. The Third Amendment, among other things, added a potential $2.5 million milestone payment for which we may be eligible. The milestone payment is based upon specified minimum policy-level reimbursement approval from Medicare, 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 of our former personnel.

Fourth Amendment to LabCorp License Agreement On March 17, 2008, we entered into the fourth amendment, or Fourth Amendment, to our 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 our Version 2 technology and restricted certain of our termination rights in the event the FDA limits LabCorp's ability to market products that

incorporate technology licensed to LabCorp under our amended license agreement. In addition, the Fourth Amendment eliminated certain of our 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 our Version 2 technology.

Our Cost Structure

In October 2006 and again in July 2007, we initiated cost reduction plans and reduced our workforce and other operating expenses, which we refer to as the 2006 Restructuring and the 2007 Restructuring, respectively, to help preserve our cash resources. The 2006 Restructuring eliminated 21 positions, or 48% of our staff at that time, across all departments. 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. Since these restructurings, our efforts have focused on the pursuit of inclusion of stool-based DNA testing in screening guidelines of the major guidelines organizations, including the guidelines of the ACS and MSTF-CRC, Medicare coverage pursuit for stool-based DNA testing, optimization and validation of our Version 2 technology and, most recently, FDA clearance or approval of our stool-based DNA screening technologies. We continue to assess our facility needs and other operating costs and, as a result, could incur additional restructuring charges in the event we undertake additional activities to reduce facility or other operating costs.

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). While we took steps in 2006 and 2007 to lower research and development costs by focusing primarily on our Version 2 technology, we may need to invest substantial funds in additional research, design and development, or clinical or other studies that may be required for FDA approval or clearance of our stool-based DNA screening technologies, and to successfully commercialize the technology that is the basis for the PreGen-Plus testing service, or any current or future versions of our technologies or products. In this regard, the costs of reproducibility, or other studies, that may be required by the FDA in connection with our proposed *de novo* 510(k) pre-market clearance notice for our Version 1 and any subsequent filings for other versions of our technologies are expected to be material. We therefore expect that our research and development costs in 2008 could be materially higher than 2007 levels, depending on the scope of studies required by the FDA. See discussion of the FDA status of our technology in "Government Regulation" above.

Selling, general and administrative expenses consist 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 do not expect to incur material sales and marketing operating expenses in 2008. We expect general and administrative expenses in 2008 to be higher than 2007 levels, primarily as a result of increased professional fees during 2008 as in connection with our ongoing efforts to obtain FDA regulatory clearance or approval of our DNA-based technologies.

Significant Accounting Policies

This management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition 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 amended our exclusive license agreement with LabCorp which, among other modifications to the terms of the license, extended the exclusive license period of the license with LabCorp from August 2008 through December 2010. Accordingly, we 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 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. 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 sales of PreGen-Plus, as reported to us each month by LabCorp. The current royalty rate is 15%, subject to increase to 17% in the event that LabCorp achieves a specified significant threshold of annual net revenues from the sales of PreGen-Plus.

Additionally, pursuant to the Second Amendment, we will potentially be obligated to reimburse LabCorp for certain third-party royalty payments, as described in Note 3 to the consolidated financial statements located elsewhere in this annual report. To the 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 is recognized upon transfer of the components provided that title passes, the price is fixed or determinable and collection of the receivable is probable.

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 us 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 may warrant revision or that the carrying value of these assets may be impaired. Such events may include whether stool-based DNA screening is included in colorectal cancer screening guidelines or a change in the regulatory requirements for PreGen-Plus. We did not record any impairment charges during the year ended December 31, 2007.

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. Under the terms of our amended license agreement with LabCorp, we are potentially liable to reimburse LabCorp for a certain third-party royalty payment made by LabCorp in connection with its sales of PreGen-Plus. Our potential liability is described under the section "Amendments to LabCorp License Agreement" above. In connection with this obligation, we recorded charges of $1.2 million under the caption "Product royalty fees" in our consolidated statements of operations during the year ended December 31, 2007. This obligation is recorded in our consolidated balance sheets under the caption "Third party royalty obligation".

Recent Accounting Pronouncements

In June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109*, or the Interpretation. The Interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes*. The Interpretation 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. The Interpretation also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Interpretation is effective for fiscal years beginning after December 15, 2006. We adopted the Interpretation effective January 1, 2007 and it did not have a material impact on our consolidated results of operations, financial position or cash flows.

In September 2006, FASB issued Statement No. 157, *Accounting for Fair Value Measurements*, or 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 would be 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, with early adoption permitted. We do not expect the adoption of this standard to have a material impact on our consolidated results of operations, financial position or cash flows.

In September 2006, the SEC issued Staff Accounting Bulletin (SAB) No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, or SAB No. 108. SAB No. 108 provides guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. SAB No. 108 establishes an approach that requires quantification of financial statement errors based on the effects on each of the company's balance sheet and statement of operations and the related financial statement disclosures. SAB No. 108 permits existing public companies to record the

cumulative effect of initially applying this approach in the first year ending after November 15, 2006 by recording the necessary correcting adjustments to the carrying values of assets and liabilities as of the beginning of that year with the offsetting adjustment recorded to the opening balance of retained earnings. Additionally, the use of the cumulative effect transition method requires detailed disclosure of the nature and amount of each individual error being corrected through the cumulative adjustment and how and when it arose. The adoption of SAB No. 108 in the first quarter of fiscal 2007 did not have any impact on our financial statements.

In February 2007, the FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities including an amendment of FASB Statement No. 115*, or SFAS No. 159. SFAS No. 159 provides entities with an option to choose to measure eligible items at fair value at specified election dates. If elected, an entity must report unrealized gains and losses on the item in earnings at each subsequent reporting date. The fair value option may be applied instrument by instrument, with a few exceptions, such as investments otherwise accounted for by the equity method, is irrevocable (unless a new election date occurs); and is applied only to entire instruments and not to portions of instruments. SFAS No. 159 is effective for the company in 2008. We are currently evaluating if we will elect the fair value option for any of our eligible financial instruments and other items and currently, we do not expect that the adoption of SFAS No. 159 will have a material impact on our financial statements.

In June 2007, the FASB issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or EITF 07-3. EITF 07-3 requires that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services are performed. EITF 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007. We are currently analyzing the effect, if any, EITF 07-3 will have on our financial position and results of operations.

Results of Operations

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.

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 "Amendments to LabCorp License Agreement" 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 anticipate in light of the current regulatory and reimbursement status of our technology, as of December 31, 2007,we have accrued $1.2 million of the total potential $1.5 million obligation related to the first measurement period, which ends 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.

During 2006, LabCorp informed the FDA that it was working on changes to PreGen-Plus that could eliminate the use of Effipure. We, therefore, do not expect to record material revenues from the sale of Effipure components to LabCorp during 2008 or beyond. The loss of this revenue during 2008 is not expected to have a material impact on our total revenues.

The prospective impact of our amended license agreement with LabCorp on our license fee revenue and our product royalty fee revenue is described above.

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.

There can be no assurance that LabCorp will be able to identify an alternative process for Effipure in connection with LabCorp's processing of the PreGen-Plus test, which could result in interruption in the PreGen-Plus testing service and could materially harm our business. There can also be no assurance that LabCorp will cease using Effipure in the processing of PreGen-Plus tests if LabCorp does not have a suitable alternative to Effipure in place. 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 Oncomethylome Sciences S.A., or OMS, on June 14, 2007 pursuant to the terms of a Manufacturing and Supply Agreement with OMS.

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" below.

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 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. During the third quarter of 2007, in connection with the Third Amendment, we terminated five employees and one employee effective August 31, 2007 and October 31, 2007, respectively. The 2007 Restructuring was principally designed to eliminate our sales and marketing functions to reduce costs and help preserve our cash resources. 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. Since the 2007 Restructuring, our efforts have been focused on:

- the pursuit of inclusion of stool-based DNA testing in screening guidelines of the major guidelines organizations, including the guidelines that resulted from the joint efforts of the ACS and the MSTF-CRC;
- Medicare coverage pursuit for stool-based DNA testing;
- validation and optimization of our Version 2 technology; and
- the pursuit of FDA clearance for our stool-based DNA screening technologies.

Restructuring charges recorded during the third quarter of 2007 of $0.8 million included $0.6 million in severance and related benefit costs expected to be paid in cash through May 2008, and $0.2 million in non-cash stock-based compensation charges. We extended by nine months, to August 31, 2008, the expiration date of stock options to purchase up to 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. Pursuant to the measurement provisions of SFAS No. 123(R), we recorded one-time non-cash stock-based compensation charges of $0.2 million in connection with these stock option modifications in our consolidated statements of operations during the quarter ended September 30, 2007. See Note 9 to our consolidated financials statements included elsewhere in this report for a description of these stock option modifications.

During the fourth quarter of 2007, we entered into a sublease agreement, or the Sublease Agreement, to sublease approximately 11,834 square feet of rentable area in our corporate headquarters. The term of the Sublease Agreement, which commenced on December 15, 2007, is 32 months with a base rent of $266,265 per year. The subtenant has no rights to renew or extend the

Sublease Agreement. Under the terms of the Sublease Agreement, the subtenant 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. We believe that our remaining 25,537 square feet of leased space is adequate for our current requirements.

