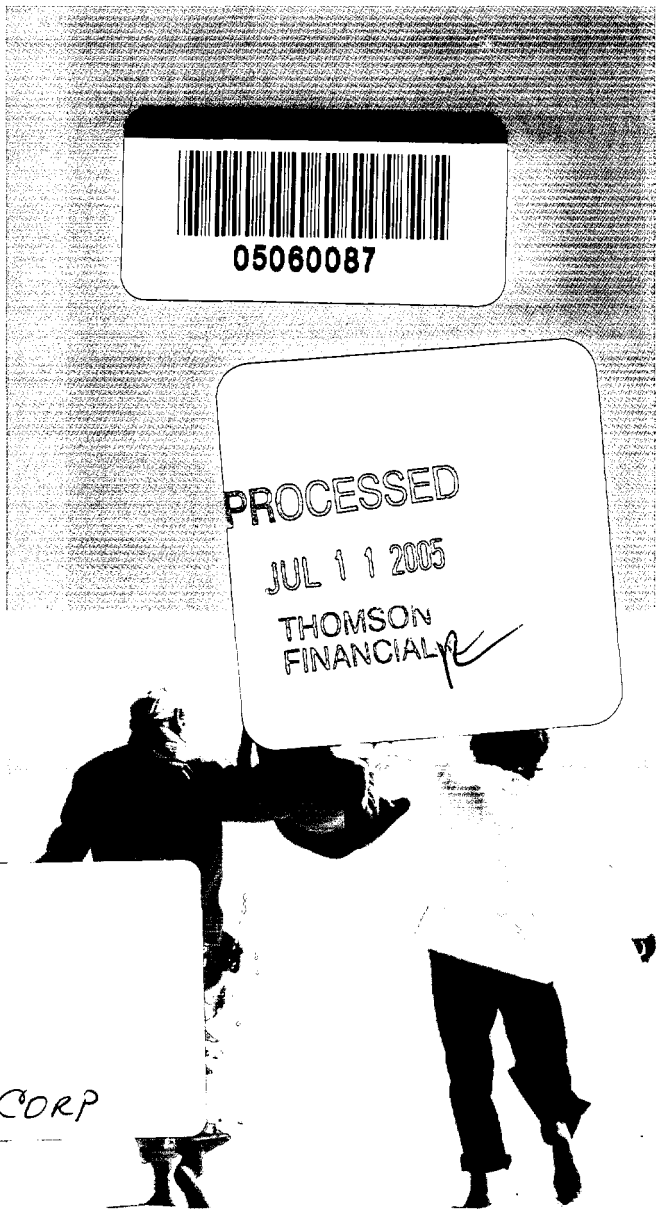
EXACT sciences

APPLYING

GENOMICS

TO ERADICATE

CANCER



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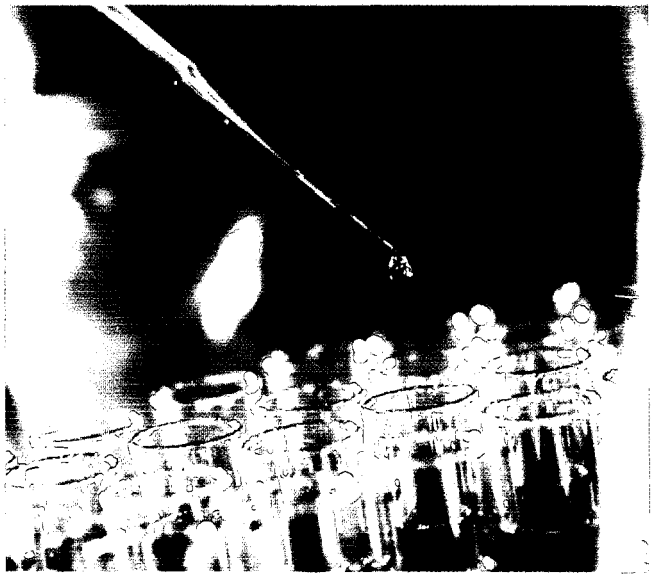


2004 ANNUAL REPORT

EXACT sciences

CORPORATE PROFILE

EXACT SCIENCES CORPORATION IS AN APPLIED GENOMICS COMPANY LOCATED IN MARLBOROUGH, MA. FOUNDED IN 1995, THE COMPANY'S MISSION IS TO PLAY A LEADING ROLE IN THE ERADICATION OF COMMON CANCERS BY APPLYING ADVANCES IN THE FIELD OF GENOMICS TO FACILITATE EARLY DETECTION OF DISEASE. EXACT SCIENCES BELIEVES ITS PROPRIETARY, GENOMICS-BASED TECHNOLOGIES WILL REVOLUTIONIZE THE EARLY DETECTION OF COLORECTAL AND OTHER COMMON CANCERS. EXACT SCIENCES BELIEVES THAT WIDESPREAD AND PERIODIC APPLICATION OF THESE NON-INVASIVE TECHNOLOGIES WILL REDUCE THE MORTALITY, MORBIDITY AND HEALTHCARE COSTS ASSOCIATED WITH THESE DISEASES.

EXACT SCIENCES' PROPRIETARY DNA-BASED TECHNOLOGY FOR THE DETECTION OF COLORECTAL CANCER IN THE AVERAGE-RISK, ASYMPTOMATIC POPULATION WAS INTRODUCED COMMERCIALLY IN AUGUST 2003.

MISSION STATEMENT

TO ERADICATE MORTALITY FROM COMMON CANCERS BY DEVELOPING AND COMMERCIALIZING HIGH VALUE, PROPRIETARY DNA-BASED ASSAYS FOR THE DETECTION OF CANCER AT ITS EARLIEST, MOST CURABLE STAGE.

TO OUR SHAREHOLDERS:

Recently, two PreGen-Plus™ experiences came to my attention that serve as poignant reminders of the importance of the work we do at EXACT Sciences, both for physicians and, more importantly, patients. The first involves a woman in her fifties who had refused colonoscopy and had failed to comply with fecal occult blood testing (FOBT). She is like millions of other people who for some reason just don't get screened for colorectal cancer. After consulting with her physician, she chose the PreGen-Plus test. When the test detected a DNA mutation, she agreed to a follow-up colonoscopy and a pre-cancerous polyp was removed. This woman believes that PreGen-Plus may very well have saved her life.

The second concerns a gastroenterologist who had a patient referred with a positive PreGen-Plus test. Initially, the physician performed the diagnostic colonoscopy and did not find any abnormality. However, because of the results of the PreGen-Plus test, he decided to view the patient's colon again. On the second pass, he found a flat lesion that he had missed the first time through. The positive PreGen-Plus test made him even more vigilant than usual and, as a result, the patient's life was likely saved.

When I hear about patient success stories like these I am reminded, in very stark terms, why our mission at EXACT Sciences is so important. Since there are more than 40 million people in the US over the age of fifty who have never been screened for colorectal cancer, I am as confident as ever, that PreGen-Plus can fill this significant void in the screening market.

While I am not at all satisfied with unit volumes to date, we continue to work diligently on scientific advances and to put in place the market conditions necessary to drive broad adoption of our technology. The market conditions we are focused on include pursuit of screening guidelines, Medicare inclusion, and obtaining formal payor policy on PreGen-Plus from the nation's largest insurers. I believe we are making good progress toward these goals.

Our work in 2004 helped build momentum toward these market conditions and, I believe brought us a step closer to the events necessary for long-term success. It was a significant achievement in 2004 that we published the results of our multi-center study (MCS) in *The New England Journal of Medicine*. As you know, we had long believed that our technology was superior to fecal occult blood testing, a method currently recommended in the primary screening guidelines. Our MCS demonstrated that our technology was four times more sensitive than the FOBT to which it was compared. In the view of many, this medical evidence supports the conclusion that DNA testing for colorectal cancer should be included in the guidelines of the American Cancer Society and in the guidelines driven by the gastroenterology community. We will continue to work hard to communicate this message loudly and clearly to the guideline policy makers.

Another important step forward for us in 2004 was the completion and submission of our application for a National Coverage Decision with the Centers for Medicare and Medicaid Services (CMS). Based on our body of clinical evidence to date, including compelling cost effectiveness data for DNA-based screening for colorectal cancer, we believe that we have armed CMS with strong and objective support showing that use of our technology in the Medicare population will help to substantially decrease mortality, morbidity and costs within the Medicare program.

In addition, we spent much time in 2004 working with payors to obtain favorable reimbursement policy for PreGen-Plus. These policy-level approvals are also critical to our long-term success. Most payors only issue such policy decisions following review and approval by a rigorous and independent medical review board. I was especially encouraged to hear that our work in 2004 resulted recently in a positive decision from Blue Shield of California's Technology Assessment Forum (CTAF), the review arm for the third-largest insurer in California. CTAF concluded that PreGen-Plus was "*safe, effective and improved net health outcomes for the general population.*" This, in my view, speaks volumes about our technology.

In addition to our work on these market conditions, we are focused on multiple research and development initiatives. Everything at EXACT Sciences starts with the science. I personally believe that our science is ground-breaking. In 2004 we received two new patents and two more have been issued so

far in 2005, bringing our current total to 34 patents with an additional 26 patents pending. I am reminded of the words of our Chief Technology Officer, Anthony Shuber, who regularly tells me that "we are never done."

As an example, in 2004 we published an article in the *Journal of Molecular Diagnostics* showing that the use of our novel DNA-capture technology allows for more abundant DNA purification from a sample and, according to the article's authors, significantly increases assay sensitivity. Additionally, our research team showed in 2004 that with proper sample management techniques (similar to those employed by our partner, Laboratory Corporation of America® Holdings, or LabCorp®) the DNA degradation that we saw in both our MCS study in 2003 and the more recent Mayo-NCI study, can be limited and assay sensitivity therefore increased. These results have been recently accepted for publication in a peer-reviewed journal. Both the improved DNA purification technology and the rigorous sample management techniques have always been used by LabCorp in the commercial test.

Our research team is also working on novel marker formulations and new technologies focused on even greater sensitivity and the detection of pre-cancerous adenomas—targets that are virtually transparent to FOBT. "Early detection" is a driving focus for us at EXACT Sciences because colorectal cancer that is detected early is curable. Our research team continues to push for even greater heights on this front.

On the sales and marketing side, we completed a number of sales experiments in 2004 that lead us to believe that we need to employ an even more focused sales and marketing effort to deliver our message to the various constituencies. We are working closely with our partner LabCorp to further develop the ongoing messaging, and effective approach for delivering that message, necessary to increase unit volume.

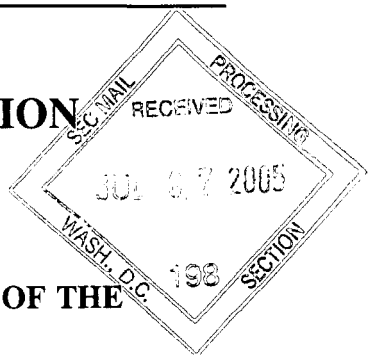
Much of what we do at EXACT Sciences toward creation of these market conditions happens outside of the public's view. We engage in countless discussions across the country with thought leaders, decision-makers, scientists, payors, physicians and others who impact what we do and where we are heading. I am encouraged by what I am hearing but I am also a realist and understand that this is truly a journey.

I believe the key for us in 2005 and beyond is to continue to focus on scientific advancement as well as progressing toward the important market conditions necessary to promote long-term growth. Looking forward, I am as excited as ever about our future. We will continue to do the blocking and tackling necessary to achieve our goals on behalf of our shareholders and our success will, as it should, continue to be measured by our science and by our sales.

I am confident that I will look back at some point in my career and be very proud that our commercial success was the by-product of offering a needed screening alternative that saved the lives of so many.

Don M. Hardison
President and Chief Executive Officer

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549



FORM 10-K

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

For the fiscal year ended: December 31, 2004

☐ **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:
None

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $.01 Par Value

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

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

Indicate by checkmark whether or the registrant is an accelerated filer (as defined in the Exchange Act Rule 12B-2). Yes ☒ No ☐

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, as of the last business day of the Registrant's most recently completed second fiscal quarter was approximately $144,886,000 (based on the closing price of the Registrant's Common Stock on June 30, 2004 of $6.16 per share).

The number of shares outstanding of the Registrant's $.01 par value Common Stock as of March 4, 2005 was 26,231,157.

DOCUMENT INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2004. 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, 2004

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PART I

Item 1. Business

This Business section and other parts of this Form 10-K may contain forward-looking statements relating to, among other things, our expectations concerning our commercial strategy, our marketing, sales and reimbursement efforts and their likely future success, our research and development efforts, and the effectiveness and market acceptance of our technologies. Our 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 "Management's Discussion and Analysis of Financial Condition and Results of Operations—Factors That May Affect Future Results" and elsewhere in this Form 10-K.

Overview

EXACT Sciences Corporation is an applied genomics company that develops and commercializes proprietary DNA-based tests for the early detection of cancer. Our first commercial test, PreGen-Plus™, is a non-invasive DNA-based test used for screening for colorectal cancer, the second leading cause of cancer death in the U.S. and the leading cause of cancer death among non-smokers. The American Cancer Society recommends that all persons age 50 and above undergo regular colorectal cancer screening. Of the nearly 80 million people in the United States for whom colorectal cancer screening is recommended, more than 42 million have never been screened. This large population of unscreened patients represents an opportunity to reduce the mortality associated with colorectal cancer because patients who are diagnosed early in the progression of their disease are more likely to have a complete recovery and to utilize lower levels of expensive medical resources.

Today, professional guidelines recommend screening by a variety of methods including colonoscopy, flexible sigmiodoscopy and fecal occult blood testing ("FOBT"). 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, requires unpleasant bowel preparation and involves certain risks, including, in rare circumstances, colon perforation. Until the commercial launch of PreGen-Plus, the only completely non-invasive option for colorectal cancer detection had been FOBT. FOBT, however, suffers from relatively low sensitivity, particularly in detecting the earliest stage, most curable cancers, and requires dietary modifications, unpleasant stool sampling and stool manipulation by the patient. With the U.S. launch of PreGen-Plus in August 2003 by our strategic partner, Laboratory Corporation of America® Holdings ("LabCorp®"), our test became the first commercially-available, completely non-invasive, DNA-based cancer screening test for the average risk population. In a study published in the December 23, 2004 issue of the *New England Journal of Medicine,* PreGen-Plus was shown to be four times more sensitive in detecting colorectal cancer than the most commonly used FOBT screening test on the market today.

We offer PreGen-Plus through LabCorp, the second largest commercial laboratory in the U.S. with 36 primary laboratories and over 1,000 patient service centers. LabCorp is the exclusive licensee, in the U.S. and Canada, of the technology that surrounds PreGen-Plus. The license is exclusive for five years following the launch of PreGen-Plus, followed by a non-exclusive license for the life of the licensed patents. LabCorp performs the PreGen-Plus test in its laboratories and sells and markets the test through its large, national sales force, and by the terms of the license, pays us a royalty on each test reimbursed. LabCorp has also already paid us $30 million of upfront license fees and milestones in association with this license. In addition, LabCorp has committed to paying an additional $45 million in milestones and performance incentives in the event that certain third party approval and performance levels are achieved. Between commercial launch and December 31, 2004, LabCorp received over 4,800 patient samples for testing from physicians across the country, billed insurers and received payment from numerous third-party payors, including nearly 200 health plans.

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 145,000 new cases and more than 56,000 deaths anticipated in 2005. We believe that many of these people die because they are not screened for colorectal cancer 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 relatively 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 ("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 IIB	T3, N0, M0 T4, N0, M0	60-85
IIIA IIIB IIIC	T1-2, N1, M0 T3-4, N1, M0 T (any), N2, M0	25-65
IV	T (any), N (any), M1	5-7

Primary Tumor (T)

TX: Primary tumor can not 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 can not 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 cancer in its earliest stages increases the likelihood of survival and reduces the significant cost associated with treating late-stage colorectal cancer. As a result, the American Cancer Society recommends that the 80 million Americans age 50 and above undergo regular colorectal cancer screening.

Our Solution

Our first commercial product for the general population is PreGen-Plus, a DNA-based test used for screening for colorectal cancer. PreGen-Plus 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 represent DNA shed from cancerous or pre-cancerous lesions. Once the human DNA in the sample is isolated, PreGen-Plus looks for specific mutations and other abnormalities in that DNA associated with colorectal cancer.

