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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, 2003

☐ **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 $166,862,000 (based on the closing price of the Registrant's Common Stock on June 30, 2003 of $10.95 per share).

The number of shares outstanding of the Registrant's $.01 par value Common Stock as of January 28, 2003 was 19,249,252.

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, 2003. 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, 2003

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PART I

Item 1. Business

This Business section and other parts of this Form 10-K contain forward-looking statements that 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

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. Each year, more than 50 million Americans over the age of 50 who should be screened annually for colorectal cancer fail to follow the American Cancer Society's screening guidelines. 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 risks of damaging the colon. Until the commercial launch of PreGen-Plus, the only non-invasive option for colorectal cancer detection had been fecal occult blood testing, or FOBT. FOBT, however, suffers from relatively low sensitivity, particularly in detecting the early stage, most curable cancers, and requires dietary modifications, unpleasant stool sampling and stool manipulation by the patient. With the U.S. launch in August 2003 of PreGen-Plus, our first commercially-available DNA-based cancer screening test for the average risk population, these patients now have a more accurate, non-invasive screening option for colorectal cancer. PreGen-Plus has been clinically shown to be four times more sensitive in detecting colorectal cancer than the most commonly used FOBT screening test on the market today.

Colorectal Cancer

Background

Colorectal cancer is the most deadly cancer in the U.S. among non-smokers and the second most deadly cancer overall. The only cancer that kills more people each year is lung cancer. According to the American Cancer Society, each year, nearly 150,000 people are diagnosed with the illness and almost 60,000 people die from it.

Medical practitioners commonly classify colorectal cancer into four stages at the time of diagnosis as shown in the following table:

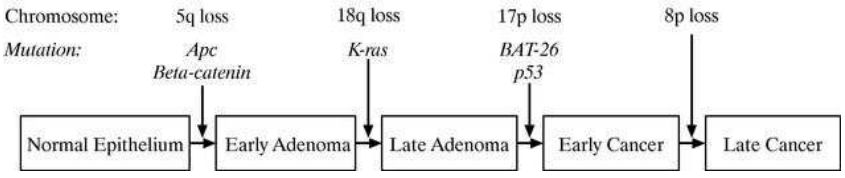
Stage	Classification	Extent of Disease	% of Patients Diagnosed at this Stage	5-Year Survival Rates *(Approximate)*	Typical Treatment
Early	Dukes' A	Confined to the surface lining of the colon	37%	95%	Surgery
	Dukes' B	Below the surface; no lymph node involvement		80%	
Late	Dukes' C	Lymph node involvement	63%	50%	Surgery and chemotherapy
	Dukes' D	Metastatic disease		5%	

Detection of pre-cancerous adenomas and cancer in its earliest stages increases the likelihood of survival and reduces the cost of treatment and care. As a result, the American Cancer Society recommends that the 80 million Americans age 50 and above undergo regular colorectal cancer screening.

Colorectal Cancer and Genomics

Genomics, broadly defined, is the study of the genome and, we believe, serves as the scientific discipline best suited for the early detection of colorectal cancer. Initial efforts in human genomics centered on identifying, mapping, sequencing and analyzing the definitive sequence of every gene in the human genome. Scientists are now focusing on applying that knowledge to the development of novel technologies used for the detection and management of disease, as well as the development of improved therapeutics.

Cancer begins to develop when the DNA in a single normal cell mutates or changes in such a way that ultimately results in unregulated cell growth. In a ground-breaking paper published in the *New England Journal of Medicine* in 1988, Dr. Bert Vogelstein, one of our scientific collaborators, and his colleagues described a multi-step model of colorectal cancer development. In 1990, Dr. Eric Fearon, a former member of our scientific advisory board, and Dr. Vogelstein published a diagram depicting the development of colorectal cancer. An updated version of this diagram showing many of the genomic events involved in the development of colorectal cancer is shown below:



The diagram illustrates that cancer develops in steps that results from alterations in multiple genes in an individual cell, and occurs frequently with chromosome loss. The diagram shows that these alterations lead to pathologic changes in the colon from normal epithelium—the tissue that lines the surface of the colon—through early and late adenomas, which are a form of pre-cancerous growth, to early cancer and late cancer. These alterations, shown in the above diagram, usually accumulate over many years, and are typically due to:

- mutations in individual genes, such as the *Apc* , *K-ras* and *p53* genes;
- larger scale effects in which large parts of a chromosome or even entire chromosome and chromosome arms, such as 5q, 18q, 17p and 8p, are deleted; or
- inactivation of the mismatch repair genes (the genes responsible for correcting misincorporated bases of DNA after DNA replication) that manifest themselves as deletions in polynucleotide DNA regions such as BAT-26.