In connection with the 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 Sublease Agreement and approximately $0.1 million of non-cash charges related to the write-off of leasehold improvements abandoned in connection with the Sublease Agreement. Our decision to enter into the 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, 2007, which are expected to be paid out through July 2010, are recorded under the caption "Accrued expenses" in our condensed consolidated balance sheets. The right of terminated employees to continue to receive severance payments from us will be dependent upon when, and if, the terminated employees secure employment with another employer during the defined severance period and, therefore, our estimate of the total restructuring charges may be adjusted in future periods.

The following table summarizes the 2007 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	$	$ 588	$ (364)	$	$ 224
Facility consolidation costs		387	(34)	(85)	268
Total	$	$ 975	$ (398)	$ (85)	$ 492

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.

We account for restructuring charges in accordance with SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, or 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.

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.

Comparison of the years ended December 31, 2006 and 2005

Revenue. Total revenue increased to $4.8 million for the year ended December 31, 2006 from $4.3 million for the year ended December 31, 2005. All of our revenues are derived from our license agreement with LabCorp. Revenue is primarily composed of the amortization of up-front technology license fees associated with agreements signed with LabCorp that are being amortized on a straight-line basis over the exclusive license period, which ends in August 2008, and, to a lesser extent, royalties on LabCorp's sales of PreGen-Plus and sales of Effipure units to LabCorp.

The increase in total revenue for the year ended December 31, 2006 as compared to the year ended December 31, 2005 was primarily the result of a one-time, non-cash reduction in revenue of $0.6 million recorded in June 2005 in connection with the amendment of a warrant issued to LabCorp in June 2002 to purchase 1,000,000 shares of our common stock, at an exercise price of $16.09 per share. At the time of issuance, the LabCorp warrant had an expiration date of June 26, 2005. On June 24, 2005, we entered into an amendment to the warrant to extend the expiration date to August 13, 2008, which is the expiration date of the exclusive period under our license agreement with LabCorp. All other terms of the warrant were unaffected. We assigned a value to the 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*, we recorded the cost of the warrant extension as a one-time, non-cash reduction in license fee revenue of $0.6 million in the quarter ended June 30, 2005.

During 2006, LabCorp informed the FDA that it was working on changes to PreGen-Plus that could eliminate the use of Effipure. We, therefore, do not expect to record material revenues from the sale of Effipure components to LabCorp during 2007 or beyond. The loss of this revenue beginning in 2007 is not expected to have a material impact on our gross margins because, under our agreement with LabCorp, our Effipure sales to LabCorp resulted in no gross margin as LabCorp reimbursed us only for our costs to provide Effipure to them.

Cost of revenue. 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. Total cost of revenue increased to $0.8 million for the year ended December 31, 2006 from $0.6 million for the year ended December 31, 2005. The increase in the cost of product revenue for the year ended December 31, 2006 as compared to the same period of the prior year was primarily the result of higher write-offs of Effipure inventory. We wrote off $0.7 million and $0.4 million in excess Effipure inventory during the years ended December 31, 2006 and 2005, respectively. Specifically, we wrote off approximately $0.5 million in excess Effipure inventory units during the quarter ended March 31, 2006 as a result of LabCorp's decision to discontinue use of Effipure in the processing of PreGen-Plus tests beyond 2006.

During the development of the manufacturing and supply chain processes for Effipure components, we entered into agreements with certain suppliers and contract manufactures to produce components utilized in Effipure. Certain of these supply agreements included minimum purchase commitments to be fulfilled by us over the life of the agreements, the last of which expired in April 2006. As of December 31, 2006, the carrying value of our Effipure inventory was $0.

There can be no assurance that LabCorp will be able to identify an alternative process for Effipure in connection with LabCorp's processing of the PreGen-Plus test, which could result in interruption in the PreGen-Plus testing service and could materially harm our business. There can also be no assurance that LabCorp will cease using Effipure in the processing of PreGen-Plus tests in 2007 if LabCorp does not have a suitable alternative to Effipure in place.

Research and development expenses. Research and development expenses decreased to $6.7 million for the year ended December 31, 2006 from $8.0 million for the year ended December 31, 2005. The decrease in the year ended December 31, 2006 as compared to the same period of 2005 was primarily the result of the completion of the primary clinical study supporting Version 2 of our stool-based DNA technology in late 2005, resulting in lower research and development expenses in the year ended December 31, 2006 as compared to the same period of 2005. In addition, as described under the heading "Restructuring" below, we took actions in October 2006 to reduce our headcount across all departments in order to lower our overall cost structure. This restructuring drove the reduction in research and development costs when comparing the year ended December 31, 2006 to December 31, 2005. Included in the decrease in research and development expenses for the year ended December 31, 2006, as compared to the year ended December 31, 2005, were decreases of $0.5 million in personnel-related expenses, $0.5 million in clinical study expenses, $0.4 million related to laboratory space and

$0.3 million in laboratory supplies. These decreases were partially offset by an increase of $0.5 million in stock-based compensation expense for the year ended December 31, 2006 as compared to the same period of 2005 as a result of the adoption of SFAS No 123(R) on January 1, 2006.

Sales and marketing expenses. Sales and marketing expenses decreased to $3.7 million for the year ended December 31, 2006 from $5.2 million for the year ended December 31, 2005. This decrease was primarily due to a decrease of $1.5 million in personnel related expenses for the year ended December 31, 2006 as compared to the same period of 2005 as a result of a reduction in the size of our sales and marketing force from seventeen employees at December 31, 2005 to five employees at December 31, 2006. We also reduced our external advertising, marketing and promotional spending by $0.7 million during the year ended December 31, 2006 as compared to the year ended December 31, 2005. These reductions reflect a focus on spending primarily on those initiatives that directly or indirectly support guidelines inclusion, as well as a shift away from direct marketing to physicians to third-party payor groups, self-insured employers and technology assessment groups. These decreases were partially offset by an increase of $0.8 million in stock-based compensation expense for the year ended December 31, 2006 as compared to the same period of 2005 as a result of the adoption of SFAS No 123(R) on January 1, 2006.

General and administrative expenses. General and administrative expenses increased to $6.9 million for the year ended December 31, 2006 from $5.5 million for the year ended December 31, 2005. This increase was primarily the result of an increase of $1.1 million in stock-based compensation expense recorded in the year ended December 31, 2006, as compared to the same period of 2005, as a result of the adoption of SFAS No. 123(R) on January 1, 2006. Also included in the increase in general and administrative expenses for the year ended December 31, 2006 as compared to the year ended December 31, 2005 were increases in professional fees of $0.2 million, and personnel related expenses of $0.1 million resulting from the accrual of retention bonuses in the fourth quarter of 2006.

Restructuring

2006 Restructuring. On October 17, 2006, we initiated a plan to reduce our cost structure by eliminating 21 positions, or 48% of our staff, across all departments to reduce expenses. This workforce reduction reflects our intention 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 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.

Amounts remaining in the restructuring accrual at December 31, 2006 are expected to be paid out through September 2007 and are recorded under the caption "Accrued expenses" in the condensed consolidated balance sheets at December 31, 2006. Amounts included in the table are in thousands.

Type of Liability	Balance, September 30, 2006	Charges	Cash Payments	Non-cash Write-downs	Balance, December 31, 2006
Employee separation costs	$	$ 671	$ (388)	$	$ 283
Total	$	$ 671	$ (388)	$	$ 283

2005 Restructuring. In February 2005, we took steps to focus our research and development efforts primarily on improving the sensitivity and other performance aspects of our technology and reduced our cost structure accordingly. We discontinued certain research efforts, reduced our workforce by ten employees, principally in the research and development functions, and amended the lease for our corporate headquarters in Marlborough, MA to reduce the total space leased at the facility from approximately 56,000 square feet to approximately 37,000 square feet.

Pursuant to the restructuring plan, we accrued charges of $0.6 million in the quarter ended March 31, 2005. As of June 30, 2005 all liabilities related to the restructuring had been paid. The table below summarizes the restructuring activities during the year ended December 31, 2005. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2004	Charges	Cash Payments	Non-cash Write-downs	Balance, December 31, 2005
Employee separation costs	$	$ 246	$ (246)	$	$
Facility consolidation costs		380	(98)	(282)	
Total	$	$ 626	$ (344)	$ (282)	$

Employee separation costs in the table above relate to severance packages and out-placement services for employees affected by the restructuring. Our decision to reduce the total space leased and abandon the related leasehold improvements was deemed to be an impairment indicator under SFAS No. 144. As a result of performing the impairment evaluations, asset impairment charges of $0.3 million (included opposite the caption "Facility consolidation costs" in the table above) 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 lease amendment to reduce the space occupied at our corporate headquarters.

Interest income. Interest income increased to $1.3 million for the year ended December 31, 2006 from $1.1 million for the year ended December 31, 2005. This increase was due to an increase in interest rates on investments held during the year ended December 31, 2006 as compared to the same period of 2005, partially offset by lower average cash, cash equivalents and marketable securities balances held during the year ended December 31, 2006 as compared to the year ended December 31, 2005.