We believe that PreGen-Plus has several advantages that will lead to increased patient compliance and decreased mortality, including:

High Sensitivity. We believe that the current commercial version of PreGen-Plus can lead to increased detection of colorectal cancer. We have conducted several clinical studies supporting the performance of PreGen-Plus, 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, PreGen-Plus demonstrated sensitivity four times greater than the leading FOBT, currently the most common non-invasive screening method for colorectal cancer, and was more than four times as effective as the leading FOBT in detecting cancer at its early stages, when survival rates approach 90%. Moreover, the version of PreGen-Plus that is commercially available incorporates several technical improvements, including the Effipure™ sample preparation technology and improved sample handling methods, which we believe result in higher assay sensitivity than that seen in our multi-center study.

Simple, non-invasive, painless and convenient testing. Unlike current invasive screening and diagnostic methods, PreGen-Plus requires no pre-examination preparation, invasive procedures or anesthesia, and a sample can be collected in the privacy of one's home. In addition, our post-market data indicates that more than half of the people who have been screened with PreGen-Plus had never been screened before, which we believe indicates that PreGen-Plus will result in greater patient screening compliance.

DNA-based test allows for continual and efficient improvements. PreGen-Plus is a DNA-based test and therefore its performance can be enhanced through technical innovations related to DNA isolation and purification. Because PreGen-Plus looks for the *threshold* indications of colorectal cancer at the molecular level (e.g., genetic changes in DNA) rather than the more traditional clinical manifestations of colorectal cancer (e.g., blood in stool, viewable polyps or identifiable lesions), we believe that it can be a more powerful screening tool for the detection of colorectal cancer at its earliest stages.

Commercial Strategy

Our goal is to become a market leader in the development and commercialization of tests for the early detection of cancer, beginning with the early detection of colorectal cancer. To accomplish this goal, we have developed a commercial strategy with respect to PreGen-Plus that includes the following components:

Increased sales growth through our joint sales and marketing efforts with LabCorp. LabCorp is the second largest commercial laboratory in the country and processes over 300,000 patient specimens daily through its system of 36 primary laboratories and over 1,000 patient service centers across the U.S. LabCorp's large sales force is devoted to selling a wide range of diagnostic tests to physicians across all specialties. We maintain a strategic sales team who focus exclusively on the sales and marketing of PreGen-Plus and guide and support LabCorp's large sales force on PreGen-Plus initiatives. In an effort

to increase physician orders of PreGen-Plus, we expanded our strategic sales team in 2004 to 18 highly experienced individuals and began participating in direct sales pilot programs. We continue to work with LabCorp to evaluate ways in which we and LabCorp can best leverage each others' skills in order to capitalize on selling opportunities for PreGen Plus.

Obtain inclusion of stool-based DNA screening in colorectal cancer screening guidelines. Today, professional guidelines recommend screening by a variety of methods including colonoscopy, flexible sigmiodoscopy and FOBT. In general, the guidelines range from the use of colonoscopy every ten years to the use of FOBT annually. Inclusion in screening guidelines is an important precondition to a test's broad acceptance and commercial use in the market as both physicians and payors frequently follow such guidelines in evaluating new technologies. The first colorectal cancer screening guidelines promulgated in 1997 by the GI Consortium, which includes physicians from the American College of Gastroenterology and the American Gastroenterological Association, among other groups, stated that future studies of new technologies did not themselves have to encompass a mortality endpoint, but instead should be shown to be equivalent to currently available technologies that had already proven such a benefit. We therefore designed the multi-center study with this in mind, believing that demonstration of superiority over FOBT with statistical significance would satisfy the directive from the GI Consortium, and thus increase the likelihood that the PreGen-Plus test would be included as an option in colorectal cancer screening guidelines. We consider inclusion in the guidelines of the American Cancer Society and the GI Consortium important to our commercial success and we continue to pursue the inclusion of PreGen-Plus within these organizations' screening guidelines. Although we believe that our published study results provide the information necessary for thought leaders to evaluate PreGen-Plus for inclusion into colorectal cancer screening guidelines, we do not expect that we will be included within any of these organizations' screening guidelines until sometime in 2006, at the earliest.

Obtain formal acceptance of stool-based DNA screening for reimbursement by Medicare and other third-party payors. Our reimbursement strategy consists primarily of educating large managed care organizations, large self-insured employers and large physician groups about the clinical benefits and cost-effectiveness of using PreGen-Plus. We believe that both the publication of our multi-center study results in the *New England Journal of Medicine* in December 2004 and our cost-effectiveness study results that were presented at the Digestive Disease Week conference in May 2003 will aid in our efforts to gain reimbursement for the test. Accordingly, on December 29, 2004 we submitted our application to the Centers for Medicare and Medicaid Services ("CMS") for inclusion into the Medicare program. CMS may accept our application, deeming it complete, or it may reject our application and request additional information or reject it outright. Although the timing of any acceptance of our application or coverage decision by CMS is out of our control, we would not expect CMS to make a coverage decision sooner than nine months from the date of any acceptance of our application.

Continue to improve PreGen-Plus performance characteristics. Our commercial strategy also includes investment in research and development activities that we believe could lead to continued optimization of PreGen-Plus. Specifically, we are working on developing methods to improve assay sensitivity and to reduce assay cost in order to enable the most cost effective commercial test. 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 our Effipure technology as compared to our older, bead-based technology used in our multi-center study, which, in turn, suggested an increased sensitivity of PreGen-Plus with Effipure of 70%. Moreover, we are undertaking efforts to automate and reduce the cost of the PreGen-Plus testing process by seeking to eliminate certain manual steps, reduce the use of expensive reagents and increase processing throughput.

Our Testing Process

Diagnostic tests typically require sample collection and preparation procedures as well as detection methods. Our 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. Our technologies for colorectal cancer are based on collecting a single whole stool sample in an easy, non-invasive manner. Utilizing our specially designed sample container, samples can be either brought by the patient to a LabCorp patient service center, a physician's office or sent directly from the patient's home 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, and that the stool sample is, therefore, 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. Our proprietary technologies are designed to allow for the reproducible isolation and amplification of human DNA found in stool.

Cancer Detection Methods. We have designed proprietary methods for detecting and identifying genomic markers associated with colorectal cancer that can be performed on existing instruments commonly available in clinical laboratories conducting molecular testing.

Clinical Studies

PreGen-Plus has been the subject of extensive research and clinical studies. In numerous studies to date, the performance of PreGen-Plus 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 PreGen-Plus in detecting colorectal cancer, the performance of PreGen-Plus was compared to the most widely-used FOBT in a 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 PreGen-Plus 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 0.001. Results from the study, which were published in the *New England Journal of Medicine* in December 2004, indicated that PreGen-Plus was four times more sensitive than this FOBT in detecting colorectal cancer (52% for PreGen-Plus versus 13% for FOBT), and more than four times more sensitive in detecting colorectal cancer in its earliest, most curable stages (57% for PreGen-Plus versus 13% for FOBT). There was no difference in specificity between PreGen-Plus and this FOBT, with both tests demonstrating a specificity of approximately 95%.

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 studies disclosed below do not include any non-published studies regarding PreGen-Plus, the results of which may differ significantly from those set forth below. All of the published studies referenced below, except the Effipure study, reflect the performance of our original, bead-based version of PreGen-Plus. Effipure is an improvement to the commercial assay designed to increase DNA yield.

Published Studies:

Pre-Commercial Technology	Completed	Number of Cancer Samples Analyzed	Sensitivity	Specificity*
Mayo Clinic I Pilot Study	1999	22	91%	93%
University of Nebraska	2002	16	69%	*
Kaiser Clinic	2002	52	63%	98%
Boston	2002	68	63%	*
Multi-Center Study	2003	31	52%**	95%

New Technology Validation Studies	Completed	Number of Cancer Samples Analyzed	Sensitivity	Specificity*
Effipure	2004	86	70%***	95%

* 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.

** 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.

*** 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 Company's Effipure technology rather than its older, bead-based technology. The study suggested that increased DNA yield can increase the sensitivity of the stool-DNA assay resulting in a sensitivity with Effipure of 70% in this study. 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 PreGen-Plus test that was intended to include approximately 4,000 patients at average risk for developing colorectal cancer. This NIH-funded multi-center study, similar to our multi-center study, was designed to compare the results of our bead-based technologies with those of the Hemoccult II, a common first-line colorectal cancer screening option. After this study commenced, Hemoccult Sensa®, another brand of FOBT, was added to the study. Subsequently, we and the Mayo Clinic sought to include EXACT Sciences' Effipure technology in the study, rather than our older, bead based technology. In connection with this technology transition, Mayo Clinic reviewed preliminary data from the study which showed that, while PreGen-Plus was nearly twice as sensitive as Hemoccult II and as sensitive as Hemoccult Sensa in detecting screen-relevant neoplasia (a category that includes high grade displasia, invasive cancer, and adenomas $\geq$1cm), Hemoccult II and Hemoccult Sensa appeared to have outperformed, at a preliminary stage, the older, bead-based version of our technology in the detection of cancer among the thirteen cancer samples collected in the study. 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 than that demonstrated in our prior published studies. In addition, although our older technology detected some adenomas, our bead-based technology was designed only to detect cancer, not "high grade dysplasia." Although we continue to collect samples for Mayo Clinic, we are not analyzing the samples under the existing study protocol. We are working with Mayo Clinic on plans to re-analyze tissue and stool samples from subjects with and without screen-relevant neoplasia against more advanced versions of our technology using banked biospecimens from the NIH-funded study. Mayo Clinic continues to process and analyze samples with Hemoccult II and Hemoccult Sensa under the existing study protocol.

In addition, we have had numerous abstracts accepted for presentation at industry and scientific meetings and have published articles in peer-reviewed journals, including *Gastroenterology,* the *New England Journal of Medicine* and the *Journal of the National Cancer Institute.*

Research and Development

Our research and development efforts are primarily focused on developing multiple, DNA-based methodologies for the early detection of cancer and pre-cancerous lesions. Our research and development expense, including stock-based compensation, for fiscal 2002, 2003, and 2004 was $20.5 million, $17.3 million and $11.1 million, respectively. Our research and development efforts are primarily focused on the following areas:

Assay performance improvement. We continue to focus our research and development efforts on improving the sensitivity of PreGen-Plus for both invasive cancer and pre-cancerous lesions. We have demonstrated that increasing the yield and purity of human DNA extracted from a stool sample will result in an increase in the sensitivity of the test. The commercial version of PreGen-Plus that was launched in August 2003 incorporates Effipure, our new sample preparation technology that results in a higher yield of DNA as compared to our first generation, bead-based test. We intend to continue development work to improve human DNA yield and purity from a sample, increase the sensitivity of the test using its current gene marker configuration, and develop new marker configurations of the test to optimize performance.

While our research efforts to date have focused on the detection of colorectal cancer, some of the new technologies that we are investigating may enable us to better detect pre-cancerous lesions, especially those that are most likely to progress to invasive colorectal cancer. As part of this effort, we have developed and are evaluating a new method for scanning regions of DNA at sites often associated with pre-cancerous lesion development.

Process improvement. We are undertaking efforts to automate and reduce the cost of the PreGen-Plus testing process by seeking to eliminate certain manual steps, reduce the use of expensive reagents and increase processing throughput. These efforts are intended to enable us to continue to offer LabCorp and future strategic partners the most sensitive, robust and low-cost genomics-based tests possible.

Extensions to other cancers. DNA Integrity Assay, or DIA®, is an epigenetic marker for the presence of cancer, as indicated by longer, less degraded strands of DNA. The presence of these longer strands of DNA is believed to be associated with escape from apoptosis (natural cell death), which itself is a hallmark of cancer. We have validated the DIA theory through a collaboration with a bioinformatics company using a virtual model of cancer. In addition, several independent papers were recently published that support our observations around DIA. We believe our proprietary DIA may potentially be applicable to the detection of other cancers in addition to colorectal cancer.

Sales and Marketing

The primary focus of our sales and marketing organization is the commercialization of PreGen-Plus for colorectal cancer. Since the August 2003 commercial launch of PreGen-Plus, we have been working with LabCorp on various sales and marketing initiatives to help stimulate demand for the test. LabCorp's large sales force calls on primary care physicians and promotes numerous products, including PreGen-Plus. We have built a strategic sales team of 18 highly experienced individuals to help strategically guide and support the LabCorp sales force on PreGen-Plus initiatives.

Our PreGen-Plus commercialization strategy being executed with LabCorp is designed to address the needs of four major constituencies:

Primary Care Physicians (including family practice, generalists, internists, and obstetricians and gynecologists, together "PCPs"). PCPs are principal targets of our promotional activities as we believe that they drive most colorectal cancer screening activities.

Gastroenterology Thought Leaders. Gastroenterologists are highly vocal in advocating colorectal cancer screening, and perform the vast majority of the reference standard diagnostic procedure, colonoscopy. Because they are key to establishing new tests as standard of care and are highly influential with local primary care physicians, we are working closely with gastroenterology thought leaders.

Consumers. Consumers are important promotional targets as we believe they can be very influential in selecting the screening option most appealing to them.

Third-Party Payors. We believe that all promotional targets, PCPs, gastroenterologists and consumers, could bring important pressure on the fourth major constituency, third party payors, such as Medicare, major national and regional managed care organizations and insurance carriers, and self-insured employer groups with the goal being payment for PreGen-Plus and, eventually, formal inclusion in plan reimbursement policies.

To address these four important constituencies, the following broad sales and marketing activities have been pursued:

Direct Sales To Physicians. Sales initiatives to date have included direct detailing of medical professionals at numerous conventions and in their offices. In addition to our own promotional efforts, we continue to conduct ongoing training programs designed to educate LabCorp's sales representatives on PreGen-Plus, and continue to provide updated training as appropriate.

Medical Education Programs. We have and will continue to execute on numerous educational initiatives directed at luminaries in the field, as well as local PCPs, to promote the potential value of PreGen-Plus in their practices. These include continuing medical education ("CME") and non-CME symposia, publications, and speaker's bureau programming. The goal of these efforts is to increase awareness of PreGen-Plus and its potential role in reducing colorectal cancer mortality as well as to increase the likelihood of PreGen-Plus being included in formal clinical practice guidelines.

Advocacy Development. We continue to work with influential advocacy groups to promote their awareness of PreGen-Plus, its performance characteristics, and its potential value in clinical practice toward the goal of reducing mortality from colorectal cancer. We intend to continue to build on growing public awareness of colorectal cancer through our activities with these advocacy groups. Our efforts to date have led to inclusion of PreGen-Plus in various well-circulated brochures, radio and television broadcasts, and support of several consumer-oriented programs designed to increase awareness of the importance of colorectal cancer screening.

Consumer Marketing Initiatives. Because PreGen-Plus promises to be a more consumer-friendly screening option, patients who are aware of PreGen-Plus are more likely to ask their doctor for

PreGen-Plus which, in turn, could help drive test volumes. Consumer initiatives may include print and other media advertising, grassroots programs, and celebrity spokespeople.

Managed Care Activities. We continue to educate Medicare, major national and regional managed care organizations and insurance carriers, and self-insured employer groups about the need and clinical rationale for PreGen-Plus. Along with LabCorp, we are having discussions with key decision makers at many of the major payors, with the goal of shortening the review time and gaining approval for the inclusion of PreGen-Plus in formal practice guidelines within each payor's plan. In addition, we also continue to address reimbursement for PreGen-Plus from government payors, primarily CMS, formerly known as the Health Care Financing Administration, by educating their senior staff about the need and clinical rationale for PreGen-Plus (See "Reimbursement"). At the end of 2004 we submitted a national coverage decision (NCD) memorandum to CMS relating to the inclusion of PreGen-Plus in Medicare.

Reimbursement

We are currently working to obtain national coverage and reimbursement approval for PreGen-Plus tests using our technologies from Medicare as well as major national and regional managed care organizations and insurance carriers, and self-insured employer groups. In connection with the commercialization of PreGen-Plus, we have been developing and implementing a reimbursement strategy, consisting primarily of educating large managed care organizations, large self-insured employers and large physician groups about the clinical benefits and cost-effectiveness of using PreGen-Plus.

Medicare and other third-party payors will independently evaluate our technologies by, among other things, reviewing the published literature with respect to the results obtained from our clinical studies. We believe that both the publication of results in the *New England Journal of Medicine* and our cost-effectiveness study results that were presented at the Digestive Disease Week conference in May 2003 will aid in our efforts to gain reimbursement for the test. Current molecular diagnostic procedural terminology ("CPT") codes are available which will allow our technologies to be billed following completion of a test prescribed (ordered) by a physician for a patient. We believe that the existence of current CPT codes with applicability to our screening test will help facilitate Medicare's reimbursement process. On December 29, 2004, we submitted our application to CMS for inclusion into the Medicare program. CMS may accept our application, deeming it complete, or it may reject our application and request additional information or reject it outright. Although the timing of any acceptance of our application or coverage decision by CMS is out of our control, we would not expect CMS to make a coverage decision sooner than nine months from the date of any acceptance of our application.