The multi-step process provides an abundance of genomic targets that may be used for the early detection of cancer when the disease can be treated at its most curable stage.

Our Solution

It is widely accepted in the medical community that colorectal cancer screening is strongly recommended and that colorectal cancer is highly curable if detected early. However, according to the American Cancer Society, each year, nearly 150,000 people are diagnosed with the illness and almost 60,000 people die from it. 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 meet the collective needs of patients, doctors and payors.

Since our founding in 1995 we have worked to apply the scientific discoveries about the human genome to address the significant unmet clinical need for an accurate, non-invasive colorectal cancer screening test that could reduce mortality through early detection and increased patient compliance. With the knowledge that survival rates approach 90% for patients whose colorectal cancers are detected in their earliest stages, but with too few patients getting adequately screened, we targeted the development of a safe, simple, non-invasive test that could save more lives. Our goal was to design a test that would be both easy to use and demonstrably more effective than other options such as FOBT in detecting early-stage cancers in an average-risk, asymptomatic population.

These development efforts led to the creation of PreGen-Plus. Our test 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 identifies specific mutations and other abnormalities in that DNA associated with colorectal cancer and pre-cancerous lesions.

We believe that no traditional screening method on the market today (or *non-traditional* screening methods, such as virtual colonoscopy and immunochemical FOBT) allows for the early and accurate detection of colorectal cancer in a manner that is acceptable to patients, medical practitioners and payors. We believe that 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), it is a powerful screening tool for the detection of colorectal cancer at its earliest stages. We have conducted several clinical studies supporting the performance of PreGen-Plus, including a recent 5,500 patient multi-center study that showed the ability of the test to detect colorectal cancer in 57% of the cases that were in the earliest stages, more than four times the detection rate of the leading FOBT on the market today, to which it was compared. Given its ease of use when compared to more traditional colorectal cancer screening methods, we believe that, based on data collected from a subset of over 3,500 patients from our multi-center study, more people will use PreGen-Plus as their screening option and, as a result, patient compliance with screening will improve. Further, we believe that PreGen-Plus, over time, can help to substantially reduce colorectal cancer mortality, just as cervical cancer deaths have been substantially reduced through regular Pap smear testing.

In August 2003, we commercialized PreGen-Plus in the United States through our exclusive licensee and strategic partner, Laboratory Corporation of America® Holdings (LabCorp®). We chose LabCorp as our strategic commercial partner for two important reasons. The first was our shared strategic vision about the influence the molecular diagnostics industry is expected to have on the healthcare system, as well as LabCorp's stated strategic focus on novel genomics-based products that could drive critical organic growth for its business. The second reason was a function of LabCorp's national breadth and distribution capability. 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. Additionally, LabCorp employs an 800-person primary care-focused sales force that has been trained extensively to sell PreGen-Plus. We expect that this will allow us to broaden our distribution reach in North America and maximize our commercial opportunity. In an effort to increase physician orders and third-party payor reimbursement, we and LabCorp are working with the physician, payor and patient communities to demonstrate the practical advantages of PreGen-Plus, including its cost-effectiveness. Given that PreGen-Plus is a safe, simple, and non-invasive test that has demonstrated a superior ability to detect early stage colorectal cancer when compared with the current non-invasive standard, we believe that physicians will increasingly order the test for their average-risk patients over the age of 50.