Liquidity and Capital Resources

We have financed our operations since inception primarily through private sales of preferred stock, public offerings of common stock in February 2001 and February 2004 and cash received from LabCorp in connection with our license agreement. As of December 31, 2007, we had approximately $12.6 million in unrestricted cash, cash equivalents and marketable securities and $0.7 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.

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 $8.8 million, $12.2 million and $16.0 million for the years ended December 31, 2007, 2006 and 2005, respectively. The principal use of cash in operating activities for each of the years ended December 31, 2007, 2006 and 2005 was to fund our net loss. The decrease in net cash used in operating activities for the year ended December 31, 2007 as compared to the year ended December 31, 2006, as well as for the year ended December 31, 2006 as compared to the year ended December 31, 2005, was primarily due to decreases in sales and marketing and applied research spending as a result of multiple restructuring and cost reduction actions taken during 2006 and 2007, 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 $8.0 million, $4.5 million and $15.8 million for the years ended December 31, 2007, 2006 and 2005, respectively. Excluding the impact of purchases and maturities of marketable securities, net cash used in investing activities was $0.1 million for the year ended December 31, 2007 and $0.4 million in each of the years ended December 31, 2006 and 2005.

Purchases of property and equipment of $0.1 million during the year ended December 31, 2007 were materially consistent with purchases of property and equipment for the years ended December 31, 2006 and 2005. Excluding activities that may be required by the FDA, we expect that purchases of property and equipment during 2008 will be consistent with amounts invested during 2007, although studies required by the FDA in connection with our technologies may require that we purchase additional property and equipment in 2008. We reduced the expenditures related to our capitalized patent portfolio for the year ended December 31, 2007 compared to the years ended December 31, 2006 and 2005, and we expect that investments made in our patent portfolio during 2008 will be materially consistent with amounts invested during 2007.

Net cash provided by financing activities was $0.4 million, $0.5 million and $0.1 million for the years ended December 31, 2007, 2006 and 2005, 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.

As discussed elsewhere in this report, we have received a report from our independent registered public accounting firm regarding our consolidated financial statements for the fiscal year ended December 31, 2007 that includes an explanatory paragraph stating that the financial statements have been prepared assuming we will continue as a going concern. The explanatory paragraph states the following condition, which raises substantial doubt about our ability to continue as a going concern: we have incurred recurring operating losses and we do not have enough cash resources to support future operations without obtaining additional financing. As a result of the restructuring actions taken in 2007 and 2006, we expect that cash, cash equivalents and short-term investments on hand at December 31, 2007 will be sufficient to fund our current operations through 2008. This projection is based on our current cost structure and our current expectations regarding the cost and timing of studies and other requirements that we believe are likely to obtain FDA regulatory clearance for our Version 1 technology. We have not yet reached final agreement with the FDA regarding any studies that would be necessary for the clearance or approval of Version 1 of our DNA-based technology, and the costs of any such studies could require us to obtain additional funding or engage in a strategic collaboration with a third party before previously expected. 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. Under the terms of our amended license agreement with LabCorp, we are eligible to receive up to an aggregate of $42.5 million in milestone payments, primarily all of which relates to the achievement of certain significant cumulative LabCorp sales thresholds that depend upon LabCorp's widespread success with respect to its sales of PreGen-Plus. Because these milestone payments are not expected in the foreseeable future, if at all, we do not believe that any payments pursuant to our agreement with LabCorp will be sufficient or timely enough to meet our liquidity needs. Since we have no current sources of material ongoing revenue, we will have to raise additional monies during 2008 through the sale of debt or equity securities, collaborations with third parties or other strategic opportunities, if any, to continue our business operations beyond the end of our 2008 fiscal year. We cannot assure you that any of these alternatives will be successful, or even available, or that our actual cash requirements will not be greater than anticipated. If we are unable to obtain the required funds to enable us to fund our operations through the completion of any financing or other strategic opportunities that may become available to us, we will be required to further reduce the scale of our business operations in which case our business, financial condition, and results of operations would be materially adversely affected and we may be required to seek bankruptcy protection. Even if we successfully raise sufficient funds to continue our operations beyond fiscal 2008, we cannot assure you that our business will ever generate sufficient cash flow from operations.

The table below reflects our estimated fixed obligations and commitments as of December 31, 2007:

		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	$ 9,164	$ 1,259	$ 3,130	$ 1,630	$ 3,145
Operating lease obligations	2,606	988	1,618		
Purchase obligations	407	407			
Total	$ 12,177	$ 2,654	$ 4,748	$ 1,630	$ 3,145

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 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. 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 $0.3 million obligation to reimburse LabCorp for certain costs related to Effipure as well as commitments associated with our research and development activities.

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 PreGen-Plus, 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;
- stool-based DNA screening becoming a standard of care among prescribing physicians;
- the scope of and progress made in our research and development activities;

threats posed by competing technologies;

new out-licensing arrangements relating to our technologies; and

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

Additionally, if our Version 1 technology is not cleared or approved by the FDA in the near term, LabCorp could decide to stop offering the current version of Pre-Gen Plus. Furthermore, LabCorp could decide not to launch Version 2 of its testing service, or could decide to defer any potential future launch of Version 2 of its testing service until that version has been approved or cleared by the FDA, if ever. Alternatively, based on a number of factors, including a finite supply of materials required to process Version 1, LabCorp may decide to discontinue the use of Version 1 of our technologies and convert to the use of Version 2. Such conversion could result in an interruption in service and a delay during which no version of the test utilizing our technologies remains on the market. Either of these situations will limit our revenue and materially adversely affect our business and cash reserves. Moreover, in a proposed decision memo dated January 30, 2008, CMS decided not to provide coverage for Version 1 of our technology because it is not cleared or approved by the FDA. While the CMS proposed decision memo from January 30, 2008 stated that it would reconsider our application for coverage of Version 1 after an FDA approval, if ever, CMS may decide to reject any subsequent application for payment outright, or may provide reimbursement at low rate that would make commercialization of our technology on a broad scale economically impossible. Additionally, if Version 1, Version 2, or any subsequent versions of our technology are not approved by the FDA, such technologies will, we believe, similarly not be approved by CMS, each of which will materially adversely affect our business and we may never be successful. Both the FDA and CMS positions with respect to any of our technologies, at any point in time, could also negatively impact any potential reimbursement of our technologies from third-party payors, which would also have a materially adverse affect on our business.

Net Operating Loss Carryforwards

As of December 31, 2007, we had net operating loss carryforwards of approximately $136.7 million and tax credit carryforwards of approximately $3.2 million. The net operating loss and tax credit carryforwards will expire at various dates through 2027, 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, 2007, we had no off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk is principally confined to our cash, cash equivalents and marketable securities. We invest our cash, cash equivalents and marketable securities in securities of the U.S. governments and its agencies and in investment-grade, highly liquid investments consisting of commercial paper, bank certificates of deposit and corporate bonds, all of which are currently invested in the U.S. and are classified as available-for-sale. We place our cash equivalents and marketable securities with high-quality financial institutions, limit the amount of credit exposure to any one institution and have established investment guidelines relative to diversification and maturities designed to maintain safety and liquidity.

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

Item 8. Financial Statements and Supplementary Data

EXACT SCIENCES CORPORATION

Index to Financial Statements

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, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of EXACT Sciences Corporation at December 31, 2007 and 2006, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that EXACT Sciences Corporation will continue as a going concern. As more fully described in Note 1, the Company's recurring operating losses and limited cash resources raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 1. The 2007 financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

As discussed in Notes 2 and 8 to the consolidated financial statements, on January 1, 2006, the Company adopted the provisions of Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment*.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), EXACT Sciences Corporation's internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 17, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 17, 2008

EXACT SCIENCES CORPORATION

Consolidated Balance Sheets

(Amounts in thousands, except share data)

	December 31, 2007	December 31, 2006
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 4,486	$ 4,831
Marketable securities	8,101	16,244
Prepaid expenses and other current assets	275	386
Total current assets	12,862	21,461
Property and Equipment, at cost:		
Laboratory equipment	3,730	3,832
Office and computer equipment	1,420	1,413
Leasehold improvements	1,161	1,259
Furniture and fixtures	299	299
	6,610	6,803
Less Accumulated depreciation and amortization	(6,009)	(5,959)
	601	844
Patent costs, net of accumulated amortization of $3,019 and $2,871 at December 31, 2007 and 2006, respectively	432	763
Restricted cash	700	800
	$ 14,595	$ 23,868
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 245	$ 158
Accrued expenses	2,811	1,844
Deferred license fees, current portion	1,350	4,363
Total current liabilities	4,406	6,365
Third party royalty obligation	1,200	
Deferred license fees, less current portion	2,701	2,545
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.01 par value		
Authorized 5,000,000 shares		
Issued and outstanding 0 shares at December 31, 2007 and 2006		
Common stock, $0.01 par value		
Authorized 100,000,000 shares		
Issued and outstanding 27,225,541 and 26,863,363 shares at December 31, 2007 and 2006, respectively	273	269
Additional paid-in capital	168,813	165,545
Treasury stock, at cost, 85,550 shares	(97)	(97)
Other comprehensive income	23	6
Accumulated deficit	(162,724)	(150,765)
Total stockholders' equity	6,288	14,958