In addition, we continue to work on building support in Congress and have met with several members of Congressional staffs and national organizations with an interest in colorectal cancer to support our application.

Government Regulation

Certain of our activities are, or have the potential to be, subject to regulatory oversight by the Food and Drug Administration ("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 our products. Failure to comply with applicable requirements can lead to sanctions, including withdrawal of products from the market, recalls, refusal to authorize government contracts, product seizures, civil money penalties, injunctions and criminal prosecution.

Generally, certain categories of medical devices, a category that may be deemed to include products based upon our technologies, require FDA pre-market approval or clearance before they may be marketed and placed into commercial distribution. The FDA has not, however, actively regulated in-house laboratory tests that have been developed and validated by the laboratory providing the tests.

Additionally, the FDA has demonstrated prior enforcement discretion and is currently undergoing internal review on its legal authority for regulating these products. Pre-market clearance or approval is not currently required for this category of products. The FDA does regulate the sale of certain reagents, including some of our reagents, used in laboratory tests. The FDA refers to the reagents used in these tests as analyte specific reagents. Analyte specific reagents react with a biological substance including those intended to identify a specific DNA sequence or protein. These reagents generally do not require FDA pre-market approval or clearance if they are (i) sold to clinical laboratories certified by the government to perform high complexity testing and (ii) labeled in accordance with FDA requirements, including a statement that their analytical and performance characteristics have not been established. A similar statement would also be required on all advertising and promotional materials relating to analyte specific reagents such as those used in our test. Laboratories also are subject to restrictions on the labeling and marketing of tests that have been developed using analyte specific reagents. We believe that in-house testing based upon our technologies, and any analyte specific reagents that we intend to sell to leading clinical reference laboratories currently do not require FDA approval or clearance. We cannot be sure, however, that the FDA will not change its policy in a manner that would result in tests based upon our technologies, or a combination of reagents, to require pre-market approval or clearance. In addition, we cannot be sure that the FDA will not change its position in ways that could negatively affect our operations either through regulation or new enforcement initiatives.

Regardless of whether a medical device requires FDA approval or clearance, a number of other FDA requirements apply to its manufacturer and to those who distribute it. Device manufacturers must be registered and their products listed with the FDA, and certain adverse events, correction and removals must be reported to the FDA. The FDA also regulates the product labeling, promotion, and in some cases, advertising, of medical devices. Manufacturers must comply with the FDA's Quality System Regulation which establishes extensive requirements for design, quality control, validation and manufacturing. Thus, manufacturers and distributors must continue to spend time, money and effort to maintain compliance, and failure to comply can lead to enforcement action. Analyte specific reagents must be manufactured in an environment designed to establish certain quality and consistency parameters. We currently rely on external third party manufactures to meet these standards. The FDA periodically inspects facilities to ascertain compliance with these and other requirements.

We and our strategic partner, LabCorp, are also subject to U.S. and state laws and regulations regarding the operation of clinical laboratories. The federal Clinical Laboratory Improvement Amendments of 1988 ("CLIA") 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 the possible 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 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 pre-market clearance or approval requirement and much of the Quality System Regulation. We believe that our specimen container falls within an applicable exemption, but we cannot be sure that the FDA will not assert that our container is not exempt and seek to impose a pre-market clearance or approval requirement.

Intellectual Property

In order to protect our proprietary technologies, we rely on combinations 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.

As of December 31, 2004, we had 32 patents issued and 27 pending patent applications in the United States and, in foreign jurisdictions, 33 patents issued and 44 pending applications. Our success depends to a significant degree upon our ability to develop proprietary products and technologies and to obtain patent coverage for such products and technologies. We intend to continue to file patent applications covering newly-developed products or technologies.

Each of our patents generally has a term of 20 years from its respective priority filing dates. Consequently, our first patents are set to expire in 2018. 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 priority filing dates.

A third-party institution has co-inventorship rights with respect to one of our issued patents relating to use of our enumerated loss of heterozygosity ("e-LOH") detection method on pooled samples from groups of patients. Our current cancer screening detection methods do not include pooled samples. If any third party asserts co-inventorship rights with respect to any of our patents and is successful in challenging our inventorship determination, such patent may become unenforceable or we may be required to add that third party inventor to the applicable patent, resulting in co-ownership of such patent with the third party. Co-ownership of a patent allows the co-owner to exercise all rights of ownership, including the right to use, transfer and license the rights protected by the applicable patent.

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 cancers of the lung, pancreas, esophagus, stomach, small intestine, bile duct, naso-pharyngeal, liver and gall bladder in stool. This patent application does not relate to the detection of colorectal cancer and designates the United States, Japan, Europe and Canada as the territories in which rights are sought.

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. The license provides us and our sublicensees, with the ability to manufacture and use the Acrydite technology in the PreGen-Plus test. The Acrydite technology is useful in connection with our proprietary electrophoretic DNA gel capture technology used in the isolation of nucleic acids and the diagnosis of disease that we purchased from MT Technologies.

We license on an exclusive basis from Johns Hopkins University certain patents owned by JHU that relate to digital amplification of DNA. We believe that this license will allow us and our partners to develop and commercialize novel detection technologies to enhance the performance of our current 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 ("SBE") technology. The license provides us and our sublicensee, LabCorp, with the ability to use SBE in the PreGen-Plus test.

LabCorp also maintains and is currently negotiating additional third-party technology license and supply agreements that are necessary for the PreGen-Plus test.

Competition

To our knowledge, none of the large genomics or diagnostics companies are developing tests to conduct stool-based DNA testing. However, these companies may be working on similar tests 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, we face competition from procedure-based detection technologies such as flexible sigmoidoscopy, colonoscopy and virtual colonoscopy, a new procedure being performed in which a radiologist views the inside of the colon through a scanner, as well as existing and possibly improved traditional screening tests such as immunochemical FOBT. 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. We believe that pharmaceutical and medical device marketing efforts directed at physicians represent competition for physician attention for the sales force selling our test.

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

- high sensitivity;
- high specificity;
- non-invasiveness;
- 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, 2004, we had seventy-one employees, five of whom have Ph.D.s and one of whom has an M.D. We terminated ten employees effective February 15, 2005, of which nine were engaged in research and development and one was engaged in sales and marketing. Accordingly, we currently have twenty-seven employees engaged in research and development, twenty-four employees in sales and marketing and ten 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 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 ("SEC"). 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 2. Properties

As of December 31, 2004, we occupied approximately 56,000 square feet of space in our headquarters located in Marlborough, Massachusetts under a lease which expires in July 2010. We amended this lease, effective January 20, 2005, to reduce the total space occupied under the lease from approximately 56,000 square feet to 37,000 square feet. We also lease approximately 4,500 square feet in Maynard, Massachusetts under a lease that expires on August 31, 2006. 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.

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 2004.

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 National Market under the symbol "EXAS." The following table provides, for the periods indicated, the high and low sales prices per share as reported by The NASDAQ National Market.

	High	Low
2004		
First quarter	$10.49	$6.57
Second quarter	8.40	5.58
Third quarter	6.14	3.17
Fourth quarter	4.09	2.41
2003		
First quarter	$12.17	$6.30
Second quarter	15.10	8.87
Third quarter	18.00	10.65
Fourth quarter	16.00	8.50

As of December 31, 2004, there were approximately 26,199,517 shares of our common stock outstanding held by approximately 104 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. Our current policy is to retain all of our earnings to finance future growth.

During the quarter ended December 31, 2004, there were no repurchases made by us or on our behalf, or by any "affiliated purchaser," of shares of our common stock registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended.

Item 6. Selected Financial Data

The selected historical financial data set forth below as of December 31, 2003 and 2004 and for the years ended December 31, 2002, 2003 and 2004 are derived from our financial statements, which have been audited by Ernst & Young LLP, independent auditors and which are included elsewhere in this Form 10-K. The selected historical financial data as of December 31, 2000 and 2001 and for the years ended December 31, 2000 and 2001 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 public auditors included elsewhere in this Form 10-K.

	Year Ended December 31,				
	2000	2001	2002	2003	2004
	(In thousands, except per share data)				
Statements of Operations Data:					
Revenue:					
Product royalty fees	$ —	$ —	$ —	$ 8	$ 166
License fees	—	51	886	2,871	4,514
Product	—	—	11	22	255
	—	51	897	2,901	4,935
Cost of revenue	—	—	9	22	487
Gross profit	—	51	888	2,879	4,448
Operating expenses:					
Research and development	5,332	13,335	19,989	17,084	10,901
Selling, general and administrative	4,814	9,078	9,701	13,515	12,244
Stock-based compensation (1)	3,184	3,788	2,043	1,118	498
	13,330	26,201	31,733	31,717	23,643
Loss from operations	(13,330)	(26,150)	(30,845)	(28,838)	(19,195)
Interest income	1,447	2,665	962	498	672
Net loss	$(11,883)	$(23,485)	$(29,883)	$(28,340)	$(18,523)
Net loss per common share:					
Basic and diluted	$ (8.13)	$ (1.42)	$ (1.62)	$ (1.50)	$ (0.73)
Weighted average common shares outstanding:					
Basic and diluted	1,462	16,487	18,433	18,911	25,334
Balance Sheet Data:					
Cash and cash equivalents	$ 26,470	$ 56,843	$ 17,439	$ 14,200	$ 13,092
Marketable securities	—	—	26,407	13,606	37,188
Total assets	29,059	63,100	50,086	34,681	56,111
Total liabilities	1,359	4,133	11,737	22,453	18,128
Stockholders equity	27,700	58,967	38,349	12,228	37,983

(1) The following table summarizes the departmental allocation of stock based compensation:

	2000	2001	2002	2003	2004
Research and development	$ 810	$ 898	$ 478	$ 249	$ 221
Selling, general and administrative	2,374	2,890	1,565	869	277
Total	$ 3,184	$ 3,788	$ 2,043	$ 1,118	$ 498

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 Form 10-K. This 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 and Exchange Act of 1934, as amended, and are subject to the "safe harbor" created by those sections. Some of the forward-looking statements can be identified by the use of forward-looking terms such as "believes," "expects," "may," "will," "should," "could," "seek," "intends," "plans," "estimates," "anticipates" or other comparable terms. Forward-looking statements involve inherent risks and uncertainties. A number of important factors could cause actual results to differ materially from those in the forward-looking statements. We urge you to consider the risks and uncertainties discussed at the end of this section under "Factors That May Impact Future Results of Operations" in evaluating our forward-looking statements. 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.

Overview

We are an applied genomics company that develops and commercializes proprietary DNA-based tests for the early detection of cancer. Our first commercial test, PreGen-Plus™, is used for screening colorectal cancer, the second leading cause of cancer death in the U.S. and the leading cause of cancer death among non-smokers. Since our inception on February 10, 1995, our principal activities have included:

- researching and developing our technologies for colorectal cancer screening;
- conducting clinical studies to validate our colorectal cancer screening tests;
- negotiating licenses for intellectual property of others;
- developing relationships with opinion leaders in the scientific and medical communities;
- conducting market studies and analyzing alternative approaches for commercializing our technologies;
- hiring research and clinical personnel, sales personnel, management and other support personnel;
- raising capital;
- licensing our proprietary technologies to LabCorp and
- working with LabCorp on activities necessary for the commercialization, marketing and sale of PreGen-Plus.

On June 26, 2002, we entered into a license agreement, subsequently amended on January 19, 2004, with LabCorp for an exclusive, long-term strategic alliance to commercialize PreGen-Plus, our proprietary, non-invasive DNA-based technology for the early detection of colorectal cancer in the average-risk population. Pursuant to this agreement, we exclusively licensed to LabCorp all U.S. and Canadian patents and patent applications owned or exclusively licensed by us relating to our technology through August 2008, followed by a non-exclusive license for the life of the patents. In return for the license, LabCorp agreed to pay us certain up-front and per-test royalty fees. 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 the per-test royalty fee, under our amended license agreement, we may also be eligible for milestone payments from LabCorp totaling up to $15 million based upon Company deliverables related to the acceptance and inclusion of PreGen-Plus in certain clinical guidelines and certain policy-level reimbursement approvals from third-party payors, as well as performance-based payments totaling up to $30 million based upon

the achievement of certain significant LabCorp revenue thresholds. The amended license agreement also clarified the obligations of each party with respect to certain third-party technology which has been incorporated into the commercial version of the PreGen-Plus test.

In conjunction with the strategic alliance, we issued to LabCorp a warrant to purchase 1,000,000 shares of our common stock, exercisable over a three-year period at an exercise price of $16.09 per share. We assigned a value to the warrant of $6.6 million under the Black-Scholes option-pricing model which was recorded as a reduction in the initial up-front deferred license fee of $15 million. We are amortizing the two up-front payments totaling $30 million, net of the $6.6 million value of the warrant, as license fee revenue over the exclusive license period.

We have generated limited operating revenues since our inception and, as of December 31, 2004, we had an accumulated deficit of approximately $123.3 million. Our losses have historically resulted from costs incurred in conjunction with our research and development initiatives, salaries and benefits associated with the hiring of additional personnel, and more recently, the initiation of marketing programs and the build-out of our sales infrastructure to support the commercialization and marketing of PreGen-Plus. We expect that our losses will continue for the next several years as a result of continuing research, development, sales and marketing expenses. Our future revenues will depend, in large part, upon whether our technologies are broadly ordered by medical practitioners, requested by patients, and ultimately reimbursed by third-party payors.

We believe that the market demand for our first commercial product, PreGen-Plus, which is being sold through LabCorp, is dependent upon a number of factors, including the following:

- inclusion of stool-based DNA screening in colorectal cancer screening guidelines;
- formal acceptance of stool-based DNA screening for reimbursement by Medicare and other third-party payors;
- patient acceptance of PreGen-Plus, including its novel sample collection process;
- stool-based DNA screening becoming a standard of care among prescribing physicians;
- the impact the publication of our multi-center study results and accompanying editorial in a peer-reviewed journal have on market acceptance of PreGen-Plus and
- effective sales processes to educate physicians and their office staff to facilitate patient compliance.

Our revenue is comprised of product royalty fees on PreGen-Plus tests sold by LabCorp, product revenue from the sale to LabCorp of certain components of our Effipure™ technology, which is incorporated into the PreGen-Plus test, and the amortization of license fees for the licensing of product rights to LabCorp under our license agreements. We account for PreGen-Plus royalty fees on a cash basis and will continue to do so until such time as we have sufficient history and experience to estimate the percentage of PreGen-Plus accessions that will ultimately result in revenue for us. Laboratory operating factors incurred at LabCorp such as turnaround times for the testing process, possible pre- and post-analytical sample deficiencies and third-party reimbursement all influence whether an accession by LabCorp will eventually be recognized as revenue by us. We recognize our license fee revenue on a straight-line basis over the applicable exclusive license period. We expect that product royalty fees and product revenue will increase in 2005 on an aggregate basis as compared to 2004 due to the ongoing commercial sales of PreGen-Plus by LabCorp. License fee revenue for 2005 is expected to be consistent with license fee revenue recorded in 2004 due to the ratable recognition of upfront license fees received from LabCorp.

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. Our research and development efforts in 2005 will focus on improving the sensitivity and other performance aspects of PreGen-Plus and thus we do not expect to engage in large-scale clinical trials.

We expect research and development expenses to decrease in 2005 from 2004 levels as we plan on allocating more resources to sales and marketing efforts than in previous years.

Selling, general and administrative expenses consist primarily of non-research personnel salaries, office expenses and professional fees. We expect selling, general and administrative expenses to be flat in 2005 as compared 2004. However, we do expect a shift in the allocation of spending which will result in higher sales and marketing expenses as we supplement the direct sales efforts of LabCorp and implement marketing initiatives in certain regions of the U.S. and lower headcount and professional fees in the general and administrative functions.

Stock-based compensation expense, a non-cash expense, primarily represents the difference between the exercise price and fair value of common stock on the date of grant for certain options granted prior to our initial public offering as well as charges resulting from stock option grants to non-employees which are recorded at fair value based on the fair value measurement criteria of Statement of Financial Accounting Standards ("SFAS") No. 123, *Accounting for Stock Based Compensation.* The stock-based compensation expense related to options granted prior to our initial public offering is being amortized on an accelerated method over the vesting period of the applicable options, which is generally 60 months, and will end in 2005. The amount of stock-based compensation expense that we record each quarter in connection with options granted to non-employees may fluctuate with changes in our stock price.