PreGen-Plus is DNA-based and, therefore, its performance is not limited by the biology of cancer. Accordingly, we are able to continuously improve the performance characteristics of the test. Our applied research and development efforts are currently focused on increasing the ability of the PreGen-Plus test to detect colorectal cancers as well as pre-cancerous lesions. For example, in the recently launched commercial version of the test, we incorporated a new sample preparation technology called Effipure™. Effipure increases the yield of DNA that can be isolated from a stool sample, resulting in improved sensitivity compared to the performance of earlier versions of the test. As PreGen-Plus is not currently subject to the lengthy approval process of the U.S. Food and Drug Administration, or FDA, improvements to the test generally can be introduced to the market through LabCorp as they are developed. This advantage provides us the flexibility to commercialize the most advanced version of the test nearly as quickly as we can develop and validate it.

PreGen-Plus has several advantages that we believe will lead to increased patient compliance and decreased mortality. These advantages include:

High sensitivity. We believe that PreGen-Plus can lead to increased detection of colorectal cancer, including early stage cancers and pre-cancerous lesions. Based on our multi- center study data, PreGen-Plus demonstrated a sensitivity four times greater than the leading FOBT, currently the most common non-invasive screening method for colorectal cancer, and more than four times as effective as the leading FOBT in detecting cancer at its early stages, when survival rates approach 90%.

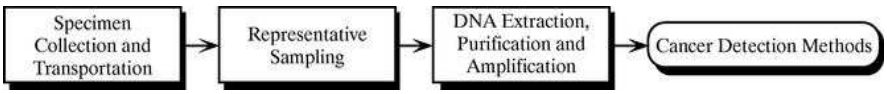
Non-invasive, painless and convenient testing. Unlike current invasive screening and diagnostic methods, PreGen-Plus requires no pre-examination preparation, invasive procedures or anesthesia, and a sample can be collected in the privacy of one's home.

Simplicity. PreGen-Plus requires no special bowel preparation, dietary restrictions, changes in medications, or manipulation of stool by the patient.

DNA-based test allows for continual and efficient improvements. Unlike FOBT, PreGen-Plus is a DNA-based test and therefore its performance is not limited by the biology of cancer. Accordingly, this allows our scientific team to continue to improve the performance characteristics of PreGen-Plus through future technical innovations.

Our Testing Process

Diagnostic tests typically require sample collection and preparation procedures as well as detection methods. We have developed a three-step sample collection and preparation process and five detection methods 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 the laboratory or patient service center performing the colorectal cancer-screening test or sent directly from the patient's home using one of the many national couriers.

Representative Sampling. Before we developed our technologies, no one had been able to reproducibly extract human DNA and consistently find mutations in DNA in stool. We believe that this was due, in part, to the non-uniform distribution of abnormal DNA in stool. We have invented proprietary homogenization methods designed to ensure that the portion of 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. Based upon our data to date, we believe these methods lead to increased sensitivity and reproducible results.

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 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.

Commercial Strategy

On June 26, 2002, we entered into a license agreement and long-term strategic alliance with LabCorp to commercialize PreGen-Plus. Since then we have been actively working with LabCorp to improve the performance characteristics of PreGen-Plus and its market acceptance through the incorporation of technical changes such as Effipure. In addition, the August 2003 commercial launch of PreGen-Plus enabled us and LabCorp to refocus our efforts on new sales and marketing initiatives to help stimulate demand for the test. We and LabCorp amended this license agreement on January 19, 2004 to, among other things, restructure certain product development milestones and increase the level of our collaboration on sales initiatives and test enhancements.

Pursuant to the license agreement, as amended, we agreed to license to LabCorp all U.S. and Canadian patents and patent applications owned or exclusively licensed by us relating to PreGen-Plus. The license with LabCorp is exclusive in the U.S. and Canada for a five-year period after the commercial launch of PreGen-Plus followed by a non-exclusive license for the life of the patents. In return for the license, LabCorp has agreed to pay us certain up-front and milestone payments, and a per-test royalty fee based on the reimbursed amount of each test ordered by a physician and processed in LabCorp's facilities. These per-test royalty fees are subject to a minimum dollar amount per test. LabCorp made an initial payment of $15 million to us upon the signing of the agreement in June 2002, and a second payment of $15 million in August 2003 upon the commercial launch of PreGen-Plus. In addition, pursuant to the amended agreement, we may be eligible for additional milestone payments from LabCorp totaling up to $45 million, of which a total of up to $15 million relates to certain clinical guideline acceptance and policy-level reimbursement approvals and a total of up to $30 million relates to the achievement of significant LabCorp revenue thresholds. As part of the agreement, in June 2002 we issued to LabCorp a warrant to purchase 1,000,000 shares of our common stock, exercisable for cash over a three-year period, at an exercise price of $16.09 per share.