	December 31, 2007	December 31, 2006
	$ 14,595	$ 23,868

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

EXACT SCIENCES CORPORATION

Consolidated Statements of Operations

(Amounts in thousands, except per share data)

	Year Ended December 31,		
	2007	**2006**	**2005**
Revenue:			
Product royalty fees	$ (1,137)	$ 179	$ 206
License fees	2,857	4,363	3,828
Product	78	208	216
	1,798	4,750	4,250
Cost of revenue:			
Product royalty fees	4	12	13
Product	45	797	553
	49	809	566
Gross profit	1,749	3,941	3,684
Operating expenses:			
Research and development(1)	4,887	6,735	7,956
Sales and marketing(1)	991	3,792	5,239
General and administrative(1)	7,541	6,910	5,497
Restructuring(1)	1,177	671	626
	14,596	18,108	19,318
Loss from operations	(12,847)	(14,167)	(15,634)
Interest income	888	1,252	1,114
Net loss	$ (11,959)	$ (12,915)	$ (14,520)
Net loss per share basic and diluted	$ (0.44)	$ (0.49)	$ (0.55)
Weighted average common shares outstanding basic and diluted	26,945	26,509	26,270

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

Research and development	$ 541	$ 653	$ 113
Sales and marketing	202	956	152
General and administrative	1,889	1,397	240
Restructuring	174		

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

EXACT SCIENCES CORPORATION
Consolidated Statements of Stockholders' 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	Notes Receivable	Deferred Compensation	Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity	Other Comprehensive Income
Balance, January 1, 2005	26,285,067	$ 263	$ 161,356	85,550	$ (97)	$ (5)	$ (89)	$ (115)	$ (123,330)	$ 37,983	
Issuance of shares under stock purchase plan	44,923		112							112	$
Exercise of common stock options	35,190		25							25	
Forgiveness of subscription receivable						5				5	
Compensation expense related to issuance of stock options and restricted stock awards	71,318	1	226				89			316	
Extension of warrant expiration date (Note 3)			630							630	
Net loss									(14,520)	(14,520)	(14,520)
Other comprehensive income								70		70	70
Comprehensive loss											$ (14,450)
Balance, December 31, 2005	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

	Common Stock			Treasury Stock						
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						103	
Compensation expense related to issuance of stock options and restricted stock awards	66,249	1	1,565						1,565	
Compensation expense related to stock option modifications (Note 9)			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	

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

EXACT SCIENCES CORPORATION

Consolidated Statements of Cash Flows

(Amounts in thousands)

	Year Ended December 31,		
	2007	**2006**	**2005**
Cash flows from operating activities:			
Net loss	$ (11,959)	$ (12,915)	$ (14,520)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and write-offs of fixed assets	228	454	750
Restructuring	85		282
Amortization and write-offs of patents	385	901	782
Stock-based compensation	2,806	3,006	505
Amortization of deferred license fees	(2,857)	(4,363)	(4,458)
Non-cash revenue reduction recorded in connection with warrant extension			630
Changes in assets and liabilities:			
Prepaid expenses and other current assets	111	772	682
Accounts payable	87	(310)	103
Accrued expenses	2,347	301	(738)
Net cash used in operating activities	(8,767)	(12,154)	(15,982)
Cash flows from investing activities:			
Purchases of marketable securities	(20,686)	(31,381)	(24,276)
Maturities of marketable securities	28,846	36,300	40,422
Purchases of property and equipment	(78)	(149)	(227)
Proceeds from sale of fixed assets	8		
Increase in patent costs and other assets	(54)	(245)	(159)
Net cash provided by investing activities	8,036	4,525	15,760
Cash flows from financing activities:			
Proceeds from exercise of common stock options and stock purchase plan	286	253	137
Decrease (increase) in restricted cash	100	220	(5)
Net cash provided by financing activities	386	473	132
Net decrease in cash and cash equivalents	(345)	(7,156)	(90)
Cash and cash equivalents, beginning of year	4,831	11,987	12,077
Cash and cash equivalents, end of year	$ 4,486	$ 4,831	$ 11,987
Supplemental disclosure of non-cash investing and financing activities:			
Issuance of 156,675 shares of restricted common stock to collaborators in lieu of cash payments	$ 466	$	$
Issuance of 34,030 shares of common stock to fund the Company's 401(k) matching contribution for 2006	$ 102	$	$
Issuance of 85,800 shares of common stock to fund the Company's 401(k) matching contribution for 2005	$	$ 184	$

	Year Ended December 31,		
Forgiveness of notes receivable and accumulated interest	$	$	$ 10

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

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007

(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 develops 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 developed by LabCorp and marketed under the name "PreGen-Plus ." PreGen-Plus is a non-invasive stool-based DNA testing service for the detection of colorectal cancer in the average-risk population. The Company has devoted the majority of its efforts to date on research and development and commercialization support of PreGen-Plus.

Basis of Presentation

The accompanying financial statements have been prepared on a basis which assumes that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

The Company has generated limited operating revenues since its inception and, as of December 31, 2007, had an accumulated deficit of approximately $162.7 million. The Company's losses have historically resulted from costs incurred in conjunction with research, development, and clinical study initiatives, salaries and benefits associated with the hiring of personnel, the initiation of marketing programs and, prior to August 31, 2007, costs related to its sales function to support the commercialization of its stool-based DNA screening technology.

The Company expects that its cash, cash equivalents and marketable securities balances at December 31, 2007 will be sufficient to fund its operations through 2008, based upon the Company's current cost structure and current assumptions regarding the studies and other requirements that it believes may be necessary to obtain U.S. Food and Drug Administration ("FDA") regulatory clearance for the DNA-based colorectal cancer screening technology described in the October 11, 2007 warning letter from the FDA to the Company (the "Warning Letter"). See note 4 for a description of the Warning Letter. The Company has not yet reached final agreement with the FDA regarding the regulatory path and any studies that would be necessary for the clearance or approval of the DNA-based technology described in the Warning Letter and, accordingly, there can be no assurance that the Company's cash, cash equivalents and marketable securities balances at December 31, 2007 will be sufficient to fund operations through 2008. The Company has no current sources of material ongoing revenue and, accordingly, it will need to raise additional capital in the next twelve months through a debt or equity financing, third-party collaboration or other strategic opportunity, if any, or further reduce the scale of the Company's operations, or some combination of the foregoing to continue operations beyond the end of 2008. Obtaining additional financing or funding through third-party collaboration efforts or other strategic opportunities is dependent upon future events, the outcome of which is presently not determinable. There can be no assurance that the Company will be successful in any future capital raising, third-party collaboration or other strategic opportunity, or that it would be able to raise additional funds at an acceptable price level. An inability to fund the Company's operations would have a material adverse effect on its business, financial condition and results of operations and the Company may be required to seek bankruptcy protection. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(1) ORGANIZATION AND BASIS OF PRESENTATION (Continued)

classification of assets or the amounts and classification of liabilities or any other adjustments that might be necessary should the Company be unable to continue as a going concern.

(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, 2007 and 2006, approximately $0.7 million and $0.8 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 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

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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, 2007, 2006 or 2005.

Investments consist of the following at December 31, 2007 and 2006. 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
2006						
Corporate debt securities	$ 16,238	$	$ 16,238	$ 6	$	$ 16,244
Total	$ 16,238	$	$ 16,238	$ 6	$	$ 16,244

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

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.

As of December 31, 2007, the majority of the recorded value of the patent portfolio related to intellectual property licensed to LabCorp in connection with PreGen-Plus. The following table

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

summarizes activity with respect to the Company's capitalized patents for the years ended December 31, 2007, 2006 and 2005. Amounts included in the table are in thousands.

Balance, January 1, 2005	$ 2,037
Patent costs capitalized	164
Amortization of patents	(560)
Write-offs of patents	(222)
Balance, December 31, 2005	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

The total recorded patent value at December 31, 2006 included approximately $0.2 million related to patents that had not commenced amortization as of December 31, 2007 because the patents had not yet been issued. The amortization expense related to issued patents as of December 31, 2007 over the next five years is as follows. Amounts included in the table are in thousands

Year	Amount
2008	$ 97
2009	64
2010	43
2011	6
	$ 210

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 year ended December 31, 2007, 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. The Company performed an impairment analysis, comparing the carrying amount of the patent assets to their fair value as determined by an estimate of discounted future cash flows related to the these assets. The Company determined that there was no impairment with respect to the net book value of the patents as of December 31, 2007.

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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:

	2007	2006	2005
Shares issuable upon exercise of stock options	3,996,688	4,125,940	4,499,927
Shares issuable upon exercise of outstanding warrants	1,000,000	1,000,000	1,000,000
	4,996,688	5,125,940	5,499,927

Accounting for Stock-Based Compensation

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 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") (See note 3) that, among other modifications to the terms of the license, extended the exclusive license period from August 2008 to December 2010, subject to carve-outs for certain named organizations. Accordingly, the Company 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.