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123 (revised 2004), *Share-Based Payment* ("SFAS No. 123(R)"), which is a revision of SFAS No. 123. SFAS No. 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach to accounting for share-based payments in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. Pro forma disclosure of the fair value of share based payments is no longer an alternative to financial statement recognition. SFAS No. 123(R) is effective for public companies (excluding small business issuers) at the beginning of the first interim or annual period beginning after June 15, 2005.

We expect the adoption of SFAS No. 123(R) to have a material effect on our financial statements, in the form of additional compensation expense, on a quarterly and annual basis. It is not possible to precisely determine the expense impact of adoption since a portion of the ultimate expense that is recorded will likely relate to awards that have not yet been granted, but are likely to be granted prior to the July 1, 2005 adoption date. The expense associated with these future awards can only be determined based on factors such as the price of our common stock, the volatility of our stock price and risk free interest rates as measured at the grant date. However, the pro forma disclosures related to SFAS No. 123 included in our historic financial statements are relevant data points for gauging the potential level of expense that might be recorded in future periods.

Significant Accounting Policies

Financial Reporting Release No. 60, which was issued in December 2001 by the Securities and Exchange Commission, requires all registrants to discuss critical accounting policies or methods used in the preparation of the financial statements. The notes to the consolidated financial statements included in this report on Form 10-K include a summary of the significant accounting policies and methods used in the preparation of our consolidated financial statements.

Further, we have made a number of estimates and assumptions that affect reported amounts of assets, liabilities, revenues and expenses, and actual results may differ from those estimates. The areas that require the greatest degree of management judgment are the assessment of the recoverability of long-lived assets, primarily intellectual property, and revenue recognition.

Patent Costs. Patent costs, which consist of related legal fees and disbursements and purchases of intellectual property, are capitalized as incurred and are amortized beginning when patents are issued in the United States over an estimated useful life of five years. Capitalized patent costs are expensed upon disallowance of the patent, or 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.

Revenue Recognition. 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.

Royalties fees earned on PreGen-Plus tests performed by LabCorp are based upon the customer's remittance to LabCorp, not the amount billed. Service revenue is recognized when services are performed (earned), amounts can be objectively determined (measurable), and collection is reasonably assured (collectible or realizable). Until such time that estimates utilized are supported by measurable, historical remittance data, we will recognize royalties as LabCorp customers make payments. The timing of payments is uncertain because of the number of parties involved in the reimbursement process.

Product revenue from the sale of certain components of our Effipure™ technology to LabCorp is recognized upon shipment of the components provided that title passes, the price is fixed or determinable and collection of the receivable is probable.

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.

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.

Results of Operations

Comparison of the years ended December 31, 2004 and 2003

Revenue. Revenue increased to $4.9 million for the year ended December 31, 2004 from $2.9 million for the year ended December 31, 2003. Revenue is primarily composed of amortization of up-front technology license fees associated with agreements signed with LabCorp that are being amortized on a straight-line basis over the license period. The increase in revenue for the year ended December 31, 2004 as compared to the year ended December 31, 2003 was primarily due to the amortization of the second $15 million up-front license fee received upon the commercial launch of PreGen-Plus in August 2003 as well as an increase in revenues related to sales of Effipure components to LabCorp.

Cost of revenue. Total cost of revenue increased to $487,000 for the year ended December 31, 2004 from $22,000 for the year ended December 31, 2003. The cost of product revenue includes the costs of Effipure components while the cost of product royalty revenue represents royalties owed to third-parties for technology currently incorporated into PreGen-Plus. The increase in the cost of product revenue for the year ended December 31, 2004 as compared to the year ended December 31, 2003 was primarily the result of an increase in the number of Effipure components shipped to LabCorp. In addition, we recorded charges of approximately $239,000 during 2004 to write-off excess and expired Effipure inventory units. We have contractual commitments to certain of our Effipure contract manufacturers which require us to pay minimum aggregate dollar amounts over the life of the commitments, which expire in April 2006. A portion of the 2004 charges to write-off excess and expired Effipure inventory units was based upon payments related to these minimum purchase commitments. As we fulfill these minimum purchase commitments, we may need to make additional provisions for

excess or obsolete inventory. For the year ended December 31, 2003, product cost of sales primarily represented the cost of performing commercial colorectal screening tests at our facilities.

Research and development expenses. Research and development expenses, excluding departmental allocations of stock-based compensation, decreased to $10.9 million for the year ended December 31, 2004 from $17.1 million for the year ended December 31, 2003. This decrease was primarily the result of the completion of our multi-center study in the fourth quarter of 2003 and the completion of certain other research and development initiatives in 2003 to support of the commercialization of PreGen-Plus. Included in the decrease in research and development expenses were decreases of $2.3 million in laboratory expenses, $1.4 million in personnel-related expenses, $1.2 million in clinical study expenses and $682,000 in professional fees. Also included in the decrease in research and development expenses for the year ended December 31, 2004 as compared to the year ended December 31, 2003 was a decrease of $297,000 in laboratory space costs as a result of the accelerated amortization of leasehold improvements recorded in 2003 associated with our former facility. The decreases noted above were partially offset by an increase of $334,000 in severance costs associated with the termination of certain officers and employees during the year ended December 31, 2004. See Note 6 to the consolidated financial statements included in this Form 10-K for additional information on employee terminations.

Selling, general and administrative expenses. Selling, general and administrative expenses, excluding departmental allocations of stock-based compensation, decreased to $12.2 million for the year ended December 31, 2004 from $13.5 million for the year ended December 31, 2003. This decrease was primarily the result of the completion of programs related to the pre-marketing of PreGen-Plus which ended in 2003 resulting in lower professional fees and expenses of $1.7 million as well as a decrease in facility related expenses of $130,000. These decreases were partially offset by an increase of $689,000 in severance costs in connection with the termination of certain officers and employees during 2004. See Note 6 to the consolidated financial statements included in this Form 10-K for additional information on employee terminations.

Stock-based compensation. Stock-based compensation, which is a non-cash expense, decreased to $498,000 for the year ended December 31, 2004 from $1.1 million for the year ended December 31, 2003. The decrease in stock-based compensation was primarily due to the accelerated method of amortization being utilized to amortize the deferred compensation recorded in connection with options granted prior to our initial public offering. In addition, during the first quarter of 2004, we recorded $228,000 of stock-based compensation associated with our agreement to forgive an outstanding loan of a former executive officer, which was offset by a reduction of $272,000 in stock-based compensation associated with the forfeitures of restricted stock and the cancellation of unvested stock options due to the departure of certain officers and employees.

Interest income. Interest income increased to $672,000 for the year ended December 31, 2004 from $498,000 for the year ended December 31, 2003. This increase was due to an increase in our average cash, cash equivalents and marketable securities balances during 2004 as compared to 2003 as a result of the completion of our public offering of 6.9 million shares of common stock in February 2004, which generated net proceeds to us of approximately $43.3 million.

Comparison of the years ended December 31, 2003 and 2002

Revenue. Revenue increased to $2.9 million for the year ended December 31, 2003 from $897,000 for the year ended December 31, 2002. Revenue is primarily composed of amortization of up-front technology license fees associated with agreements signed in July 2001 and June 2002 with LabCorp that are being amortized on a straight-line basis over the respective license periods.

Cost of revenue. Cost of revenue increased to $22,000 for the year ended December 31, 2003 from $9,000 for the year ended December 31, 2002. The cost of product revenue includes the costs of Effipure components sold to LabCorp as well as the estimated cost of performing commercial

colorectal screening tests at our facilities while the cost of product royalty fees represents royalties owed to third-parties for technology currently incorporated into PreGen-Plus.

Research and development expenses. Research and development expenses, excluding departmental allocations of stock-based compensation, decreased to $17.1 million for the year ended December 31, 2003 from $20.0 million for the year ended December 31, 2002. This decrease was primarily attributable to the completion of our 5,500 patient multi-center study which was initiated in October 2001 and included a decrease of $4.5 million in trials and studies expenses partially offset by increases of $452,000 in personnel-related expenses, $148,000 in professional fees and expenses, $347,000 in laboratory expenses, and $667,000 related to the leasing of additional laboratory space. The increase in the expenses noted above were primarily attributable to an increase in the number of tests being performed in support of our multi-center study and the Mayo Clinic study, in addition to other research and development initiatives undertaken to further develop our technologies in support of the commercial launch of PreGen-Plus.

Selling, general and administrative expenses. Selling, general and administrative expenses, excluding departmental allocations of stock-based compensation, increased to $13.5 million for the year ended December 31, 2003 from $9.7 million for the year ended December 31, 2002. This increase was attributable primarily to increases in sales personnel and marketing programs in support of the commercial launch of PreGen-Plus and included increases of $1.3 million in personnel-related expenses, $2.3 million in professional fees and expenses, $125,000 in travel-related expenses and $110,000 related to office space and related office expenses.

Stock-based compensation. Stock-based compensation, a non-cash expense, decreased to $1.1 million for the year ended December 31, 2003, of which $249,000 related to research and development personnel and $869,000 related to general and administrative personnel from $2.0 million for the year ended December 31, 2002. The decrease in stock-based compensation in 2003 from 2002 is due to the accelerated method of amortization being used to record this expense.

Interest income. Interest income decreased to $498,000 for the year ended December 31, 2003 from $962,000 for the year ended December 31, 2002. This decrease was primarily due to lower interest rates on our investments and overall decreases in our average cash, cash equivalents and marketable securities balances.

Employee terminations

On February 9, 2005, we reduced our workforce by ten employees, principally in the research and development functions. Employees terminated were eligible to receive three to four months of salary and benefits, depending on their position and length of service with the Company. In connection with the employee terminations, we expect to record severance charges ranging from $200 to $250 in the quarter ended March 31, 2005. With the completion of our 5,500-patient multi-center study in 2003, and with no large clinical studies anticipated in the near term, we determined that a reduction in force was warranted to reduce costs. This workforce reduction reflects our intention to validate product improvements through smaller, less expensive research studies that leverage the results of our prior studies including our large-scale multi-center study that was published in the *New England Journal of Medicine* in December 2004.

Liquidity and Capital Resources

We have financed our operations since inception primarily through private sales of preferred stock, our initial public offering of common stock in February 2001, cash received from LabCorp in connection with our strategic alliance and a public offering of 6.9 million shares of common stock in February 2004. As of December 31, 2004, we had approximately $50.3 million in cash, cash equivalents and marketable securities, of which approximately $1.0 million has been pledged as collateral for an outstanding letter of credit.

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

Net cash used in operating activities was $21.2 million, $13.9 million and $11.9 million for the years ended December 31, 2004, 2003 and 2002, respectively. Excluding the impact of the upfront deferred licensing fees from LabCorp, net cash used in operating activities would have been $28.9 million and $26.9 million for the years ended December 31, 2003 and 2002, respectively. On this basis, the decrease in net cash used in operating activities for the year ended December 31, 2004 as compared to the year ended December 31, 2003 was primarily due to the decrease in our operating loss, which was the result of lower research and development spending due to the completion of our 5,500 patient multi-center study in late 2003, partially offset by approximately $1.0 million in severance costs associated with the termination of certain employees and officers during 2004. The increase in net cash used in operating activities for the year ended December 31, 2003 as compared to the year ended December 31, 2002 was primarily due to the increase in our operating loss, which was the result of higher research and development spending during our 5,500 patient multi-center study as well as an increases in selling, general and administrative expenses to support the commercial launch of PreGen-Plus in 2003.

Net cash used in investing activities was $23.9 million for the year ended December 31, 2004, as compared to net cash provided by investing activities of $9.5 million in 2003 and net cash used by investing activities of $28.1 million in 2002. Excluding the impact of the purchases and maturities of marketable securities, net cash used in investing activities was $180,000, $3.2 million and $1.8 million for the years ended December 31, 2004, 2003 and 2002, respectively.

Purchases of property and equipment of $287,000 during 2004 were significantly lower than purchases of property and equipment of $2.6 million in 2003 and $1.3 million in 2002. Investment in property and equipment in 2003 was related to the relocation of our corporate headquarters and lab operations to Marlborough, Massachusetts while the investment in 2002 related to the expansion of our laboratory operations to prepare for our multi-center study and the Mayo Clinic study. We expect that purchases of property and equipment in 2005 will be consistent with amounts spent in 2004.

Cash used for the expansion of our intellectual property portfolio was $353,000 for the year ended December 31, 2004, as compared to $608,000 in 2003 and $417,000 in 2002. Patent costs, which historically consisted of related legal fees, are capitalized as incurred and are amortized beginning when patents are issued in the United States over an estimated useful life of five years.

Net cash provided by financing activities was $43.9 million for the year ended December 31, 2004, as compared to $1.2 million in 2003 and $615,000 in 2002. In February 2004, we completed an offering of 6.9 million shares of our common stock which generated net proceeds to us of approximately $43.3 million. Also in 2004, issuances of common stock under our stock option and employee stock purchase plans and the repayment of notes receivable provided an additional $636,000 in cash to us. During the years ended December 31, 2003 and 2002, issuances of common stock under our stock

option and employee stock purchase plans and the repayment of notes receivable provided $1.2 million and $615,000, respectively, in cash flows from financing activities.

We expect that cash, cash equivalents and short-term investments currently on hand at December 31, 2004, will be sufficient to fund our operations for the at least the next two years, based upon our current operating outlook. Product royalty fee payments and milestone payments from LabCorp may supplement our liquidity position. However, as we are in the early stage of commercialization of PreGen-Plus, we cannot forecast how rapidly sales of PreGen-Plus and, consequently, royalty payments from LabCorp, will increase, if at all. Further, milestone and other performance-based payments from LabCorp for which we may be eligible under our strategic agreement may supplement our liquidity position. However, the timing and receipt of milestone and performance-based payments is similarly unpredictable at this time. Of the remaining $45 million of payments for which we may be eligible under our amended agreement with LabCorp, $15 million relates to milestone payments associated with the inclusion of PreGen-Plus into certain clinical guideline acceptance and policy-level reimbursement approvals that, in large part, depend upon decisions to be made by third parties, and $30 million relates to the achievement of certain significant cumulative LabCorp revenue thresholds that depend upon LabCorp's success with respect to its sales of PreGen-Plus and are not expected for the next several years, if at all. As such, no assurance can be given that any payments pursuant to our agreement with LabCorp will be sufficient or timely enough to meet our liquidity needs. If revenue and other payments from LabCorp are insufficient to meet our liquidity needs, we will be required to raise additional capital or reduce the scale of our operations.

Our shelf registration statement on Form S-3 filed with the SEC was declared effective on September 26, 2003, which permits us to offer, from time to time, any combination of common stock, preferred stock, debt securities and warrants to purchase each of the foregoing, up to an aggregate of $100 million. On February 10, 2004, we completed an offering of 6.9 million shares of common stock under this shelf registration statement which generated net proceeds of $43.3 million. While we may, from time to time, seek to access the capital markets, there can be no assurance that we will be successful in any future capital raising efforts, or that we would be able raise additional funds at an acceptable price level.

The table below reflects our estimated fixed obligations and commitments as of December 31, 2004:

	Payments Due by Period				
	Total	Less Than One Year	1 - 3 Years	3 - 5 Years	More Than 5 Years
			(in Thousands)		
Operating lease obligations	$ 5,622	$1,088	$1,928	$2,004	$ 602
Purchase obligations	339	339	—	—	—
Obligations under license and collaborative agreements	5,216	766	530	530	3,390
Total	$11,177	$2,193	$2,458	$2,534	$3,992

Operating leases reflect remaining obligations associated with leased facilities in Marlborough and Maynard, Massachusetts. Effective January 20, 2005, we amended the lease for our corporate headquarters in Marlborough to reduce the total space leased at that facility from approximately 56,000 square feet to approximately 37,000 square feet. In connection with this lease amendment, we expect to write off approximately $300 in the quarter ended March 31, 2005, relating to leasehold improvements to the space being vacated. In addition, we expect to save approximately $1.8 million in lease costs over the remaining term of the lease as a result of this amendment. The fixed obligation and commitments table above reflects this lease amendment. Purchase obligations represent purchase commitments associated with the manufacture and production of Effipure. Obligations under license and collaboration agreements represent on-going commitments under various research collaborations and

licensing agreements. Commitments under license agreements generally expire concurrent with the expiration of the intellectual property licensed from the third party. We do not have any special purpose entities or any other off balance sheet financing arrangements.