In connection with the commercialization of PreGen-Plus, we have been developing and implementing a marketing and reimbursement strategy. We have built a strategic sales team of 11 highly skilled and experienced individuals to help strategically guide and support the 800-person LabCorp sales force on PreGen-Plus initiatives. 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 anticipated publication of our multi-center study results in a peer-reviewed journal 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. Between commercial launch and December 31, 2003, LabCorp received over 500 patient samples for testing from physicians across the country, billed insurers and received payment from numerous third-party payors. Furthermore, payors representing approximately 10 million covered lives have approved reimbursement of PreGen-Plus for their appropriate patients, including two large employer groups who have agreed to pay for PreGen-Plus for their employees.

Clinical Studies

Our DNA-based technologies, including PreGen-Plus, have 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 FOBT in a multi-center clinical 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 option. The primary endpoint of the clinical study demonstrated strong statistical significance, with a p-value of less than 0.001. Results from the study, which were presented in October 2003 at the American College of Gastroenterology's Annual Conference, 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%.

Scientifically and clinically, study results provide validation for the technology and its use in clinical practice. Commercially, published clinical study results provide the information necessary for thought leaders to evaluate PreGen-Plus for inclusion into colorectal cancer screening guidelines. Guideline inclusion is important both to physicians and to payors, who 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, stated that future studies of new technologies did not themselves have to encompass a mortality endpoint, but instead should be compared to currently available technologies that had already proven such a benefit. We therefore designed our multi-center study with this in mind, believing that demonstration of superiority 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.

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. The multi-center study referenced above, as well as all of our published clinical studies to date, reflect the performance of our original, bead-based version of PreGen-Plus. The commercial test currently available includes several technological improvements, including Effipure, which we believe enhances the overall performance of the test.

Published Study	Completed	Number of Cancer Patients	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%	*

* 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.

In October 2001, Mayo Clinic initiated a clinical study of PreGen-Plus, which is ultimately intended to include approximately 4,000 patients and is designed to compare the results of PreGen-Plus with those of FOBT. Our role in this study is limited to sample processing. Based on our information to date, we expect Mayo Clinic to complete enrollment in this clinical study in 2005.

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* .

We expect that virtually all validations of PreGen-Plus technology improvements, including sensitivity improvements, will be based on internal research studies that take advantage of past empirical data and research results. With the results of our existing body of clinical data to date, we do not believe that additional, large, multi-year clinical studies will be necessary to achieve validations of our technology improvements in the future.

Research and Development

Our research and development efforts focus on developing multiple, DNA-based methodologies for the early detection of cancer and pre-cancerous lesions. Specifically, we are working on developing methods to automate and simplify the collection, preparation and analysis of samples to produce cost-effective commercial tests. Our research and development expense, including stock-based compensation, for fiscal 2001, 2002, and 2003 was $14.2 million, $20.5 million and $17.3 million, respectively. Our research and development efforts for the near-term will focus almost exclusively on PreGen-Plus in the following areas:

Technical 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 that was used in all of our published studies to date. 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 configuration, and develop new 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. We believe our proprietary DNA Integrity Assay, or DIA®, may potentially be applicable to the detection of other cancers in addition to colorectal cancer. DIA is a non-gene-specific 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, and we are now working with our collaborators on a pre-clinical model. In addition, several independent papers were recently published that support our observations around DIA. We intend to investigate the potential of DIA in other applications, including:

- early detection of other common cancers among average-risk individuals;
- individual monitoring of transitions from benign proliferative disorders, such as polyps, cysts and warts, to malignant tumors;
- intra-individual therapeutic monitoring; and
- post-therapy screening for disease recurrence.

Sales and Marketing

The current 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. We have built a strategic sales team of 11 highly skilled and experienced individuals to help strategically guide and support the 800-person 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 the screening process.