Product royalty fees 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.

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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. 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 sales of PreGen-Plus, 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 PreGen-Plus.

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 3 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 is recognized upon transfer of the components provided that title passes, the price is fixed or determinable and collection of the receivable is probable.

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 $0.1 million of media advertising in each of the years ended December 31, 2007, 2006 and 2005, respectively.

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

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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.

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.

All of the Company's revenues are derived from its license agreement with LabCorp.

Recent Accounting Pronouncements

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 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, 2007.

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 would be 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, with early adoption permitted. The Company does not expect the adoption of this standard to have a material impact on its consolidated results of operations, financial position or cash flows.

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

In September 2006, the SEC issued Staff Accounting Bulletin (SAB) No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* ("SAB No. 108"). SAB No. 108 provides guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. SAB No. 108 establishes an approach that requires quantification of financial statement errors based on the effects on each of the company's balance sheet and statement of operations and the related financial statement disclosures. SAB No. 108 permits existing public companies to record the cumulative effect of initially applying this approach in the first year ending after November 15, 2006, by recording the necessary correcting adjustments to the carrying values of assets and liabilities as of the beginning of that year with the offsetting adjustment recorded to the opening balance of retained earnings. Additionally, the use of the cumulative effect transition method requires detailed disclosure of the nature and amount of each individual error being corrected through the cumulative adjustment and how and when it arose. The adoption of SAB No. 108 in the first quarter of fiscal 2007 did not have any impact on the Company's financial statements.

In February 2007, the FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities including an amendment of FASB Statement No. 115* ("SFAS No. 159"). SFAS No. 159 provides entities with an option to choose to measure eligible items at fair value at specified election dates. If elected, an entity must report unrealized gains and losses on the item in earnings at each subsequent reporting date. The fair value option may be applied instrument by instrument, with a few exceptions, such as investments otherwise accounted for by the equity method, is irrevocable (unless a new election date occurs); and is applied only to entire instruments and not to portions of instruments. SFAS No. 159 is effective for the company in 2008. The Company is currently evaluating if it will elect the fair value option for any of our eligible financial instruments and other items and currently, the Company does not expect that the adoption of SFAS No. 159 will have a material impact on its financial statements.

In June 2007, the FASB issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ("EITF 07-3"). EITF 07-3 requires that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services are performed. EITF 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007. The Company is currently analyzing the effect, if any, EITF 07-3 will have on its financial position and results of operations.

Reclassifications

Prior to 2005, the Company combined sales and marketing expenses and general and administrative expenses as "Selling, general and administrative" expenses in its consolidated statements of operations. Beginning in 2005, the Company began to separately report "Sales and marketing" and "General and administrative" expenses and reclassified the 2004 consolidated statements of operations accordingly. The change had no impact on the Company's net loss or net loss per share as previously reported.

Prior to December 31, 2006, the Company classified cash pledged as collateral for an outstanding letter of credit in connection with the lease for its corporate headquarters under the caption "Cash and cash equivalents" in its consolidated balance sheets. Beginning on December 31, 2006, the Company

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

began to report cash pledged as collateral for an outstanding letter of credit in connection with the lease for its corporate headquarters under the caption "Restricted cash" in its consolidated balance sheets and reclassified the 2005 amount accordingly. In addition, the Company's statement of cash flows for the year ended December 31, 2005 has been revised from its original presentation to reflect these reclassifications. This change had no impact on the Company's net loss or net loss per share as previously reported.

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) STRATEGIC ALLIANCE AGREEMENT

On June 26, 2002, the Company entered into a license agreement (subsequently amended on January 19, 2004, June 27, 2007, and August 31, 2007) with LabCorp for an exclusive, strategic alliance between the parties to commercialize PreGen-Plus, LabCorp's proprietary, non-invasive DNA-based technology 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 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.

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(3) STRATEGIC ALLIANCE AGREEMENT (Continued)

Second Amendment to LabCorp License Agreement On June 27, 2007, the Company entered into the Second Amendment with LabCorp. The Second Amendment modified LabCorp's exclusive rights to the Company's DNA technology for colorectal cancer screening to permit the Company to license its technology to select third-party organizations and commercial service laboratories, subject to LabCorp's preferential pricing terms, and to extend LabCorp's modified exclusive period under the Second Amendment until December 31, 2010. Additionally, the Second Amendment clarifies the rights and obligations with respect to the Company's next-generation version of 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 PreGen-Plus net revenue threshold. LabCorp also retains preferential pricing terms 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. Under 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 liability to pay LabCorp pursuant to this provision of the Second Amendment is based on LabCorp's sales volumes of PreGen-Plus during three separate measurement periods, as defined below. A significant increase in PreGen-Plus test sales volumes during any measurement period, as compared to historical PreGen-Plus sales volumes, could reduce the Company's potential obligation to zero 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 sales of PreGen-Plus 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 PreGen-Plus sales volumes that the Company anticipates prior to any potential FDA approval of its technology, as of December 31, 2007, the Company has accrued $1.2 million of the total potential $1.5 million obligation related to the first measurement period, which ends in December 2008. This charge was recorded under the caption "Product royalty fees" in the Company's consolidated statements of operations for the year ended December 31, 2007.

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(3) STRATEGIC ALLIANCE AGREEMENT (Continued)

This obligation is recorded in the Company's consolidated balance sheets under the caption "Third party royalty obligation".

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

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.

(4) RECEIPT OF FDA WARNING LETTER

FDA History

Laboratories that make and perform certain types of laboratory-developed tests, known in the industry as "homebrew" testing services, have generally not been required to submit premarket submissions to FDA including performance data on the test for FDA review and approval or clearance. Instead the FDA has exercised enforcement discretion, which allowed laboratories that develop their

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(4) RECEIPT OF FDA WARNING LETTER (Continued)

own clinical diagnostic test by following the regulations of the Clinical Laboratory Improvement Amendments of 1988, or CLIA. The Company had historically believed, since the commercial launch of PreGen-Plus in 2003, that PreGen-Plus met the requirements to qualify for regulation under CLIA as a homebrew test and that in-house testing utilizing certain of our technologies, and using any analyte specific reagent that it developed, did not require FDA approval or clearance.

Since the commercial launch of PreGen-Plus in August 2003, LabCorp has offered the PreGen-Plus testing service as an in-house developed laboratory test, or homebrew. On January 13, 2006, the FDA sent correspondence to the Company and to LabCorp with respect to the PreGen-Plus testing service, as well as the Effipure component used in processing 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 pre-market 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 has continued to market, sell and process the PreGen-Plus test as a homebrew testing service. LabCorp's supply of Effipure includes components that have a finite useful life the duration of which, the Company believes, may be nearly exhausted. If LabCorp is unable to extend the useful life of these components, or is unable to otherwise take steps necessary to extend the useful life of Effipure, then LabCorp may be unable to continue to process PreGen-Plus tests in the near term. The Company further believes that certain finite resources required for the ongoing processing of the Version 1 test may also be nearly exhausted as well which may result in an interruption in the Version 1 testing service.

On October 11, 2007 the FDA sent the Warning Letter to the Company with respect to the PreGen-Plus testing service, 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 FDA. The Company is currently in communication with the FDA to specifically address the matters raised in the Warning Letter and to determine the appropriate regulatory approval process to resolve the matters raised in the Warning Letter. In February 2008, the Company met with the FDA to discuss the regulatory filing path for the technology that was the subject of the Warning Letter. Based on these discussions, the Company believes that a *de novo* 510(k) regulatory path remains available to us with respect to the Company's Version 1 technology based on the strategy that the Company presented to the FDA.

Company Interactions with the FDA

On November 2, 2007, in response to the FDA Warning Letter, the Company submitted to the FDA a pre-Investigational Device Exemption request ("pre-IDE"), that described the intended 510(k) filing approach, including the reproducibility studies that the Company proposed to perform in connection therewith. The FDA responded by letter to the Company's pre-IDE submission in December 2007, and, in an in-person meeting with the FDA in February 2008, the Company learned that the most likely regulatory path forward with respect to its Version 1 technology would be a *de novo* 510(k) application, which would likely include a single-site reproducibility study.

The FDA has not yet indicated definitively whether the submission with respect to Version 1 of the Company's technology would be a *de novo* 510(k). Moreover, the FDA may determine that a pre-

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(4) RECEIPT OF FDA WARNING LETTER (Continued)

market approval application ("PMA") is the appropriate path forward for us with respect to Version 1 of its stool-based DNA technology. The FDA may also determine that additional clinical studies, which could be costly and time-intensive, are required in connection with the Company's submission, or that the Company's proposal is otherwise inadequate. Accordingly, the costs of any such studies could require that the Company seek additional capital in the near term, which could have an adverse and material impact on the Company's financial position. There can be no assurance that the filing of a *de novo* 510(k) for the Company's Version 1 technology will bring it into compliance with the matters raised by the FDA in the Warning Letter, or that the FDA will not issue a similar letter to LabCorp or otherwise require LabCorp to stop offering its PreGen-Plus testing service during the regulatory clearance process.