Our future capital requirements include, but are not limited to, continued investment in our research and development programs and related initiatives, supporting research and clinical study efforts on our technologies, sales and marketing efforts associated with the commercialization of PreGen-Plus, capital expenditures primarily associated with purchases of laboratory equipment and continued investment in our intellectual property estate. Our future capital requirements will depend on many factors, including the following:

- the success of our applied research efforts and clinical studies;
- the inclusion of stool DNA screening in colorectal cancer screening guidelines;
- formal acceptance of stool DNA screening for reimbursement by Medicare and other third-party payors;
- our ability to achieve milestones under our strategic agreement with LabCorp:
- the scope of and progress made in our research and development activities and
- the successful commercialization and sales growth of PreGen-Plus.

We cannot assure you that our business will generate sufficient cash flow from operations, or that we will be able to liquidate our investments or obtain financing when needed or desirable. An inability to fund our operations would have a material adverse effect on our business, financial condition and results of operations.

Net Operating Loss Carryforwards

As of December 31, 2004, we had net operating loss carryforwards of approximately $86.7 million and tax credit carryforwards of approximately $2.6 million. The net operating loss and tax credit carryforwards will expire at various dates through 2024, 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.

Factors That May Affect Future Results

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. 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. If any of the following risks or uncertainties actually occurs, our business, financial condition and operating results would likely suffer.

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 product introduction in August 2003. From our date of inception on February 10, 1995 through December 31, 2004, we have accumulated a total deficit of approximately $123.3 million. We expect that our losses will continue for the next several years as a result of continuing research and development expenses, as well as increased sales and marketing expenses. If our revenue does not grow significantly to offset these expenses, 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 our technologies are broadly ordered by medical practitioners, requested by patients, and ultimately reimbursed by third-party payors. We believe that the market demand for our first commercial product, PreGen-Plus, which is being sold through LabCorp, is dependent upon a number of factors, including the following:

- inclusion of stool-based DNA screening in colorectal cancer screening guidelines;
- formal acceptance of stool-based DNA screening for reimbursement by Medicare and other third-party payors;
- patients acceptance of PreGen Plus, including its novel sample collection process;
- stool-based DNA screening becoming a standard of care among prescribing physicians;
- the impact the publication of our multi-center study results and accompanying editorial in a peer-reviewed journal have on market acceptance of PreGen Plus and
- effective sales processes to educate physicians and their office staff to facilitate patient compliance.

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.

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

Pursuant to our exclusive license agreement with LabCorp, our current operating revenue is primarily dependent upon LabCorp's commercial sales of PreGen-Plus. Although we are actively working together with LabCorp on initiatives designed to promote our joint success with regard to PreGen-Plus, we cannot assure you that we or LabCorp will be successful in achieving sufficient sales of PreGen-Plus for us to become profitable. Such initiatives include the following:

- physician and consumer education and demand;
- implementation of marketing and sales initiatives and programs;
- broad-based reimbursement initiatives;
- advocacy development;
- sales force training and
- contracting with manufacturers and suppliers.

If we or LabCorp are unsuccessful in our efforts with respect to one or more of the foregoing initiatives, our revenues could be materially adversely affected. Moreover, given the number of products that LabCorp sells, we cannot assure you that LabCorp will devote the resources and attention necessary to make PreGen-Plus commercially successful. Any failure of the LabCorp sales force or our sales and marketing employees, in whole or in part, to give continued and sustained focus to PreGen-Plus would harm the demand creation for PreGen-Plus and, in turn, could materially adversely effect our revenues and delay any performance-based payments for which we might otherwise be

eligible under our strategic agreement with LabCorp. Any change in the senior management or organizational structure within LabCorp or EXACT Sciences, could negatively impact our ability to successfully commercialize PreGen-Plus.

Further, laboratory operating factors incurred at LabCorp such as turnaround times for the testing process, possible pre- and post-analytical sample deficiencies, and efforts to obtain third-party reimbursement all influence the rate of market adoption of PreGen-Plus. If LabCorp encounters difficulty performing PreGen-Plus 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 relationship with LabCorp.

We have a strategic alliance with LabCorp, under which we licensed to LabCorp certain of our technologies that are required for the commercialization of PreGen-Plus, a proprietary, non-invasive DNA-based screening test for the early detection of colorectal cancer in the average-risk population. The license to LabCorp is exclusive within the United States and Canada for a five-year term followed by a non-exclusive license for the life of the underlying patents. LabCorp has the ability to terminate this agreement for, among other things, a material breach by us. If LabCorp were to terminate the agreement, fail to meet its obligations under the agreement 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. Further, 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 to us.

In January 2004, we and LabCorp amended our license agreement, to among other things, restructure certain product development milestones and increase the level of our collaboration on sales and product enhancement initiatives. Although this amendment does not change the $45 million of total milestone payments that we may be eligible to receive under the agreement, the amendment makes it more difficult for us to fully realize these payments if LabCorp is unable to achieve significant revenue thresholds with respect to its sales of PreGen-Plus or if we are unable to obtain clinical guideline acceptance and policy-level reimbursement approvals for PreGen-Plus. Moreover, we cannot assure you that this amendment or other strategic initiatives with LabCorp will accomplish the long-term goals of either party. If one or more additional amendments to our agreement with LabCorp become necessary as a result of the continuing evolution of PreGen-Plus, developments in our relationship with LabCorp or otherwise, we cannot assure you that any such amendment could be entered into on more favorable terms, if at all.

We cannot effectively control whether LabCorp will devote sufficient resources to PreGen-Plus under our strategic agreement or whether it will elect to pursue the development or commercialization of competing products or services. 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 effect 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 commercialize the test ourselves. We cannot assure you that we would be able to license our technology to another commercial laboratory or otherwise successfully commercialize the technology, and our failure to do either of the foregoing would materially and adversely affect our ability to generate revenues.

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

The current configuration of PreGen-Plus that we have commercialized with LabCorp requires access to certain technologies and supplies of raw materials, including components for our Effipure technology, for which licensing and supply agreements are required. There can be no assurance that we, or LabCorp, can obtain these technologies and raw materials on acceptable terms, if at all. Any such licenses may require us to pay royalties or other fees to third parties, which would have an adverse effect on our revenues or gross margin. Furthermore, there can be no assurance that any current contractual arrangements between us and third parties, us and LabCorp, or between our strategic partners and other third parties, will be continued, or not breached or terminated early, or that we or our strategic partners will be able to enter into any future relationships necessary to the continued commercial sale of PreGen-Plus or necessary to our realization of material revenues. Any failure to obtain necessary technologies or raw materials would require PreGen-Plus to be re-configured which could negatively impact its commercial sale and increase the costs associated with PreGen-Plus, which could have a material adverse effect on our revenues and gross margin, respectively.

The time and attention of our management team may be diverted from domestic sales and operational issues if opportunities in foreign markets are pursued.

Our license with LabCorp is exclusive in North America and Canada and we have the ability to license our technologies for colorectal cancer screening in other markets beyond these territories. Our success materially depends upon our management team devoting adequate time and attention to sales and operational issues within the United States. In the event we enter into business relationships with entities abroad, there can be no assurance that our management team will be able to continue to devote the time and attention necessary to adequately manage and support domestic initiatives.

If our clinical studies do not prove the superiority of PreGen-Plus, 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, thought leaders and colorectal cancer screening guideline writers of the clinical value of PreGen-Plus, we may never successfully commercialize PreGen-Plus and, as a consequence, we may not be able to remain a viable business.

In 2003, we completed our multi-center study of our PreGen-Plus technology that included approximately 5,500 asymptomatic, average-risk patients aged 50 and older from over 80 academic and community-based medical practices. The goal of this study was to provide additional data supporting the superiority of tests utilizing our technology versus the most widely used brand of FOBT, Hemoccult II, in detecting colorectal cancer in this average-risk population. Although this study achieved its primary endpoint of showing that our original, bead-based DNA capture version of PreGen-Plus was more sensitive than Hemoccult II, the point sensitivity from our multi-center study was lower than that seen in our previous research and clinical studies. Accordingly, we and LabCorp may experience reluctance or refusal on the part of third-party payors to pay for tests using our technologies which could slow the demand for the PreGen-Plus test and adversely and materially impact revenues and profitability.

In October 2001, Mayo Clinic initiated a study of the bead-based version of our PreGen-Plus test that was intended to include approximately 4,000 patients at average risk for developing colorectal cancer. This three-year study, similar to our multi-center study, was designed to compare the results of our bead-based technologies with those of the Hemoccult II, a common first-line colorectal cancer screening option. After this study commenced, Hemoccult Sensa®, another brand of FOBT, was added to the study. Subsequently, we and the Mayo Clinic sought to include EXACT Sciences' Effipure technology in the study, rather than our older, bead based technology. In connection with this technology transition, Mayo Clinic reviewed preliminary data from the study which showed that, while

PreGen-Plus was nearly twice as sensitive as Hemoccult II and as sensitive as Hemoccult Sensa in detecting screen-relevant neoplasia (a category that includes high grade displasia, invasive cancer, and adenomas ≥1cm), Hemoccult II and Hemoccult Sensa appeared to have outperformed, at a preliminary stage, the older, bead-based version of our technology in the detection of cancer among the thirteen cancer samples collected in the study. While 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 than that demonstrated in our prior published studies, this preliminary data is susceptible to varying interpretations that could negatively impact the market acceptance of our technologies. Moreover, although we believe that the preliminary data from the Mayo Clinic study is clinically inconclusive given the small sample size of significant colorectal lesions and the DNA degradation that resulted from the sample collection methods used in the study, thought-leading gastroenterologists and primary care physicians may be reluctant to order tests using our technologies based on this preliminary data, which would materially harm our business and materially adversely affect our revenues. There is additional risk that thought-leading gastroenterologists, guidelines organizations, primary care physicians and others may, despite the small sample size referenced above, assign disproportionate significance to this preliminary data, if published by the NCI and/or Mayo Clinic, which may significantly adversely affect commercialization.

Although we may work with Mayo Clinic in the future on studies involving our newer technologies, we cannot assure you that we will reach an agreement with Mayo Clinic regarding acceptable study protocols or that the NCI will agree to fund such a study. If the NCI declines to fund a study with us, we may decide to devote considerable financial resources to such a study on our own, which could harm our results of operations. Moreover, if we cannot work with Mayo Clinic on a study of our technologies, under study protocols that are mutually acceptable to us and Mayo Clinic, such an outcome could materially harm the ability of PreGen-Plus to be included in colorectal cancer screening guidelines, to obtain adequate third-party reimbursement, or to achieve market acceptance.

If the results of our clinical studies, including the results of a Mayo Clinic study, do not show that tests using our technologies are superior to existing screening methods, including Hemoccult II and Hemoccult Sensa, or show that our tests 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, and successful commercialization of, PreGen-Plus.

If Medicare and other third-party payors, including managed care organizations, do not provide adequate reimbursement for PreGen-Plus, the commercial success of PreGen-Plus could 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, and covered by managed care organizations. There is significant uncertainty concerning third-party reimbursement for the use of any test 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; medically necessary; appropriate for the specific patient; and cost-effective. While we and LabCorp have had some success in obtaining reimbursement from third-party payors for tests performed to date, neither we nor LabCorp has secured any broad-based policy-level reimbursement approval from Medicare or a sufficient amount of third-party payors to ensure the long-term commercial success of PreGen-Plus.

If PreGen-Plus cannot be effectively sold at a price acceptable to the market, we may not be able to successfully commercialize PreGen-Plus.

The success of PreGen-Plus 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 using our technology is more expensive than FOBT because it is labor-intensive and uses highly complex processes and expensive reagents. In order to make our technologies less costly and

more commercially attractive to consumers, physicians and third party payors, we or 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 us to earn a profit, if at all. If we or LabCorp fail 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 we and LabCorp are unable to sell a sufficient number of tests at favorable pricing levels, we will not be successful and we may not be able to remain viable as a company.

If our Effipure technology and our or LabCorp's other 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 PreGen-Plus through research on technical innovations such as our Effipure technology. However, there can be no assurance that future generations of PreGen-Plus, or the commercial version of the PreGen-Plus test currently offered by LabCorp, which incorporates Effipure and other technology improvements, will have sufficient sensitivity or performance to be commercially successful. We have conducted studies of the PreGen-Plus test, which included our Effipure technology. These studies, which have consisted of cohorts from previously conducted clinical studies, including the multi-center study, have shown that the PreGen-Plus test, which includes Effipure, detected cancer in additional samples that the original bead-based version of our technology did not. However, the number of samples in each of these studies has been small and the ranges of sensitivity improvement with Effipure have been broad, thus making it difficult to definitively quantify the increase in sensitivity of the PreGen-Plus test including Effipure, as compared to the original bead-based test. If future generations of the PreGen-Plus test, or the commercial version of the PreGen-Plus test with Effipure, does not significantly increase the sensitivity or performance over that of the original bead-based technology in a cost effective manner, we may never achieve the expected demand for tests using our technologies or such demand could be significantly reduced, either of which would have a material adverse effect on our revenues.

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

If we, or LabCorp, fail to convince a sufficient number of medical practitioners to order tests using our technologies, we will not be able to create sufficient demand for tests using our technologies in sufficient volume for us to become profitable. An important element to the successful commercialization of PreGen-Plus is the inclusion of the test in colorectal cancer screening guidelines. We and LabCorp will need to make gastroenterologists and primary care physicians aware of the benefits of tests using our technologies 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 or to be included within colorectal cancer screening guidelines would make it difficult for us, or LabCorp, to convince medical practitioners to order colorectal cancer screening tests using our technologies for their patients which could materially adversely affect our revenues.

We may experience limits on our revenue and profitability 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 American Cancer Society that all Americans over the age of 50 be screened for colorectal cancer, most 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 profitability.

If we or our partners fail to comply with FDA requirements, we may be limited or restricted in our ability to market our products and services and may be subject to stringent penalties.

The FDA does not actively regulate laboratory tests that are developed and used by a laboratory to conduct in-house testing. The FDA does regulate specific reagents and certain components, some of which are used with our technologies and react with a biological substance including those designed to identify a specific DNA sequence or protein. For instance, a key component of our technologies includes our Effipure technology for the recovery of DNA from biological samples. The FDA's regulations provide that most such reagents, which the FDA refers to as analyte specific reagents, or ASRs, are exempt from the FDA's pre-market review requirements. We believe the ASRs that we provide currently fall within these exemptions. However, if the FDA were to decide to more actively regulate in-house developed laboratory tests, or significantly change the regulations for ASRs, commercial sales of PreGen-Plus and the sale of Effipure components to LabCorp could be delayed, halted or prevented. If the FDA were to view any of our or LabCorp's actions as non-compliant, it could initiate enforcement action, which could involve criminal or civil penalties. Moreover, while we believe that Effipure qualifies as an ASR, and is therefore exempt from the FDA's pre-market review requirements, there can be no assurance that the FDA or other regulatory bodies will agree with our assessment and the commercialization of our products and services could be impacted by being delayed, halted or prevented altogether. Finally, any ASRs that we provide will be subject to a number of FDA requirements, including compliance with restrictions regarding performance claims as well as the FDA's Quality System Regulation, which establishes extensive regulations for quality assurance and control as well as manufacturing procedures. Failure to comply with these regulations could result in enforcement action against us, our partners, or our contract manufacturers. Adverse FDA action in any of these areas could significantly increase our expenses and limit our revenue and profitability.

We may be subject to substantial costs and liability or be prevented from selling our screening tests for cancer 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 in foreign countries. We have filed patent applications that we believe cover methods we have designed to detect colorectal cancer and other cancers, including our testing process. 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 effect 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, 2004, we have 32 issued patents, 5 allowed patent applications and 23 pending patent applications in the United States and we also have 34 issued foreign patents and 43 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 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 and a third-party institution have filed a joint patent application that is co-owned by us and that third-party institution relating 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-pharyngeal, liver and gall bladder in stool under the Patent Cooperation Treaty. This patent application designates the United States, Japan, Europe and Canada. Co-ownership of a patent allows the co-owner to exercise all rights of ownership, including the right to use, transfer and license the rights protected by the applicable patent.

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

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

If we become subject to additional regulations from the U.S. Department of Transportation, or other domestic and international regulatory agencies, for the transport of diagnostic specimens, it could increase the cost of transporting stool specimens and limit revenue growth.