Third-Party Payors. We believe that all promotional targets, PCPs, gastroenterologists and consumers, will 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, we have engaged in the following broad sales and marketing activities:

Direct Sales To Physicians. Sales initiatives to date have included direct detailing of medical professionals at numerous conventions and in their individual offices, resulting in widespread awareness of the product.

Sales Force Training. We have completed a robust, training program designed to educate of LabCorp's sales representatives on PreGen-Plus.

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, and radio and television broadcasts.

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, should help drive test volumes.

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 most 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 the Centers for Medicare and Medicaid Services ("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").

Reimbursement

We are currently working to obtain national coverage and reimbursement approval for 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. We believe that both the anticipated publication of our multi-center study results in a peer-reviewed journal 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. Between commercial launch and December 31, 2003, LabCorp received over 500 patient samples for testing from physicians across the country, billed insurers and received payment from numerous third-party payors. Payors representing approximately 10 million covered lives have approved reimbursement of PreGen-Plus for their appropriate patients, including two large employer groups who have agreed to pay for PreGen-Plus for their employees.

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 intend to assist these organizations in evaluating our technologies by providing scientific and clinical data in support of our assertions regarding the superiority and appropriateness of our technologies. In addition, data analysis has been presented showing the benefits of early disease detection and the resulting cost-effectiveness of our technologies. 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.

The Federal Balanced Budget Act of 1997 required Medicare to reimburse for colorectal cancer screening for average-risk patients beginning on January 1, 1998 and mandated Medicare coverage for FOBT preformed by the guaiac method and flexible sigmiodoscopy. Congress amended the Budget Act of 1997 to include coverage for double contrast barium enema, a radiographic imaging test used to detect colorectal cancer in areas beyond the reach of flexible sigmiodoscopy. This was further expanded to include a screening colonoscopy every 10 years as an available option effective July 2001. We believe these actions provide evidence of the public interest in colorectal cancer screening methods and the federal government's willingness to fund these methods.

Most importantly, the Federal Balanced Budget Act of 1997 allows new technologies to be included as colorectal cancer screening tests by action of the Secretary of Health and Human Services without the need for additional Congressional action. In the spring of 1999, we met with senior staff members of CMS to apprise them of our progress and to determine the steps we would need to take prior to a reimbursement determination. Following that meeting, we successfully petitioned the CMS staff to cover all medical expenses of a patient participating in our clinical studies who tests positive for colorectal cancer, which we believe was a favorable departure from prior CMS policy of not reimbursing for these costs.

In October of 2002, we met with CMS to discuss the reimbursement process. Subsequent to that meeting, CMS published its approach to expanding the colorectal cancer screening benefit to include new technologies by use of a national coverage decision process, thereby avoiding the time-consuming notice and comment procedures otherwise applicable.

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. In October 1999, we testified before the Subcommittee on Health of the House Ways and Means Committee in support of the Eliminate Colorectal Cancer Act of 1999. The Eliminate Colorectal Cancer Act of 1999 requires private insurers to cover colorectal cancer screening tests deemed appropriate by physicians and patients to the same extent as the Federal Balanced Budget Act of 1997 covers for Medicare.

We believe that colorectal cancer screening tests based on our technologies will add a potentially lifesaving and cost-effective alternative to currently available colorectal cancer screening methods. We believe that reimbursement for FOBT tests ranges from $5 to $30, but, as stated earlier, FOBT sensitivity is relatively low, and is most effective in detecting later stage cancers when survival rates are low and treatment costs are high. We believe that reimbursement for flexible sigmiodoscopy ranges from $80 to $500, but at best, can directly detect no more than half of all colorectal cancers and adenomas since it only reaches the first third of the colon, where approximately 50% of lesions develop. Medicare and some private insurers currently reimburse for colonoscopy for cancer screening once every 10 years in average risk individuals. We believe that the cost of this procedure ranges from $700 to $2,000, and while colonoscopy is sensitive, the use of colonoscopy as a screening test to date has been limited due to low patient compliance and capacity constraints which result in generally long scheduling lead times for the procedure.

Government Regulation

General

Certain of our activities are, or have the potential to be, subject to regulatory oversight by the Food and Drug Administration, or 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. 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 we or LabCorp fail 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.