The Company also intends to engage in discussions with the FDA to determine the appropriate regulatory approval path for its Version 2 technology. The clearance or approval process for any version of the Company's DNA-based technologies may require, among other things, successfully completing additional clinical and other studies, may require a PMA (rather than a 510(k) or *de novo* 510(k)) and may also necessitate the Company submitting PMAs with the FDA for multiple versions of its technology simultaneously or in sequence, all of which could take substantial time and resources including investment by the Company of substantial additional funds.

The FDA Warning Letter, and the time that it may take for the Company to obtain FDA clearance for any of its products, may also negatively impact any potential third party reimbursement to licensees of the Company's technologies. The Centers for Medicare and Medicaid Services ("CMS") issued a Proposed Decision Memo for Screening DNA Stool Test for Colorectal Cancer (CAG-00144N) on January 30, 2008 that proposed not to provide coverage of the Company's Version 1 technology because the FDA has determined that the Company's Version 1 technology required premarket clearance. The Proposed Decision Memo also indicated that CMS would reconsider our application for coverage once the Company receives FDA clearance or approval for its technology, if ever. The FDA Warning Letter may have a similar impact on private third-party payors in that those payors may defer reimbursement policy decisions with respect to the Company's technology until the Company obtains FDA clearance for its technologies, if ever.

There can be no assurance that any version of the Company's stool-based DNA technology will be cleared or approved by the FDA, that the Company's proposed *de novo* 510(k) approach will satisfy the FDA's regulatory requirements for our Version 1 technology or any subsequent version of its technology, or that such FDA clearance or approval process can be completed without significant delays or material additional expense resulting from additional FDA required clinical or other studies. The Company may not have sufficient funds to complete any FDA regulatory clearance or approval process for its DNA-based technologies. Ongoing compliance with FDA regulations will also increase the cost of conducting the Company's business, subject the Company and LabCorp to inspection by FDA and to the requirements of FDA and penalties for failure to comply with these requirements.

Moreover, the Company cannot assure you that the commercial sales of PreGen-Plus will not be delayed, halted or prevented during the regulatory approval process, or that the FDA will not initiate enforcement action, which could involve criminal or civil penalties and cause material harm to the Company's business. Additionally, LabCorp could decide to stop offering the current version of PreGen-Plus, could decide not to launch the Version 2 technology, or could decide to defer any potential future launch of the Version 2 technology until that version has been approved or cleared by the FDA, if ever, any of which would materially increase the Company's costs, limit the Company's

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(4) RECEIPT OF FDA WARNING LETTER (Continued)

revenue and cause material harm to its business and result in impairments of the Company's fixed assets or capitalized patent portfolio ($0.4 million at December 31, 2007) or personnel or facility related restructuring charges.

(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.

2005 Restructuring In February 2005, the Company took steps to focus its research and development efforts primarily on improving the sensitivity and other performance aspects of its technology and reduced its cost structure accordingly. The Company discontinued certain research efforts, reduced its workforce by ten employees, principally in the research and development functions, and amended the lease for its corporate headquarters in Marlborough, MA to reduce the total space leased at the facility from approximately 56,000 square feet to approximately 37,000 square feet (the "2005 Restructuring").

Pursuant to the 2005 Restructuring plan, the Company recorded restructuring charges of $0.6 million in the year ended December 31, 2005. As of December 31, 2005 all liabilities related to the restructuring had been paid

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

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(5) RESTRUCTURING (Continued)

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. Since the 2007 Restructuring, the Company's efforts have been focused on:

- the pursuit of inclusion of stool-based DNA testing in screening guidelines of the major guidelines organizations, including the guidelines that resulted from the joint efforts of the American Cancer Society ("ACS") and the U.S. Multi-Society Task Force on Colorectal Cancer ("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 Medicine;

- Medicare coverage pursuit for stool-based DNA testing;

- validation and optimization of the Company's Version 2 technology; and

- the pursuit of FDA clearance for its stool-based DNA screening technologies.

Restructuring charges recorded during the third quarter of 2007 of $0.8 million included $0.6 million in severance and related benefit costs expected to be 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. See note 9 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 "Sublease Agreement") with INTRINSIX Corporation (the "Subtenant") to sublease to the Subtenant approximately 11,834 square feet of rentable area in the Company's corporate headquarters. The term of the Sublease Agreement, which commenced on December 15, 2007, is 32 months with a base rent of $266,265 per year. Pursuant to the Sublease Agreement, the Subtenant has no rights to renew or extend the Sublease Agreement. Under the terms of the Sublease Agreement, the Subtenant 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. The Company believes that its remaining 25,537 square feet of leased space is adequate for its current requirements.

In connection with the 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 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 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, 2007, 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 right of terminated employees to receive severance

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(5) RESTRUCTURING (Continued)

payments from the Company will be dependent upon when, and if, the terminated employees secure employment with another employer during the defined severance period and, therefore, the Company's estimate of the total restructuring charges may be adjusted in future periods.

The following table summarizes the 2007 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	$	$ 588	$ (364)	$	$ 224
Facility consolidation costs		387	(34)	(85)	268
Total	$	$ 975	$ (398)	$ (85)	$ 492

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.

(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.

In connection with the October 2006 restructuring described in note 5 above, the Company entered into retention agreements ("Retention Agreements") with its then remaining 22 remaining employees ("Remaining Employees"), including Jeffrey R. Luber, the Company's current President and Charles R. Carelli, Jr., the Company's current Senior Vice President, Chief Financial Officer and Treasurer. Under the terms of the Retention Agreements, in addition to their existing salary and

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Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(6) EMPLOYMENT ARRANGEMENTS (Continued)

benefits, Remaining Employees were be eligible to earn a one-time retention bonus in the aggregate amount of approximately $0.9 million payable on December 31, 2007 (subject to acceleration in certain instances), provided that the Remaining Employees continue to be employed by the Company on the payment date. As of December 31, 2007, the Company had paid out all one-time retention bonuses. The Retention Agreements also provide that upon the occurrence of certain triggering events, such as a change of control or termination without cause, Remaining Employees will be entitled to receive severance payments for periods ranging from three to twelve months at a rate equal to their base salary at the time of termination of employment. As of December 31, 2007, the total potential severance obligation upon the occurrence of certain triggering events, such as a change of control or termination without cause was $1.1 million.

(7) NOTES RECEIVABLE

Prior to the initial public offering in February 2001, the Company issued more than 2.2 million restricted common shares to employees, primarily as a result of early exercise of common stock options. The shares were sold at the then fair market value or the exercise price of the common stock options. The Company obtained full recourse notes receivable from employees and executives for the purchase of the restricted stock. Such shares vested over the remaining option vesting period or, generally, three to five years. At December 31, 2005, vesting of such shares was completed, no common shares were subject to restriction and all notes receivable had been either repaid or forgiven.

(8) ISSUANCES OF COMMON STOCK

On March 24, 2003, the Company entered into a license agreement, subsequently amended on November 17, 2004, May 11, 2006 and again on March 19, 2007, 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 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 $0.3 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 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.

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(9) 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, 2007, options to purchase 359,201 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, 2007, 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 prior to January 1, 2006 generally vest over a period of three to five years. Grants made from the 2000 Option Plan subsequent to January 1, 2006 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 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, 2007, options to purchase 3,637,487 shares were outstanding under the 2000 Option Plan and 3,059,462 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

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(9) STOCK-BASED COMPENSATION (Continued)

(ii) such lesser number as may be approved by the Company's board of directors. At December 31, 2007, 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 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.

Offering period ended	Number of Shares	Price per Share
January 31, 2005	20,445	$ 2.82
July 31, 2005	24,478	$ 2.22
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 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 $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 will be 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

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(9) STOCK-BASED COMPENSATION (Continued)

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. Prior to the adoption of SFAS No. 123(R) on January 1, 2006, the Company, in accordance with APB No. 25, recognized expenses related to non-employee consultant stock option grants and restricted stock awards and the Company's 401(k) match in its consolidated statements of operations.

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, 2007, 2006 and 2005 was determined as outlined below.

Pro Forma Information Under SFAS No. 123 for Periods Prior to January 1, 2006

The following table illustrates the effect on net loss and loss per common share as if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation for the year ended December 31, 2005. Note that the pro forma disclosure below is provided for the year ended December 31, 2005 only because employee stock options were not accounted for using the fair value method during that period.

(In thousands, except per share data)	December 31, 2005
Net loss as reported	$ (14,520)
Add: Stock-based compensation included in reported net loss	505
Deduct: Total stock-based employee compensation determined under SFAS 123 for all awards	(7,821)
Pro forma net loss SFAS No. 123	$ (21,836)
Basic and diluted net loss per share:	
As reported	$ (0.55)
Pro forma net loss SFAS 123	$ (0.83)

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.

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(9) STOCK-BASED COMPENSATION (Continued)

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. Expected volatility was lower in the year ended December 31, 2006 when compared to prior periods as the Company refined its expectation because, as of January 2006, it had at least five years of historical volatility data on which to base its expectation. Prior to January 1, 2006, sufficient historical volatility data did not exist to reasonably justify a lower expected volatility and the Company determined its expected volatility using peer analysis.