On August 14, 2002, the U.S. Department of Transportation, or DOT, issued revised Hazardous Materials Regulations for the packaging and transport of infectious materials, including diagnostic specimens. In anticipation of the application of these regulations to our current specimen container and transport system, we submitted an exemption request to the DOT to minimize the changes that would be necessary for our specimen collection system, while still providing an equivalent level of safety. On February 13, 2003, the DOT issued a formal determination that stool samples intended for clinical

research or diagnostic purposes would not be deemed an infectious substance subject to the Hazardous Materials Regulations. While this decision is favorable, we cannot be certain that the DOT, or other domestic and international regulatory agencies, will not more actively regulate or restrict the transportation of stool samples, such as those used in our diagnostic tests. Any regulation or restriction on the transportation of stool samples used in the PreGen-Plus test could require us to make time consuming and costly changes to the specimen collection system which could materially adversely impact our revenues and profitability.

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 80 million Americans age 50 and above, of which over 42 million fail to follow the American Cancer Society's screening guidelines. 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 new procedure being performed in which a radiologist views the inside of the colon through a scanner, as well as existing and possibly improved traditional screening tests such as immunochemical FOBT. In addition, some companies are developing serum-based tests, or screening tests based on the detection of proteins or nucleic acids produced by colon cancer in the blood including proteomics in which protein patterns are analyzed for links to disease. 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 rely 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 the current configuration of the PreGen-Plus test, including our Effipure technology. 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 agreements with such suppliers on a timely basis on acceptable terms, if at all. Furthermore, prior to August 2003, PreGen-Plus 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 PreGen-Plus, we may need to reconfigure the PreGen-Plus test which would result in delays in commercialization or an interruption in sales and would materially adversely impact our revenues.

The failure of LabCorp or any other laboratory using PreGen-Plus to comply with regulations governing clinical laboratories would materially adversely affect our business.

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

The loss of key members of our senior management team could adversely affect our business.

Our success depends largely on the skills, experience and performance of key members of our senior management team, including Don M. Hardison, our President and Chief Executive Officer and Anthony P. Shuber, our Executive Vice President and Chief Technology Officer. Anthony P. Shuber has been critical to the development of our technologies and business. Although Messrs. Hardison and Shuber have each signed a non-disclosure and assignment of intellectual property agreement and a non-compete agreement, they have no employment agreements currently in place. We also have a severance agreement with each of Messrs. Hardison and Shuber that provides for twelve months severance under certain circumstances. The efforts of each of these persons will be critical to us as we continue to develop our technologies and testing processes. If we were to lose one or more of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies.

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

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

Our inability to apply our proprietary technologies successfully to detect other common cancers may limit our revenue growth and profitability.

While, to date, we have focused substantially all of our research and development efforts on colorectal cancer, we have used our technologies to detect cancers of the lung, pancreas, esophagus, stomach and gall bladder. In the future, we intend to evaluate and potentially extend our technology platform to the development of screening tests for these or other common cancers. To do so, we may need to overcome technological challenges to develop reliable screening tests for these cancers. There can be no assurance that our technologies will be capable of reliably detecting cancers, beyond colorectal cancer, with the sensitivity and specificity necessary to be clinically and commercially useful for such other cancers, or that we can develop such technologies at all. We may never realize any commercial benefit from our research and development activities.

Changes in healthcare policy could subject us to additional regulatory requirements that may interrupt commercialization of the PreGen-Plus test and increase our costs.

Healthcare policy has been a subject of extensive discussion in the executive and legislative branches of the federal and many state governments. We and LabCorp developed our commercialization strategy for PreGen-Plus based on existing healthcare policies. Changes in healthcare policy could substantially interrupt the sales of PreGen-Plus, increase costs, and divert management's attention. We cannot predict what 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.

Our inability to raise additional capital on acceptable terms in the future may limit our growth.

If our capital resources become insufficient to meet future requirements, we will have to raise additional funds to continue the development and commercialization of our technologies. Our inability

to raise capital would seriously harm our business and development efforts. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operations. These funds may not be available on favorable terms, or at all. If adequate funds are not available on attractive terms, we may have to restrict our operations significantly or obtain funds by entering into agreements on unattractive terms. Further, to the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in dilution to our stockholders.

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 our test, or activities related to our research and clinical studies, could lead to the filing of product liability claims if someone were to allege that one of our products contained a design or manufacturing defect which resulted in the failure to detect the disease for which it was designed. A product liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm our business or financial condition. We cannot assure you that our product liability insurance would protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing insurance coverage in the future.

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

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

Our stock price may be volatile.

The market price of our common stock has fluctuated widely. Consequently, the current market price of our common stock may not be indicative of future market prices and we may be unable to sustain or increase the value of an investment in our common stock.

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

- technological innovations or new products and services by us or our competitors;
- clinical trial results relating to the PreGen-Plus tests or those of our competitors;
- inclusion of stool DNA screening in colorectal cancer screening guidelines;
- stool DNA screening becoming a standard of care among prescribing physicians;
- reimbursement decisions by Medicare and other third party payors;
- FDA regulation of our products and services;
- 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 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 National 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.

Item 7a. Quantitative and Qualitative Disclosures about Market Risk

The Company's exposure to market risk is principally confined to its 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, 2003 and 2004, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2004. 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, 2003 and 2004, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of EXACT Sciences Corporation's internal control over financial reporting as of December 31, 2004, 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 11, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 11, 2005

EXACT SCIENCES CORPORATION

Consolidated Balance Sheets

(Amounts in thousands, except per share data)

	December 31, 2003	December 31, 2004
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 14,200	$ 13,092
Marketable securities	13,607	37,188
Prepaid expenses and other current assets	1,283	1,835
Total current assets	29,090	52,115
Property and Equipment, at cost:		
Laboratory equipment	4,114	4,242
Office and computer equipment	1,360	1,383
Leasehold improvements	1,460	1,482
Furniture and fixtures	299	299
	7,233	7,406
Less—Accumulated depreciation and amortization	(4,314)	(5,452)
	2,919	1,954
Patent Costs and Other Assets, net of accumulated amortization of approximately $1,392 and $1,718 at December 31, 2003 and 2004, respectively	2,672	2,042
	$ 34,681	$ 56,111
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 657	$ 365
Accrued expenses	1,553	2,034
Deferred license fees, current portion	4,514	4,459
Total current liabilities	6,724	6,858
Deferred License Fees, less current portion	15,729	11,270
Commitments and contingencies (Note 11)		
Stockholders' Equity:		
Common stock, $0.01 par value		
Authorized—100,000,000 shares		
Issued and outstanding—19,306,936 and 26,285,067 shares at December 31, 2003 and 2004, respectively	193	263
Additional paid-in capital	118,225	161,356
Treasury stock, 60,959 and 85,550 shares at December 31, 2003 and 2004, respectively	(12)	(97)
Notes receivable	(641)	(5)
Deferred compensation	(729)	(89)
Other comprehensive loss	(1)	(115)
Accumulated deficit	(104,807)	(123,330)
Total stockholders' equity	12,228	37,983
	$ 34,681	$ 56,111

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,		
	2002	2003	2004
Revenue:			
Product royalty fees	$ —	$ 8	$ 166
License fees	886	2,871	4,514
Product	11	22	255
	897	2,901	4,935
Cost of revenue:			
Product royalty fees	—	1	11
Product	9	21	476
	9	22	487
Gross profit	888	2,879	4,448
Operating Expenses:			
Research and development	19,989	17,084	10,901
Selling, general and administrative	9,701	13,515	12,244
Stock-based compensation (1)	2,043	1,118	498
	31,733	31,717	23,643
Loss from operations	(30,845)	(28,838)	(19,195)
Interest income	962	498	672
Net loss	$(29,883)	$(28,340)	$(18,523)
Net loss per share—basic and diluted	$ (1.62)	$ (1.50)	$ (0.73)
Weighted average common shares outstanding—basic and diluted	18,433	18,911	25,334

(1) The following summarizes the departmental allocation of stock-based compensation:

Research and development	$ 478	$ 249	$ 221
Selling, general and administrative	1,565	869	277
Total	$ 2,043	$ 1,118	$ 498

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		Additional	Treasury Stock				Other		Total	Other
	Number of Shares	$0.01 Par Value	Paid In Capital	Number of Shares	Value	Notes Receivable	Deferred Compensation	Comprehensive Income (Loss)	Accumulated Deficit	Stockholders' Equity	Comprehensive Income
Balance, January 1, 2002	18,790,807	$188	$ 110,497	50,646	$ (8)	$(947)	$(4,179)	$ —	$ (46,584)	$ 58,967	$ —
Repurchase of common stock	—	—	—	10,313	(4)	—	—	—	—	(4)	—
Issuance of shares under stock purchase plan	17,840	—	137	—	—	—	—	—	—	137	—
Exercise of common stock options	262,120	3	231	—	—	—	—	—	—	234	—
Repayment of subscription receivable	—	—	—	—	—	248	—	—	—	248	—
Compensation expense related to issuance (forfeitures) of stock options	—	—	(159)	—	—	—	2,202	—	—	2,043	—
Non-cash cost related to issuance of warrant	—	—	6,550	—	—	—	—	—	—	6,550	—
Net loss	—	—		—	—	—	—	—	(29,883)	(29,883)	(29,883)
Other comprehensive income	—	—	—	—	—	—	—	57	—	57	57
Comprehensive loss											$(29,826)
Balance, December 31, 2002	19,070,767	$191	$ 117,256	60,959	$(12)	$(699)	$(1,977)	$ 57	$ (76,467)	$ 38,349	
Issuance of shares under stock purchase plan	28,621	—	216	—	—	—	—	—	—	216	—
Exercise of common stock options	207,548	2	883	—	—	—	—	—	—	885	—
Repayment of subscription receivable	—	—	—	—	—	58	—	—	—	58	—
Compensation expense related to issuance (forfeitures) of stock options	—	—	(130)	—	—	—	1,248	—	—	1,118	—
Net loss	—	—		—	—	—	—	—	(28,340)	(28,340)	(28,340)
Other comprehensive loss	—	—	—	—	—	—	—	(58)	—	(58)	(58)
Comprehensive loss											$(28,398)
Balance, December 31, 2003	19,306,936	$193	$ 118,225	60,959	$(12)	$(641)	$ (729)	$ (1)	$(104,807)	$ 12,228	
Sale of common stock, net of issuance costs of $3,270,014	6,900,000	69	43,236	—	—	—	—	—	—	43,305	—
Issuance of shares under stock purchase plan	45,524	—	250	—	—	—	—	—	—	250	—
Exercise of common stock options	32,607	1	15	—	—	—	—	—	—	16	—
Repayment of subscription receivable	—	—	—	—	—	370	—	—	—	370	—
Repurchase of restricted stock through forgiveness of notes receivable	—	—	—	24,591	(85)	266	—	—	—	181	—
Compensation expense related to issuance (forfeitures) of stock options	—	—	(370)	—	—	—	640	—	—	270	—
Net loss	—	—	—	—	—	—	—	—	(18,523)	(18,523)	(18,523)
Other comprehensive loss	—	—	—	—	—	—	—	(114)	—	(114)	(114)
Comprehensive loss											$(18,637)
Balance, December 31, 2004	26,285,067	$263	$ 161,356	85,550	$(97)	$ (5)	$ (89)	$(115)	$(123,330)	$ 37,983	

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,		
	2002	2003	2004
Cash flows from operating activities:			
Net loss	$(29,883)	$(28,340)	$(18,523)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1,663	1,897	1,252
Amortization	495	912	476
Stock based compensation expense	2,043	1,118	498
Amortization of deferred licensing fees	(886)	(2,871)	(4,514)
Changes in assets and liabilities:			
Prepaid expenses and other current assets	(389)	(172)	(552)
Accounts payable	(19)	(501)	(292)
Deferred license fees	15,000	15,000	—
Accrued expenses	59	(913)	481
Net cash used in operating activities	(11,917)	(13,870)	(21,174)
Cash flows from investing activities:			
Purchases of marketable securities	(26,350)	(11,009)	(74,162)
Maturities and sales of marketable securities	—	23,751	50,467
Purchases of property and equipment	(1,335)	(2,560)	(287)
(Increase) decrease in patent costs and other assets	(417)	(710)	107
Net cash (used in) provided by investing activities	(28,102)	9,472	(23,875)
Cash flows from financing activities:			
Net proceeds from sale of common stock	—	—	43,305
Proceeds from exercise of common stock options and stock purchase plan	371	1,101	266
Repayment of notes receivable	248	58	370
Repurchase of treasury shares	(4)	—	—
Net cash provided by financing activities	615	1,159	43,941
Net decrease in cash and cash equivalents	(39,404)	(3,239)	(1,108)
Cash and cash equivalents, beginning of year	56,843	17,439	14,200
Cash and cash equivalents, end of year	$ 17,439	$ 14,200	$ 13,092
Supplemental disclosure of non-cash investing and financing activities:			
Repurchase of restricted stock through forgiveness of notes receivable	$ —	$ —	$ 85
Forgiveness of notes receivable and accumulated interest	$ —	$ —	$ 228
Issuance of warrants	$ 6,550	$ —	$ —

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

(1) ORGANIZATION

EXACT Sciences Corporation (the "Company") was incorporated on February 10, 1995. The Company is an applied genomics company that develops and commercializes proprietary DNA-based tests for the early detection of cancer. The Company has selected colorectal cancer as the first application of its technology platform. The Company has devoted a majority of its efforts on research and development activities related to its PreGen™ technologies, including several large multi-center clinical studies. More recently, the Company has also been focused on the marketing of PreGen-Plus™, the Company's proprietary, non-invasive DNA-based technology for the early detection of colorectal cancer in the average-risk population being offered commercially through a license agreement with Laboratory Corporation of America® Holdings ("LabCorp®").

(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. At December 31, 2004, approximately $1,015 of the Company's cash has been pledged as collateral for an outstanding letter of credit in connection with the lease for our corporate headquarters. Cash equivalents primarily consist of money market funds.

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

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

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

the specific identification method. Interest and dividends on securities classified as available-for-sale are included in investment income.

All of the Company's investments are comprised of fixed income investments and all are deemed available-for-sale. The objectives of this portfolio are to provide liquidity and safety of principal while striving to achieve the highest rate of return, consistent with these two objectives. The Company's investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer. There were no realized gains or losses on the sales of available-for sale securities during the years ended December 31, 2002, 2003 or 2004.

Investments consist of the following at December 31:

	Amortized Cost			Gross Unrealized		
	Due Under One Year	Due After One Year	Amortized Cost	Gains	Losses	Aggregate Fair Value
2003						
Corporate debt securities	$13,608	$ —	$13,608	$—	$ (1)	$13,607
Total	$13,608	$ —	$13,608	$—	$ (1)	$13,607
2004						
U.S. government obligations	$ 755	$ —	$ 755	$—	$ (5)	$ 750
Corporate debt securities	33,705	2,843	36,548	4	(114)	36,438
Total	$34,460	$2,843	$37,303	$ 4	$(119)	$37,188

Depreciation and Amortization

Depreciation and amortization of fixed assets is computed using the straight-line method based on the estimated useful lives of the related assets, 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. In November 2001, however, the Company purchased intellectual property of MT Technologies (formerly known as Mosaic Technologies, Inc.) relating to its Hybrigel technology which consisted of four issued patents and 40 pending patent applications. The purchase price for the assets included $1,250 in cash and warrants to purchase 40,000 shares of fully vested common stock, exercisable over a three-year

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

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

period, at an exercise price of $7.33 per share which the Company valued at $188 in accordance with Emerging Issues Task Force 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling Goods or Services*, using the Black-Scholes option pricing model. During the second quarter of 2002, these warrants were exercised utilizing the net settlement (cashless) election per the warrant agreements, which resulted in the Company issuing 19,881 shares of common stock. Capitalized patent costs are expensed upon disapproval or upon a decision by the Company to no longer pursue the patent. Other assets principally consist of license fees and deposits.

The amortization expense for capitalized patents as of December 31, 2004 over the next five years is as follows:

Year	Amount
2005	$446
2006	383
2007	65
2008	25
2009	2
Total	$921

The Company has approximately $1.1 million of additional intangible assets as of December 31, 2004 that have not yet commenced amortization due to uncertainty as to the timing of issuance, and are therefore, not included in the table above.

The Company applies SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets and for Long-Lived Assets,* 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.

Net Loss Per Share

Basic and diluted net loss per share is presented in conformity with SFAS No. 128, *Earnings per Share,* 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.