Diagnostic Kits

Any diagnostic test kits that we, or our partners, may sell would require FDA clearance or approval before they could be placed into commercial distribution. There are two regulatory review procedures by which a product may receive such approval or clearance. Some products may qualify for clearance under a pre-market notification, or 510(k) process. Under such a process, the manufacturer provides to the FDA a pre-market notification that it intends to begin marketing the product, and demonstrates to the FDA's satisfaction, through appropriate studies, that the product is substantially equivalent to a comparative product that has been legally marketed and is currently in commercial distribution. Clearance of a 510(k) means that the product has the equivalent intended use, is as safe and effective as, and does not raise significant questions of safety and effectiveness than a legally marketed device. A 510(k) submission for an *in vitro* diagnostic device generally must include labeling information, performance data, and in some cases, it must include data from human clinical studies. Marketing may commence under a 510(k) submission when the FDA issues a clearance letter determining the product to be substantially equivalent to a comparative device.

If a medical device does not qualify for the 510(k) submission process by not being substantially equivalent or raising new issues of safety and effectiveness, the FDA may require submission of a pre-market approval application, or PMA, before marketing can begin. PMA applications must demonstrate, among other matters, that the medical device is safe and effective. A PMA application is a more comprehensive submission than a 510(k) submission, resulting in longer review and approval

timeframes and usually includes the results of extensive pre-clinical and clinical studies and detailed information on the product, design and manufacturing system. Before the FDA will approve an original PMA, the manufacturer must undergo and pass a pre-approval inspection that assesses its compliance with the requirements of the FDA's Quality System Regulations.

We believe that if our products are sold in FDA approved diagnostic test kit form; they would likely require PMA approval. As compared to the 510(k) process, the PMA process is traditionally more lengthy and costly, and we cannot be sure that the FDA will approve PMAs for our products in a timely fashion, or at all. Additionally, FDA requests for additional studies during the review period are not uncommon, and can significantly delay approvals. Even if we were able to gain approval of a product for one indication, significant changes to the product, its indication for use, its labeling or manufacturing and quality assurance would likely require additional approvals in the form of a PMA Supplement.

Specimen Container

Once a physician orders a test, the patient will need to receive a specimen container to collect the patient's stool. Although specimen transport and storage containers are also medical devices regulated by the FDA, such 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, 2003, we had 30 patents issued and 29 pending patent applications in the United States and, in foreign jurisdictions, 33 patents issued and 98 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 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 a non-exclusive basis certain polymerase chain reaction ("PCR") technology from Roche Molecular Systems, Inc. This license relates to a gene amplification process used in almost all genetic testing, and the patent that we utilize expires in mid-2004. Roche may terminate this license upon notice if we fail to pay royalties, fail to submit reports or breach a material term of the license agreement. In exchange for the license, we have agreed to pay Roche a royalty based on net revenues we receive from commercial tests that we perform at our facility. Our strategic relationship with LabCorp, however, contemplates commercial tests being performed in LabCorp's facilities, rather than in our facility, and therefore, LabCorp is now maintaining a license and paying royalties to Roche for the use of PCR in connection with performing the PreGen-Plus test at LabCorp.

We license on a non-exclusive basis technology from Genzyme Corporation, a licensee of patents owned by Johns Hopkins University and of which Dr. Vogelstein is an inventor. This license relates to the use of the *Apc* and *p53* genes (the "Genes") and methodologies related thereto in connection with our products and services and lasts through 2013, the life of the patent term of the last-licensed Genzyme patent. In exchange for the license, we have agreed to pay Genzyme a royalty based on net revenues we receive from commercial tests we perform at our facility and the sale of analyte specific diagnostic test kits, as well as certain milestone payments and maintenance fees. In addition, we must use reasonable efforts to make products and services based on these patents available to the public. Genzyme may terminate this license upon notice if we fail to pay milestone payments and royalties, achieve a stated level of sales or submit reports. In addition, if we fail to request FDA clearance for a diagnostic test as required by the agreement, Genzyme may terminate the license. As noted previously, our strategic relationship with LabCorp contemplates commercial tests being performed in LabCorp's facilities, rather than our facility, and therefore, LabCorp is now maintaining a license and paying royalties to Genzyme for the use of the Genes in connection with performing the PreGen-Plus test at LabCorp. However, pursuant to our agreement with LabCorp, we may be obligated to bear a portion of certain payments by LabCorp to Genzyme if LabCorp does not achieve certain PreGen-Plus sales thresholds.