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

Forfeitures 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,		
	2007	2006	2005
Option Plan Shares			
Risk-free interest rates	4.04% 4.60%	4.59% 5.03%	3.94% 4.06%
Expected term (in years)	6	6	7
Expected volatility	70%	70%	100%
Dividend yield	0%	0%	0%
Weighted average fair value per share of options granted during the period	$1.87	$1.67	$3.21
ESPP Shares			
Risk-free interest rates	5.10% 5.17%	4.57% 5.22%	3.94% 4.06%
Expected term (in years)	0.5 2	0.5 2	0.5 2
Expected volatility	70%	70%	100%
Dividend yield	0%	0%	0%
Weighted average fair value per share of stock purchase rights granted during the period	$1.08	$0.94	$1.42

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(9) 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 2007, 2006 and 2005 is as follows:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value(1)
			(Aggregate intrinsic value in thousands)	
Outstanding, January 1, 2005	4,857,484	$6.69		
Granted	758,442	3.54		
Exercised	(106,508)	0.61		
Cancelled	(1,009,491)	8.03		
Outstanding, December 31, 2005	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	4.8	$1,385
Exercisable, December 31, 2007	3,127,334	$5.45	3.5	$1,020
Vested and expected to vest, December 31, 2006	3,996,688	$4.88	4.8	$1,385

(1) The aggregate intrinsic value of options outstanding at December 31, 2007 is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for the 2,066,295 options that had exercise prices that were lower than the $3.22 market price of our common stock at December 31, 2007. The aggregate intrinsic value of options exercisable at December 31, 2007 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 1,232,091 options that had exercise prices that were lower than the $3.22 market price of our common stock at December 31, 2007. The total intrinsic value of options exercised during the years ended December 31, 2007, 2006 and 2005 was $0.1 million, $0.5 million, and $0.2 million, respectively, determined as of the date of exercise.

As of December 31, 2007, there was $1.6 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under all equity compensation plans. Total unrecognized compensation cost will be adjusted for future changes in forfeitures. The Company expects to recognize that cost over a weighted average period of 1.6 years.

The Company received $0.3 million, $0.2 million and $25,000 from stock option exercises during the years ended December 31, 2007, 2006 and 2005, respectively. During the years ended December 31, 2007, 2006 and 2005, 16,987, 46,520 and 44,923 shares, respectively, of common stock were issued

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Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(9) STOCK-BASED COMPENSATION (Continued)

under the Company's 2000 Purchase Plan resulting in proceeds to the Company of $27,000, $0.1 million and $0.1 million, respectively.

The following table summarizes information relating to currently outstanding and exercisable stock options as of December 31, 2007:

	Outstanding			Exercisable	
Exercise Price	Number of Options	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
$ $2.00	66,704	4.5	$0.26	47,953	$0.37
$2.01 $2.50	463,873	3.8	$2.09	462,122	$2.09
$2.51 $3.00	1,479,218	7.1	$2.78	690,629	$2.70
$3.01 $4.00	421,137	4.7	$3.52	391,440	$3.55
$4.01 $5.00	314,743	4.2	$4.40	284,209	$4.42
$5.01 $7.00	235,000	1.7	$6.78	235,000	$6.78
$7.01 $9.00	596,138	2.4	$7.83	596,106	$7.83
$9.01 $14.33	419,875	3.2	$12.56	419,875	$12.56
	3,996,688	4.8	$4.88	3,127,334	$5.45

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.

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).

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(9) STOCK-BASED COMPENSATION (Continued)

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.

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 and outstanding warrants at December 31, 2007:

Shares reserved for issuance	
2000 Option Plan	6,696,974
Outstanding Warrants	1,000,000
2000 Stock Purchase Plan	720,780
1995 Option Plan	359,201
	8,776,955

(10) COMMITMENTS AND CONTINGENCIES

Operating Leases

The Company conducts its operations in a leased facility under a noncancelable operating lease expiring in July 2010. The lease for the Company's headquarters contains one three-year extension option. Future minimum payments under its operating lease as of December 31, 2007 are as follows. Amounts included in the table are in thousands.

Year Ending December 31,	
2008	988
2009	1,016
2010	602
Total lease obligations	$ 2,606

Rent expense included in the accompanying consolidated statements of operations was approximately $1.0 million, $1.0 million and $1.1 million for the years ended December 31, 2007, 2006 and 2005, respectively. As described in note 5, during the fourth quarter of 2007, the Company entered into the Sublease Agreement with Subtenant to sublease approximately 11,834 square feet of rentable area in the Company's corporate headquarters. The term of the Sublease Agreement, which commenced on December 15, 2007, is 32 months. The Company expects to receive approximately

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(10) COMMITMENTS AND CONTINGENCIES (Continued)

$0.7 million in sublease payments over the life of the Sublease Agreement. Pursuant to the Sublease Agreement, the Subtenant has no rights to renew or extend the Sublease Agreement. Under the terms of the Sublease Agreement, the Subtenant 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. The Company believes that its remaining 25,537 square feet of leased space is adequate for its current requirements.

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 and again on March 19, 2007, with 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 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 $0.3 million, over the life of the licensed patents, or 2023. The Company has recorded research and development expense associated with license agreements of $1.2 million, $0.3 million and $0.3 million, respectively, for the years ended December 31, 2007, 2006 and 2005.

Future minimum payments due under the Company's technology licenses as of December 31, 2007 are as follows. Amounts included in the table are in thousands.

Year ending December 31,		
2008	$	865
2009		315
2010		315
2011		315
2012		315
Thereafter		3,145
	$	5,270

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. The Company has recorded research and development expense associated with clinical research agreements of $0.2 million, $0.5 million and $1.0 million, respectively, for the years ended December 31, 2007, 2006 and 2005. As of December 31, 2007, the Company's remaining obligation under these agreements was approximately $0.4 million, which is expected to be paid during 2008.

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. Our potential liability of $3.5 million is described in note 3

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(10) COMMITMENTS AND CONTINGENCIES (Continued)

above. In connection with this obligation, the Company recorded charges of $1.2 million under the caption "Product royalty fees" in its consolidated statements of operations during the year ended December 31, 2007. This obligation is recorded in the Company's consolidated balance sheets under the caption "Third party royalty obligation".

Employee Severance Commitments

As described in Note 6, the Company entered into Retention Agreements with employees remaining after the Company's 2006 Restructuring. The Retention Agreements provide that upon the occurrence of certain triggering events, such as a change of control or termination without cause, Remaining Employees will be entitled to receive severance payments for periods ranging from three to twelve months at a rate equal to their base salary at the time of termination of employment. As of December 31, 2007, the total potential severance obligation upon the occurrence of certain triggering events, such as a change of control or termination without cause was $1.1 million. As of December 31, 2007, the Company has not recorded any amount related to the potential severance payments because no triggering events had occurred as of that date.

(11) ACCRUED EXPENSES

Accrued expenses at December 31, 2007 and 2006 consisted of the following. Amounts included in the table are in thousands.

	December 31,	
	2007	2006
Research and trial related expenses	$ 538	$ 523
Licenses	525	
Restructuring	492	283
Professional fees	481	273
Compensation	452	522
Occupancy costs	168	159
Other	154	84
	$ 2,811	$ 1,844

(12) RELATED PARTY TRANSACTIONS

In March 2001, the Company entered into a consulting agreement with a member of its Board of Directors. This consulting agreement was terminated during 2005. The Company paid approximately $0.1 million for services provided under the agreement in the year ended December 31, 2005.

(13) 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.

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(13) EMPLOYEE BENEFIT PLAN (Continued)

The Company's Board of Directors approved 401(k) Plan matching contributions for each of 2007, 2006 and 2005 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 $0.1 million, $0.1 million and $0.2 million, respectively, in the consolidated statements of operations for the years ended December 31, 2007, 2006 and 2005 in connection with 401(k) Plan matching contributions.

(14) 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, 2007, the Company had net operating loss and research tax credit carryforwards of approximately $136.7 million and $3.2 million respectively, for financial reporting purposes, which may be used to offset future taxable income. The carryforwards expire through 2027 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.

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,	
	2007	2006
Deferred tax assets:		
Operating loss carryforwards	$ 53,926	$ 50,094
Tax credit carryforwards	3,231	3,188
Deferred revenue	1,605	2,736
Other temporary differences	2,649	1,828
Tax assets before valuation allowance	61,411	57,846
Less Valuation allowance	(61,411)	(57,846)
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 $3.6 million during 2007 primarily as a result of operating losses incurred in the year ended December 31, 2007.

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(14) INCOME TAXES (Continued)

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

	2007	2006	2005
Federal	34.0%	34.0%	34.0%
State	5.6	5.6	5.6
Research and development tax credit	0.8	1.9	2.0
Revenue reduction recorded in connection with warrant extension			(1.7)
Stock-based compensation expense	(5.6)	(4.1)	(0.2)
Other adustments	4.4	(10.2)	0.1
Valuation allowance	(39.2)	(27.2)	(39.8)
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 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, 2007.