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

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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:

	2002	2003	2004
Shares issuable upon exercise of stock options	2,892,291	3,591,603	4,857,484
Shares issuable upon vesting of restricted common stock	342,391	132,482	25,921
Shares issuable upon exercise of outstanding warrants	1,000,000	1,000,000	1,000,000
	4,234,682	4,724,085	5,883,405

Accounting for Stock-Based Compensation

The Company accounts for its stock-based compensation plan under Accounting Principal Bulletin Opinion ("APB") No. 25, *Accounting for Stock Issued to Employees* ("APB Opinion No. 25"). SFAS No. 123, *Accounting for Stock-Based Compensation* ("SFAS No. 123"), establishes the fair-value-based method of accounting for stock-based compensation plans. The Company has adopted the disclosure-only alternative for options granted to employees and directors under SFAS No. 123, which requires disclosure of the pro forma effects on earnings as if SFAS No. 123 had been adopted, as well as certain other information. Options granted to scientific advisory board members and other non-employees are recorded at fair value based on the fair value measurement criteria of SFAS No. 123. Compensation expense of $68, $87 and $141 with respect to options granted to non-employees computed using the Black-Scholes option pricing model was recorded in the accompanying consolidated statements of operations for the years ended December 31, 2002, 2003 and 2004, respectively

In connection with certain 1999 and 2000 stock option grants to employees and directors, the Company recorded deferred compensation of $52 and $11,359 during the years ended December 31, 1999 and 2000, respectively. The deferred compensation represents the aggregate difference between the option exercise price and the estimated fair value of the common stock on the date of grant and is being charged to operations over the related vesting period using the accelerated method prescribed under FASB Interpretation 28, *Accounting for Stock Appreciation Rights and other Variable Stock Option or Award Plans—An Interpretation of APB Opinion Nos. 15 and 25.*

The Company has computed the pro forma disclosures required under SFAS No. 123 for all stock options granted to employees and directors of the Company as of December 31, 2002, 2003 and 2004, using the Black-Scholes option pricing model prescribed by SFAS No. 123.

The assumptions used for the years ended December 31, 2002, 2003, and 2004 are as follows:

	December 31,		
	2002	2003	2004
Risk-free interest rates	1.71%-3.71%	1.23%-1.91%	1.69%-3.04%
Expected lives	7 years	7 years	7 years
Expected volatility	100%	100%	100%
Dividend yield	0%	0%	0%
Weighted average fair value of grants	$7.41	$6.43	$4.27

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

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

The effect of applying SFAS No. 123 would be as follows:

	December 31,		
	2002	2003	2004
Net loss as reported	$(29,883)	$(28,340)	$(18,523)
Add: Stock-based compensation included in reported net loss	2,043	1,118	498
Deduct: Total stock-based employee compensation determined under SFAS 123 for all awards	(5,524)	(6,540)	(6,008)
Pro forma net loss—SFAS 123	$(33,364)	$(33,762)	$(24,033)
Basic and diluted net loss per share:			
As reported	$ (1.62)	$ (1.50)	$ (0.73)
Pro forma—SFAS 123	$ (1.81)	$ (1.79)	$ (0.95)

Revenue Recognition

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.

Royalties fees earned on PreGen-Plus tests performed by LabCorp are based upon the customer's remittance to LabCorp, not the amount billed. Service revenue is recognized when services are performed (earned), amounts can be objectively determined (measurable), and collection is reasonably assured (collectible or realizable). Until such time that estimates utilized are supported by measurable, historical remittance data, the Company will recognize royalties as LabCorp customers make payments. The timing of payments is uncertain because of the number of parties involved in the reimbursement process.

Product revenue from the sale of certain components of its Effipure™ technology to LabCorp is recognized upon shipment of the components provided that title passes, the price is fixed or determinable and collection of the receivable is probable.

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 take place. The Company expensed $201, $1,338 and $214 of media advertising during the years ended December 31, 2002, 2003 and 2004, 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.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Segment Information

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

Fair Value of Financial Instruments

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

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.

Recent Accounting Pronouncements

In January 2003 and December 2003, the FASB issued Financial Interpretation No. ("FIN") 46, *Consolidation of Variable Interest Entities*, and its revision, FIN 46-R, respectively. FIN 46 and FIN 46-R address the consolidation of entities whose equityholders have either not provided sufficient equity at risk to allow the entity to finance its own activities or do not possess certain characteristics of a controlling financial interest. FIN 46 and FIN 46-R require the consolidation of these entities, known as variable interest entities (a "VIE"), by the primary beneficiary of the entity. The primary beneficiary is the entity, if any, that is subject to a majority of the risk of loss from the VIE's activities, entitled to receive a majority of the VIE's residual returns, or both. FIN 46 and FIN 46-R are applicable for financial statements of public entities that have interests in VIEs or potential VIEs referred to as special purpose entities for periods ending after December 15, 2003, of which the Company had none. Application by public entities for all other types of entities is required in financial statements for periods ending after March 15, 2004. The Company has applied the provisions of FIN 46 and FIN 46-R, and the adoption of these statements was not material to the Company's consolidated financial position and results of operations.

In December 2004, the FASB issued Statement of Financial Standards No. 123 (revised 2004), *Share-Based Payment* ("SFAS No. 123(R)"), which is a revision of SFAS No. 123. SFAS No. 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach to accounting for share-based

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

payments in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. Pro forma disclosure of the fair value of share based payments is no longer an alternative to financial statement recognition. SFAS No. 123(R) is effective for public companies (excluding small business issuers) at the beginning of the first interim or annual period beginning after June 15, 2005.

The Company expects the adoption of SFAS No. 123(R) to have a material effect on its financial statements, in the form of additional compensation expense, on a quarterly and annual basis. It is not possible to precisely determine the expense impact of adoption since a portion of the ultimate expense that is recorded will likely relate to awards that have not yet been granted, but are likely to be granted prior to the July 1, 2005 adoption date. The expense associated with these future awards can only be determined based on factors such as the price of the Company's common stock, volatility of the Company's stock price and risk free interest rates as measured at the grant date. However, the pro forma disclosures related to SFAS No. 123 included in the Company's historic financial statements are relevant data points for gauging the potential level of expense that might be recorded in future periods.

(3) STRATEGIC ALLIANCE AGREEMENT

On June 26, 2002, the Company entered into a license agreement, subsequently amended on January 19, 2004, with LabCorp for an exclusive, long-term strategic alliance between the parties to commercialize PreGen-Plus, the proprietary, non-invasive DNA-based technology for the early detection of colorectal cancer in the average-risk population. Pursuant to this 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 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 the per-test royalty fee, under our amended license agreement, we may also be eligible for milestone payments from LabCorp totaling up to $15 million based upon the acceptance and inclusion of PreGen-Plus in certain clinical guidelines and certain policy-level reimbursement approvals from third-party payors, as well as performance-based payments totaling up to $30 million based upon the achievement of certain significant LabCorp revenue thresholds. The amended license agreement also clarified the obligations of each party with respect to certain third-party technology which has been incorporated into the commercial version of the PreGen-Plus test.

In conjunction with the strategic alliance, the Company issued to LabCorp a 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.

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

(4) INCOME TAXES

The Company accounts for income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes.* 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, 2004, the Company had net operating loss and research tax credit carryforwards of approximately $86,674 and $2,563, respectively, for financial reporting purposes, which may be used to offset future taxable income. The carryforwards expire through 2024 and are subject to review and possible adjustment by the Internal Revenue Service. The Internal Revenue Code contains provisions that may limit the net operating loss and research tax credit carryforwards in the event of certain changes in the ownership interests of significant stockholders.

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:

	December 31,	
	2003	2004
Deferred tax assets:		
Operating loss carryforwards	$26,508	$34,332
Tax credit carryforwards	2,132	2,563
Deferred revenue	10,455	6,170
Other temporary differences	2,723	3,651
Tax assets before valuation allowance	41,818	46,716
Less—Valuation allowance	(41,818)	(46,716)
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.

(5) 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. Such shares vest over the remaining option vesting period or, generally, three to five years. At December 31, 2004, 25,921 common shares were still restricted.

The Company obtained full recourse notes receivable from various employees and executives for the purchase of the restricted stock. The notes originally had interest rates ranging from 8.5% to 9.5% with principal and interest payments due over a five to ten year period. In December 2001, the Company elected to reduce the prospective interest rate on all notes receivable to executives and employees to 5% to reflect the current interest rate environment and individual borrowing rates. All other provisions of the notes remained in effect.

During the year ended December 31, 2004, the majority of outstanding notes receivable were either repaid, or forgiven in connection with employee terminations. See Note 6 for additional information on employee terminations. At December 31, 2004, approximately $5 in notes receivable were outstanding.

(6) EMPLOYEE TERMINATIONS

During 2004, the Company reduced its workforce by 13 employees, including five vice president level positions. Employees terminated were eligible to receive three to six months of salary and benefits, depending on their position and length of service with the Company. In connection with the employee terminations, the Company recorded severance charges of $1,023 ($334 as research and development expense and $689 as general and administrative expense) in the consolidated statements of operations for the year ended December 31, 2004.

In February 2004, following the resignation of Mr. John A. McCarthy, Jr. as Executive Vice President, Chief Financial Officer and Treasurer, the Company entered into a transition agreement with Mr. McCarthy whereby, among other things, he agreed to provide to the Company certain consulting services and a general release. Under the terms of the transition agreement, the Company agreed to continue to pay Mr. McCarthy his base salary of $260 and related benefits until the earlier of March 1, 2005 or the termination of Mr. McCarthy's consulting relationship. The Company also agreed to suspend all future interest on a promissory note executed in the Company's favor by Mr. McCarthy in November 2000, the proceeds of which were used by Mr. McCarthy to exercise options to purchase 41,250 shares of restricted common stock. Subject to the completion of Mr. McCarthy's performance obligations under the transition agreement, the Company has agreed to pay Mr. McCarthy, on March 1, 2005, an additional $140 and forgive any then outstanding amounts under such promissory note of $228 including accumulated interest. The total cost of the transition agreement ($641) was accrued for and reflected in the accompanying consolidated statement of operations for the year ended December 31, 2004.

(7) RELATED PARTY TRANSACTIONS

In October 2001, the Company signed a Clinical Trial Agreement with the Mayo Foundation and Mayo Clinic pursuant to which the Company's colorectal cancer technology will be the subject of an independent study by the Mayo Clinic. The Company agreed to process all the stool samples at its laboratory and to pay total fees of $654 over approximately three years. The Company paid approximately $109, $218, $218 and $109 to the Mayo Clinic for the years ended December 31, 2001, 2002, 2003 and 2004, respectively, related to this study and recorded these as research and development expense as incurred. As of December 31, 2004, the obligation to the Mayo Foundation and the Mayo Clinic was satisfied in full.

In March 2001, the Company entered into a consulting agreement with a member of its Board of Directors. The Company paid approximately $55, $55 and $50 for services provided under the agreement for the years ended December 31, 2002, 2003 and 2004, respectively.

(8) EMPLOYEE BENEFIT PLAN

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

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

(9) EMPLOYEE STOCK PURCHASE PLAN

The 2000 Employee Stock Purchase Plan (the "2000 Purchase Plan") provides for the issuance of up to an aggregate of 728,764 shares of common stock to participating employees. The 2000 Purchase Plan provides that the number of shares authorized for issuance will automatically increase on each February 1, by 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 such lesser number as may be approved by the Board of Directors.

The compensation committee of the Board of Directors administers the 2000 Purchase Plan. Generally, all employees who have completed three months of employment and 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. The right to purchase common stock under the 2000 Purchase Plan will be made available through a series of offerings. Participating employees will be required to authorize an amount, between 1% and 10% 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 will be 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 plan and no employee can purchase more than $25 of the Company common stock under the plan in any calendar year. Rights granted under the 2000 Purchase Plan terminate upon an employee's voluntary withdrawal from the 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
July 31, 2001	4,737	$6.85
January 31, 2002	7,388	$6.86
July 31, 2002	10,422	$8.32
January 31, 2003	13,375	$7.65
July 31, 2003	15,246	$7.48
January 31, 2004	22,208	$6.92
July 31, 2004	23,316	$4.15

(10) STOCK OPTION PLANS

1995 Stock Option Plan

Under the 1995 stock option plan (the "1995 Option Plan"), the Board of Directors could grant incentive and non-qualified stock options to purchase an aggregate of 3,987,500 shares of common stock to employees and consultants of the Company. Non-qualified stock options may be granted to any employee or consultant 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 will remain outstanding and may be exercised in accordance with their terms, unless sooner

(10) STOCK OPTION PLANS (Continued)

terminated by vote of the Board of Directors. At December 31, 2004, 1,101,082 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, 2004, a total of 3,956,190 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 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 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, stock awards or opportunities to make direct purchases of common stock to employees, officers, directors, consultants and advisors. Options granted under the 2000 Option Plan expire ten years from the date of grant.

The 2000 Option Plan is administered by the compensation committee of the 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, 2004, options to purchase 3,756,402 were outstanding under the 2000 Option Plan and 126,382 shares were available for future grant under the 2000 Option Plan.

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

(10) STOCK OPTION PLANS (Continued)

Information with respect to activity under the 1995 and 2000 Option Plans is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding, January 1, 2002	2,228,077	$5.58
Granted	1,013,150	9.09
Exercised	(239,204)	1.00
Canceled	(109,732)	8.74
Outstanding, December 31, 2002	2,892,291	$7.07
Granted	1,003,500	7.82
Exercised	(216,212)	4.12
Canceled	(87,976)	6.35
Outstanding, December 31, 2003	3,591,603	$7.48
Granted	1,740,500	5.30
Exercised	(32,607)	0.37
Canceled	(442,012)	8.03
Outstanding, December 31, 2004	4,857,484	$6.69
Exercisable, December 31, 2002	1,071,983	$5.65
Exercisable, December 31, 2003	1,698,315	$7.40
Exercisable, December 31, 2004	2,445,149	$7.37

The following table summarizes information relating to currently outstanding and exercisable stock options as of December 31, 2004:

	Outstanding			Exercisable	
Exercise Price	Number of Shares	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
$0.00–$0.38	296,268	4.64	$ 0.36	289,944	$ 0.36
$2.05–$2.05	394,391	5.42	2.05	343,756	2.05
$2.76–$5.00	1,063,500	9.89	3.76	—	—
$5.50–$6.95	636,771	8.11	6.78	315,188	6.78
$7.27–$9.90	1,612,054	7.68	7.95	770,719	8.02
$10.03–$12.89	543,000	6.68	11.50	466,563	11.60
$13.00–$14.33	311,500	7.55	13.56	258,979	13.51
	4,857,484	7.73	$ 6.69	2,445,149	$ 7.37

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, stock options plans,

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

(10) STOCK OPTION PLANS (Continued)

including all outstanding stock option grants noted above, and outstanding warrants at December 31, 2004:

2000 Stock Purchase Plan	632,072
1995 Option Plan	1,101,082
2000 Option Plan	3,882,784
Outstanding warrants	1,000,000
	6,615,938

(11) COMMITMENTS

Operating Leases

The Company conducts its operations in leased facilities under noncancelable operating leases expiring through July 2010. Effective January 20, 2005, the Company amended the lease for its corporate headquarters in Marlborough, MA to reduce the total space leased at that facility from approximately 56,000 square feet to approximately 37,000 square feet. In connection with this lease amendment, the Company expects to write off approximately $300 in the quarter ended March 31, 2005, relating to leasehold improvements to the space being vacated. In addition, the Company expects to save approximately $1.8 million in lease costs over the remaining term of the lease as a result of this amendment. Future minimum payments under operating leases as of December 31, 2004, including those with respect to the lease amendment, are as follows:

Year Ending December 31,	
2005	$1,088
2006	968
2007	960
2008	988
2009	1,016
Thereafter	602
Total lease obligations	$5,622

Rent expense included in the accompanying consolidated statements of operations was approximately $348, $871 and $1,441 for the years ended December 31, 2002, 2003, and 2004, respectively.

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 and also has entered into several clinical research agreements which require the Company to fund certain research projects. 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, 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

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

(11) COMMITMENTS (Continued)

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 $225, over the life of the licensed patents, or 2023. The Company has recorded research and development expense associated with license agreements of $50, $250 and $270 for the years ended December 31, 2002, 2003 and 2004, respectively.