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.

We and LabCorp are 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 is 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 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.

The market for colorectal cancer screening is large, approximating 80 million Americans age 50 and above, of which over 50 million fail to follow the American Cancer Society's screening guidelines. As a result, the colorectal 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 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 serum-based testing is not able to detect disease at the earliest stages of cancer at levels of sensitivity and specificity comparable to that of stool-based testing.

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;
- cost-effectiveness; and
- patent protection.

Employees

As of December 31, 2003, we had eighty-two employees, seven of whom have Ph.D.s and two of whom have M.D.s. Forty-nine employees are engaged in research and development, sixteen employees in sales and marketing and seventeen employees in general and administration. None of our employees is 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

We lease approximately 56,000 square feet of space in our headquarters located in Marlborough, Massachusetts under a seven-year term. We also lease approximately 4,500 square feet in Maynard, Massachusetts 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. We are not currently a party to any material legal proceedings.

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 2003.

PART II

Item 5. Market for Registrant's Common Equity and Related Stockholder Matters

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
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
2002		
First quarter	$ 12.16	$ 7.27
Second quarter	17.40	9.32
Third quarter	15.90	9.75
Fourth quarter	15.99	9.65

On January 28, 2004, the last sale price reported on The Nasdaq National Market for our common stock was $7.56 per share. As of December 31, 2003, there were approximately 19,245,977 shares of our common stock outstanding held by approximately 100 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.

Item 6. Selected Financial Data

The selected historical financial data set forth below as of December 31, 2002 and 2003 and for the years ended December 31, 2001, 2002 and 2003, are derived from our financial statements, which have been audited by Ernst & Young LLP, independent auditors, as of December 31, 2002 and 2003 and for the years then ended, and by Arthur Andersen LLP, our former independent public accountants, for the year ended December 31, 2001, and which are included elsewhere in this Form 10-K. The selected historical financial data as of December 31, 1999, 2000 and 2001 and for the years ended December 31, 1999 and 2000 are derived from our audited financial statements, which have been audited by Arthur Andersen LLP, our former independent public accountants and which are 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,				
	1999	2000	2001	2002	2003
	(Dollars in thousands, except share and per share data)				
Statement of Operations Data:					
Revenue:					
License fees	$ —	$ —	$ 51	$ 886	$ 2,871
Product royalty fees	—	—	—	—	8
Product	—	—	—	11	22
	—	—	51	897	2,901
Cost of revenues	—	—	—	9	22
Gross profit	—	—	51	888	2,879
Operating expenses:					

Research and development	3,689	5,332	13,335	19,989	17,084
Selling, general and administrative	1,560	4,814	9,078	9,701	13,515
Stock-based compensation (1)	14	3,184	3,788	2,043	1,118
	5,263	13,330	26,201	31,733	31,717
Loss from operations	(5,263)	(13,330)	(26,150)	(30,845)	(28,838)
Interest income	299	1,447	2,665	962	498
Net loss	$ (4,964)	$ (11,883)	$ (23,485)	$ (29,883)	$ (28,340)
Net loss per common share:					
Basic and diluted	$ (5.32)	$ (8.13)	$ (1.42)	$ (1.62)	$ (1.50)
Weighted average common shares outstanding:					
Basic and diluted	933	1,462	16,487	18,433	18,911
Balance Sheet Data:					
Cash and cash equivalents	$ 3,553	$ 26,470	$ 56,843	$ 17,439	$ 14,200
Marketable securities	—	—	—	26,407	13,606
Total assets	4,754	29,059	63,100	50,086	34,681
Total liabilities	344	1,359	4,133	11,737	22,453
Stockholders' equity	4,410	27,700	58,967	38,349	12,228

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

	1999	2000	2001	2002	2003
Research and development	$ 9	$ 810	$ 898	$ 478	$ 249
Selling, general and administrative	5	2,374	2,890	1,565	869
Total	$ 14	$ 3,184	$ 3,788	$ 2,043	$ 1,118

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

This report and other documents we have filed with the SEC contain 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 below and elsewhere in this report and in the other documents filed with the SEC 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;
- hiring management and other support personnel;
- hiring sales personnel
- raising capital;
- licensing our proprietary technologies to LabCorp; and
- working with LabCorp on activities necessary for commercial launch and marketing of PreGen-Plus.