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, 2007, 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 2007, and to state income tax examinations for the tax years 2003 through 2007. The Company recognizes accrued interest related to unrecognized tax benefits in interest expense and

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(14) INCOME TAXES (Continued)

penalties in operating expense. No amounts were accrued for the payment of interest and penalties through December 31, 2007. 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.

(15) 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, 2007. In the opinion of management, this information has been prepared on the same basis as the audited financial statements appearing elsewhere in this Form 10-K, and all necessary adjustments, consisting only of normal recurring adjustments, have been included in the amounts stated below to present fairly the unaudited quarterly results of operations. The quarterly data should be read in conjunction with our audited financial statements and the notes to the financial statements appearing elsewhere in this Form 10-K.

	Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
	(Amounts in thousands, except per share data)			
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
2006				
Revenue	$ 1,194	$ 1,221	$ 1,155	$ 1,180
Cost of revenue	588	93	102	26
Research and development	1,960	1,918	1,705	1,152
Sales and marketing	1,324	1,077	890	500
General and administrative	1,803	1,692	1,861	1,555
Restructuring				671
Loss from operations	(4,481)	(3,559)	(3,403)	(2,724)
Interest income	318	313	320	301

	Quarter Ended			
Net loss	$ (4,163)	$ (3,246)	$ (3,083)	$ (2,423)
Net loss per share basic and diluted	$ (0.16)	$ (0.12)	$ (0.12)	$ (0.09)
Weighted average common shares outstanding basic and diluted	26,376	26,402	26,562	26,692

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007

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

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

Certain expenses reported in the Company's 2007 and 2006 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	
2006				
Sales and marketing expenses as reported on Form 10-Q and Form 10-K	$ 1,486	$ 1,272	$ 1,051	$ 624
Less: Amounts reclassified as general and administrative expenses	(162)	(195)	(161)	(124)
Sales and marketing expenses revised	$ 1,324	$ 1,077	$ 890	$ 500
General and administrative expenses as reported on Form 10-Q	$ 1,641	$ 1,497	$ 1,700	$ 1,431
Add: Amounts reclassified as general and administrative expenses	162	195	161	124
General and administrative expenses revised	$ 1,803	$ 1,692	$ 1,861	$ 1,555

(16) SUBSEQUENT EVENTS

Fourth Amendment to LabCorp License Agreement

On March 17, 2008, the Company entered into the fourth amendment (the "Fourth Amendment") to its exclusive license agreement with LabCorp. Among other things, the Fourth Amendment further clarified certain license rights of the parties, amended LabCorp's termination rights relating to the failure to launch the Company's Version 2 technology and restricted certain of the Company's termination rights in the event the FDA limits LabCorp's ability to market products that incorporate technology licensed to LabCorp under the amended license agreement. In addition, the Fourth Amendment eliminated certain of the Company's termination rights for a specified period of time

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EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2007 (Continued)

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

(16) SUBSEQUENT EVENTS (Continued)

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.

Colorectal Cancer Screening Guidelines Inclusion

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 MSTF-CRC 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. PreGen-Plus is therefore now the first non-invasive, DNA-based colorectal cancer screening test to be included in the colorectal cancer screening guidelines of the ACS and MSTF-CRC in the United States for the average risk population. 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 PreGen-Plus, the Company believes that FDA clearance for its current and future technologies, and reimbursement from CMS and other third-party payors will be necessary in order to achieve significant increases in demand for its technologies.

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. 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, 2007. 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, 2007, the Company's internal control over financial reporting is effective based on those criteria.

Management's assessment of the effectiveness of internal control over financial reporting as of December 31, 2007, has been audited by Ernst & Young LLP, our independent registered public accounting firm, who also audited the Company's consolidated financial statements. Ernst & Young LLP's attestation report on management's assessment of the Company's internal control over financial reporting appears on page 88 hereof.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of EXACT Sciences Corporation

We have audited EXACT Sciences Corporation's internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). EXACT Sciences Corporation's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, EXACT Sciences Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2007 consolidated financial statements of EXACT Sciences Corporation and our report dated March 17, 2008 expressed an unqualified opinion with an explanatory paragraph related to going concern uncertainties thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 17, 2008

Item 9B. Other Information

On March 17, 2008, we entered into the fourth amendment, or Fourth Amendment, to our 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 our Version 2 technology and restricted certain of our termination rights in the event the FDA limits LabCorp's ability to market products that incorporate technology licensed to LabCorp under our amended license agreement. In addition, the Fourth Amendment eliminated certain of our 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 our Version 2 technology.

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, 2007.

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, 2007.

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, 2007.

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, 2007.

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, 2007.

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)
4.2+	Warrant between the Registrant and Laboratory Corporation of America Holdings, Inc. dated June 26, 2002
4.3	Amendment No. 1 to Common Stock Purchase Warrant between the Registrant and Laboratory Corporation of America Holdings, Inc. dated June 24, 2005 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed June 27, 2005, 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 (previously filed as Exhibit 10.2 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
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*	Restricted Stock Purchase Agreement between the Registrant and Don M. Hardison dated as of June 23, 2000, as amended (previously filed as Exhibit 10.7 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.6	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)
10.7	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)

10.8	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)
10.9	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)
10.10+**	Agreement between the Registrant and Laboratory Corporation of America Holdings, Inc. dated June 26, 2002
10.11+	Lease Agreement, dated January 23, 2003, between Marlborough Campus Limited Partnership and the Registrant, as amended
10.12+**	Exclusive License Agreement between Matrix Technologies Corporation, d/b/a Apogent Discoveries, and the Registrant dated as of November 26, 2002
10.13**	First Amendment to License Agreement by and between the Registrant and Laboratory Corporation of America Holdings, Inc. dated January 19, 2004 (previously filed as Exhibit 10.32 to our Annual Report on Form 10-K for the period ended December 31, 2003, which is incorporated herein by reference)
10.14**	Sublicense Agreement between the Registrant and Beckman Coulter dated July 28, 2003 (previously filed as Exhibit 10.33 to our Annual Report on Form 10-K for the period ended December 31, 2003, which is incorporated herein by reference)
10.15*	Form of Incentive Stock Option Agreement (previously filed as Exhibit 10.3 to our Report on Form 8-K filed on October 1, 2003, which is incorporated herein by reference)
10.16*	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)
10.17*	The Registrant's 2004 Executive Incentive Plan (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on January 27, 2005, which is incorporated herein by reference)
10.18*	The Registrant's 2004 Executive Incentive Plan, as amended (previously filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the period ended June 30, 2005, which is incorporated herein by reference)
10.19*	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)
10.20*	Employment Agreement between the Registrant and Don M. Hardison dated June 27, 2006 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on June 29, 2006, which is incorporated herein by reference)
10.21*	Employee Retention Agreement between the Registrant and Jeffrey R. Luber dated October 23, 2006 (previously filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q filed on November 9, 2006, which is incorporated herein by reference)
10.22*	Employee Retention Agreement between the Registrant and Charles R. Carelli, Jr. dated October 23, 2006 (previously filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q filed on November 9, 2006, which is incorporated herein by reference)
10.23**	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)
10.24*	Non-Employee Director Compensation Policy (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on August 15, 2007, which is incorporated herein by reference)

10.25*	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)
10.26**	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)
10.27*	Separation Agreement and Release between the Registrant and Don M. Hardison, dated as of August 31, 2007 (previously filed as Exhibit 10.2 to our Report on Form 8-K filed on September 7, 2007, which is incorporated herein by reference)
10.28	Sublease Agreement between EXACT Sciences Corporation 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)
10.29+	Form of Restricted Stock Award Agreement
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.

SIGNATURES

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

EXACT SCIENCES CORPORATION

Date: March 17, 2008 By: /s/ JEFFREY R. LUBER

Jeffrey R. Luber
President

POWER OF ATTORNEY AND SIGNATURES

We, the undersigned officers and directors of EXACT Sciences Corporation, hereby severally constitute and appoint Patrick J. Zenner, Jeffrey R. Luber and Charles R. Carelli, Jr., and each of them singly, our true and lawful attorneys, with full power to them and each of them singly, 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/ SALLY W. CRAWFORD Sally W. Crawford	Chairperson of the Board and Director	March 17, 2008
/s/ PATRICK J. ZENNER Patrick J. Zenner	Executive Chairman, Interim Chief Executive Officer and Director (Principal Executive Officer)	March 17, 2008
/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 17, 2008
/s/ EDWIN M. KANIA, JR. Edwin M. Kania, Jr.	Director	March 17, 2008
/s/ CONNIE MACK, III Connie Mack, III	Director	March 17, 2008
/s/ LANCE WILLSEY, MD Lance Willsey, MD	Director	March 17, 2008

Exhibit Index to Annual Report on Form 10-K

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10.24*	Non-Employee Director Compensation Policy (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on August 15, 2007, which is incorporated herein by reference)
10.25*	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)
10.26**	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)
10.27*	Separation Agreement and Release between the Registrant and Don M. Hardison, dated as of August 31, 2007 (previously filed as Exhibit 10.2 to our Report on Form 8-K filed on September 7, 2007, which is incorporated herein by reference)
10.28	Sublease Agreement between EXACT Sciences Corporation 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)

10.29+	Form of Restricted Stock Award Agreement
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.