Supply Agreements

The Company has entered into several agreements with various suppliers and manufacturers for certain components utilized in the Effipure technology which the Company sells to LabCorp. In connection with these agreements, the Company has minimum purchase obligations of approximately $339 at December 31, 2004, which are to be satisfied by April, 2006. The Company relies on a single source of supply for a critical component used in PreGen Plus. One of the contracts with the manufacturer of that component expires in April 2006, and includes a bilateral right to earlier termination. The Company's reliance on contract manufacturers exposes it to a number of risks, including reduced control over manufacturing capacity and component availability, product completion and delivery times, product quality, manufacturing costs and inadequate or excess inventory levels which could lead to product shortage or charges for excess or obsolete inventory.

(12) ACCRUED EXPENSES

Accrued expenses at December 31, 2003 and 2004 consisted of the following:

	December 31,	
	2003	2004
Compensation	$ 535	$ 730
Research and trial related expenses	200	425
Professional fees	244	384
Occupancy costs	250	152
Consulting	48	41
Other	276	302
	$1,553	$2,034

(13) SUBSEQUENT EVENT

Employee terminations

On February 9, 2005, the Company reduced its workforce by ten employees, principally in the research and development functions. Employees terminated were eligible to receive three to four months of salary and benefits, depending on their position and length of service with the Company. In connection with the employee terminations, the Company expects to record severance charges ranging from $200 to $250 in the quarter ended March 31, 2005. With the completion of its 5,500-patient multi-center study in 2003, the Company determined that a reduction in force was warranted to reduce costs.

(14) QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)

The following table sets forth unaudited quarterly statement of operations data for each of the eight quarters ended December 31, 2004. 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.

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

	Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
	(Amounts in thousands, except per share data)			
2004				
Revenue	$ 1,177	$ 1,222	$ 1,261	$ 1,275
Cost of revenue	32	60	223	172
Research and development	3,134	2,640	2,518	2,609
Selling, general and administrative	3,294	2,853	2,946	3,151
Stock-based compensation	126	120	154	98
Loss from operations	(5,409)	(4,451)	(4,580)	(4,755)
Interest income	118	172	177	205
Net loss	$ (5,291)	$ (4,279)	$ (4,403)	$ (4,550)
Net loss per share—basic and diluted	$ (0.23)	$ (0.16)	$ (0.17)	$ (0.17)
Weighted average common shares outstanding—basic and diluted	22,949	26,081	26,138	26,167
2003				
Revenue	$ 408	$ 406	$ 918	$ 1,169
Cost of revenue	3	—	13	6
Research and development	5,013	4,592	4,312	3,167
Selling, general and administrative	3,114	3,494	3,229	3,678
Stock-based compensation	328	330	329	131
Loss from operations	(8,050)	(8,010)	(6,965)	(5,813)
Interest income	167	126	103	102
Net loss	$ (7,883)	$ (7,884)	$ (6,862)	$ (5,711)
Net loss per share—basic and diluted	$ (0.42)	$ (0.42)	$ (0.36)	$ (0.30)
Weighted average common shares outstanding—basic and diluted	18,808	18,801	19,024	19,093

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

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, Chief Financial Officer and Principal Accounting Officer, the Chief Executive Officer, Chief Financial Officer and Principal Accounting 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, 2004. 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, 2004, 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, 2004, has been audited by Ernst & Young, LLP, the independent registered public accounting firm who also audited the Company's consolidated financial statements. Ernst & Young's attestation report on management's assessment of the Company's internal control over financial reporting appears on page 58 hereof.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of EXACT Sciences Corporation

We have audited management's assessment, included in the accompanying *Management's Report on Internal Control over Financial Reporting*, that EXACT Sciences Corporation maintained effective internal control over financial reporting as of December 31, 2004, 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. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of 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, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, 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, management's assessment that EXACT Sciences Corporation maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, EXACT Sciences Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2004 consolidated financial statements of EXACT Sciences Corporation and our report dated March 11, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 11, 2005

Item 9B. Other Information

We intend to hold our next annual meeting of stockholders on July 22, 2005, at the offices of Goodwin Procter, Exchange Place, 53 State Street, Boston, Massachusetts 02109 (the "Annual Meeting"). The record date for determining the stockholders who are entitled to notice of and to vote at the Annual Meeting is currently expected to be the close of business on Tuesday, May 24, 2005. The Annual Meeting will be held more than thirty days after the anniversary of last year's annual meeting date. The advance notice provision of our by-laws requires that any stockholder proposal submitted for consideration at the Annual Meeting must have been received by us no earlier than December 1, 2004, and no later than December 31, 2004, in order to be timely. Consequently, stockholder proposals must have been received by us no later than the close of business on December 31, 2004, in order to be included in the proxy statement and form of proxy for the Annual Meeting.

PART III

Item 10. Directors and Executive Officers of the Registrant

The information under the Sections "Election of Directors," "Occupations of Directors, The Nominee for Director and Officers" and "Section 16(a) Beneficial Ownership Reporting Compliance" from the registrant's definitive proxy statement for the annual meeting of stockholders to be held on July 22, 2005, which is to be filed with the Securities and Exchange Commission not later than 120 days after the close of the registrant's fiscal year ended December 31, 2004, is hereby incorporated by reference.

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 under the Section "Compensation and Other Information Concerning Directors and Officers" from the registrant's definitive proxy statement for the annual meeting of stockholders to be held on July 22, 2005, which is to be filed with the Securities and Exchange Commission not later than 120 days after the close of the registrant's fiscal year ended December 31, 2004, is hereby incorporated by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The information required by this Item 12 is hereby incorporated by reference to the Sections "Securities Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" from the registrant's definitive proxy statement for the annual meeting of stockholders to be held on July 22, 2005, which is to be filed with the Securities and Exchange Commission not later than 120 days after the close of the registrant's fiscal year ended December 31, 2004.

Item 13. Certain Relationships and Related Transactions

The information under the Sections "Compensation and Other Information Concerning Directors and Officers" and "Compensation Committee Interlocks, Insider Participation and Other Related

Transactions" from the registrant's definitive proxy statement for the annual meeting of stockholders to be held on July 22, 2005, which is to be filed with the Securities and Exchange Commission not later than 120 days after the close of the registrant's fiscal year ended December 31, 2004, is hereby incorporated by reference.

Item 14. Principal Accountant Fees and Services

The information under the Section "Independent Public Accountants" from the registrant's definitive proxy statement for the annual meeting of stockholders to be held on July 22, 2005, which is to be filed with the Securities and Exchange Commission not later than 120 days after the close of the registrant's fiscal year ended December 31, 2004, is hereby incorporated by reference.

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)
4.5	Warrant between the Registrant and Laboratory Corporation of America Holdings, Inc. dated June 26, 2002 (previously filed as Exhibit 4.1 to our Quarterly Report on Form 10-Q for the period ended June 30, 2002, 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 10.12 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference) (certain portions of this agreement have been accorded confidential treatment until March 25, 2003)
10.7	PCR Diagnostic Services Agreement between the Registrant and Roche Molecular Systems, Inc. (previously filed as Exhibit 10.13 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference) (certain portions of this agreement have been accorded confidential treatment until July 2004)
10.8	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)

Exhibit Number	Description
10.9	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)
10.10	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)
10.11*	Severance Agreement between the Registrant and Don M. Hardison dated January 4, 2001 (previously filed as Exhibit 10.21 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.12*	Severance Agreement between the Registrant and Anthony P. Shuber dated January 4, 2001 (previously filed as Exhibit 10.23 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
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10.15**	Exclusive License Agreement between Matrix Technologies Corporation, d/b/a Apogent Discoveries, and the Registrant dated as of November 26, 2002 (previously filed as Exhibit 10.32 to our Annual Report on Form 10-K for the period ended December 31, 2002, which is incorporated herein by reference)
10.16**	Services, Manufacturing and Supply Agreement dated as of April 7, 2003, by and between the Company and Discovery Labware, Inc. (previously filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the period ended June 30, 2003, which is incorporated herein by reference)
10.17**	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)
10.18**	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)
10.19*	Executive Change of Control Agreement between the Registrant and Jeffrey R. Luber dated September 28, 2004 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on October 1, 2003, which is incorporated herein by reference)
10.20*	Executive Change of Control Agreement between the Registrant and Harry W. Wilcox, III dated September 28, 2004 (previously filed as Exhibit 10.2 to our Report on Form 8-K filed on October 1, 2003, which is incorporated herein by reference)
10.21*	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)
10.22*	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)
10.23*	Executive Agreement between the Registrant and Charles R. Carelli, Jr. dated November 12, 2004 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on November 12, 2004, which is incorporated herein by reference)
10.24*	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)

Exhibit Number	Description
12.1+	Ratio of Earnings to Fixed Charges and Earnings to Combined Fixed Charges and Preferred Stock Dividends
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 Ernst & Young LLP
24.1	Power of Attorney (included on signature page)
31.1+	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934
31.2+	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934
31.3+	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 14, 2005

By: /s/ DON M. HARDISON

Don M. Hardison
President, Chief Executive Officer and Director

POWER OF ATTORNEY AND SIGNATURES

We, the undersigned officers and directors of EXACT Sciences Corporation, hereby severally constitute and appoint Don M. Hardison and Harry W. Wilcox, III, 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.

SIGNATURE	TITLE	DATE
/s/ STANLEY N. LAPIDUS Stanley N. Lapidus	Chairman of the Board and Director	March 14, 2005
/s/ DON M. HARDISON Don M. Hardison	President, Chief Executive Officer and Director (Principal Executive Officer)	March 14, 2005
/s/ HARRY W. WILCOX, III Harry W. Wilcox, III	Senior Vice President, Chief Financial Officer and Treasurer (Principal Financial Officer)	March 14, 2005
/s/ CHARLES R. CARELLI, JR. Charles R. Carelli, Jr.	Controller and Principal Accounting Officer	March 14, 2005
/s/ RICHARD W. BARKER Richard W. Barker	Director	March 14, 2005
/s/ SALLY W. CRAWFORD Sally W. Crawford	Director	March 14, 2005
/s/ EDWIN M. KANIA, JR. Edwin M. Kania, Jr.	Director	March 14, 2005
/s/ CONNIE MACK, III Connie Mack, III	Director	March 14, 2005
/s/ LANCE WILLSEY Lance Willsey	Director	March 14, 2005
/s/ PATRICK J. ZENNER Patrick J. Zenner	Director	March 14, 2005

Exhibit Index to Annual Report on Form 10-K

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10.18**	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)
10.19*	Executive Change of Control Agreement between the Registrant and Jeffrey R. Luber dated September 28, 2004 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on October 1, 2003, which is incorporated herein by reference)
10.20*	Executive Change of Control Agreement between the Registrant and Harry W. Wilcox, III dated September 28, 2004 (previously filed as Exhibit 10.2 to our Report on Form 8-K filed on October 1, 2003, which is incorporated herein by reference)
10.21*	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)
10.22*	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)
10.23*	Executive Agreement between the Registrant and Charles R. Carelli, Jr. dated November 12, 2004 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on November 12, 2004, which is incorporated herein by reference)
10.24*	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)
12.1+	Ratio of Earnings to Fixed Charges and Earnings to Combined Fixed Charges and Preferred Stock Dividends
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 Ernst & Young LLP
24.1	Power of Attorney (included on signature page)
31.1+	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934
31.2+	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934

Exhibit Number	Description
31.3+	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.

MANAGEMENT

Don M. Hardison
President and CEO

Anthony P. Shuber
Executive Vice President and Chief Technology Officer

Harry W. Wilcox, III
Senior Vice President, Chief Financial Officer and Treasurer

Barry M. Berger, M.D.
Vice President of Laboratory Medicine

Jeffrey R. Luber
General Counsel and Secretary

David W. Nikka
Vice President of Resources and Development

Robert B. Rochelle
Vice President of Marketing and Sales

Charles R. Carelli, Jr.
Controller

BOARD OF DIRECTORS

Stanley N. Lapidus
Chairman, EXACT Sciences
CEO, Helicos BioSciences Corp.

Don M. Hardison
President, Chief Executive Officer and Director

Richard W. Barker, Ph.D.
Director General of the Association of the British Pharmaceutical Industry

Sally W. Crawford
Independent healthcare consultant
Director, Chittenden Corp. and Cytyc Corporation.

Edwin M. Kania, Jr.
Senior Managing Director and Chairman, Flagship Ventures
Director, Aspect Medical Systems

Connie Mack, III
Senior policy advisor, King & Spaulding LLP.
Director, Darden Restaurants Inc., Genzyme Corporation, Moody's Corporation and Mutual of America Life Insurance Company.

Lance Willsey, M.D.
Director, Exelixis, Inc.

Patrick J. Zenner
Director, ArQule, Inc., Curagen Corporation, Dendrite International, Inc., First Horizon Pharmaceuticals Corporation, Geron Corporation, Praecis Pharmaceuticals, Inc., West Pharmaceutical Services, Inc. and Xoma Ltd.
Trustee, Creighton University and Fairleigh Dickinson University.

SCIENTIFIC ADVISORY BOARD

Dennis Ahnen, M.D.
Professor of Medicine at the University of Colorado Health Sciences Center. Staff Physician and Head, Section of Gastroenterology and Hepatology, Department of Veteran Affairs Medical Center, Denver, CO.

C. Richard Boland, M.D.
Chief of Gastroenterology, Baylor University Medical Center, Dallas, TX.
Clinical Professor of Internal Medicine, University of Texas Southwestern Medical Center at Dallas.

Randall E. Brand, M.D.
Associate Professor of Medicine, Northwestern University Feinberg School of Medicine, Evanston Northwestern Healthcare.

Robert H. Fletcher, M.D., M.Sc.
Professor Emeritus, Department of Ambulatory Care and Prevention, Harvard Medical School and Harvard Pilgrim Health Care. Adjunct Professor, Departments of Epidemiology and Social Medicine, The University of North Carolina at Chapel Hill.

David A. Lieberman, M.D.
Professor of Medicine, and Chief, Division of Gastroenterology, Oregon Health and Science University.

Jonathan P. Terdiman, M.D.
Associate Professor of Clinical Medicine, University of California, San Francisco.

Sidney J. Winawer, M.D.
Paul Sherlock Chair, Attending Physician and Member with Tenure, Memorial Sloan-Kettering Cancer Center. Professor of Medicine, Weill Medical College of Cornell University.

Certain statements contained herein that are not based on historical information are express or implied forward-looking statements which are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements relate to EXACT Sciences' expectations concerning, among other things, its business outlook and business momentum, the likelihood of third-party reimbursement of its technologies and the future inclusion of its products in reimbursement guidelines, EXACT Sciences' marketing and sales strategies and programs and their likely future success, and the development, effectiveness and market acceptance of its technologies. These statements are neither promises nor guarantees, but are subject to a variety of risks and uncertainties such as those set forth in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Annual Report, which could cause actual results to differ materially from those contemplated in these forward-looking statements. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof.

Designed by Curran & Connors, Inc. / www.curran-connors.com

EXACT sciences

CORPORATE INFORMATION

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100 Campus Drive
Marlborough, Massachusetts 01752
Telephone 508.683.1200
Fax 508.683.1201

Corporate Counsel
Goodwin Procter LLP
Boston, Massachusetts

Independent Auditors
Ernst & Young LLP
Boston, Massachusetts

Registrar and Transfer Agent
American Stock Transfer &
Trust Company
59 Maiden Lane
New York, New York 10038
Telephone 800.937.5449
Fax 718.236.2641

Stockholder Inquiries
Inquiries related to stock transfers or lost certificates should be directed to American Stock Transfer & Trust Company (see above). General information regarding the Company can be obtained by contacting EXACT Sciences' Chief Financial Officer at 508.683.1200, ext. 275. Recent news releases and other information can also be obtained by accessing the Company's web site at www.exactsciences.com

Annual Report on Form 10-K
A copy of the EXACT Sciences Annual Report on Form 10-K for the year ended December 31, 2004, filed with the Securities and Exchange Commission, is available without charge on request to:

Investor Relations Department
EXACT Sciences Corporation
100 Campus Drive
Marlborough, Massachusetts 01752
Telephone 508.683.1200, ext. 404.
Web site www.exactsciences.com

Stock Information
The Company's common stock trades on NASDAQ under the symbol EXAS. As of May 24, 2005, there were 96 holders of record of the Company's common stock. No cash dividends have been paid on the common stock to date, and the Company does not anticipate paying any cash dividends in the foreseeable future.

Annual Meeting
The annual meeting will be held on July 22, 2005, at 10:00 AM at the offices of Goodwin Procter LLP, Exchange Place, 53 State Street, Boston, Massachusetts 02109.