On June 26, 2002, we entered into a license agreement and long-term strategic alliance with LabCorp to commercialize PreGen-Plus. Pursuant to the license agreement, we agreed to license to LabCorp all U.S. and Canadian patents and patent applications owned or exclusively licensed by us relating to PreGen-Plus. The license with LabCorp is exclusive in the U.S. and Canada for a five-year period followed by a non-exclusive license for the life of the patents. In return for the license, LabCorp has agreed to pay us certain up-front and milestone payments, and a per-test royalty fee based on the reimbursed amount of each test ordered by a physician and processed in LabCorp's facilities. These per-test royalty fees are subject to a minimum dollar amount per test. LabCorp made an initial payment of $15 million to us upon the signing of the agreement in June 2002, and a second payment of $15 million in August 2003 upon the commercial launch of PreGen-Plus. As part of the agreement, we issued to LabCorp a warrant to purchase 1,000,000 shares of our common stock, exercisable for cash over a three-year period, at an exercise price of $16.09 per share.

On August 13, 2003, LabCorp commercially launched the PreGen-Plus test for the detection of colorectal cancer in the average risk, asymptomatic population. As a result, our principal activities are now focused on implementing marketing and sales initiatives in conjunction with LabCorp to support the on-going commercialization of PreGen-Plus as well as focusing on various research and development initiatives aimed at further optimization of the test.

Since the signing of our license agreement with LabCorp in June 2002, we have been actively working with LabCorp to improve the performance characteristics of PreGen-Plus and its market acceptance through the incorporation of technical changes such as Effipure. In addition, the August 2003 commercial launch of PreGen-Plus enabled us and LabCorp to refocus our efforts on new sales and marketing initiatives to help stimulate demand for the test. We and LabCorp amended this license agreement on January 19, 2004 to, among other things, restructure certain product development milestones and increase the level of our collaboration on sales initiatives and test enhancements. This amendment eliminated certain product development milestones and added the aggregate payments associated with those milestones to the amounts we are eligible to receive upon the achievement of certain significant LabCorp revenue thresholds as originally contemplated in the agreement. Pursuant to the amended agreement, we may be eligible for additional milestone

payments from LabCorp totaling up to $45 million, of which a total of up to $15 million relates to certain clinical guideline acceptance and policy-level reimbursement approvals and a total of up to $30 million relates to the achievement of significant LabCorp revenue thresholds. Additionally, the amendment 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, and also modified LabCorp's five-year exclusive license period which now begins effective August 13, 2003, the commercial launch date of PreGen-Plus.

We have generated no material operating revenues since our inception and, as of December 31, 2003, we had an accumulated deficit of approximately $104.8 million. Our losses have historically resulted from costs incurred in conjunction with our research and development initiatives, and more recently, costs associated with selling, general and administrative expenses as we hire additional personnel, initiate marketing programs and build our infrastructure to support the commercial launch and marketing of PreGen-Plus.

Research and development expenses include costs related to scientific and laboratory personnel, clinical studies and reagents and supplies used in the development of our technologies. We expect research and development expenses to decrease in 2004 from 2003 levels due to the completion of one of our two large clinical trials that have comprise the majority of our research and development expense for the past two years. In addition to the costs already incurred, our estimated cost to complete the Mayo Clinic trial is approximately $1.0 million to $1.5 million depending on the ultimate number of patients recruited and the final number of stool samples processed.

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 remain relatively flat in 2004 from 2003 levels as we expect marketing program spend, primarily associated with pre-commercialization activities, to decline in 2004, but will be offset by an increase in selling expense associated with the development of our strategic sales team as we focus our attention on joint sales initiatives of PreGen-Plus with LabCorp.

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. The stock-based compensation expense is being amortized on an accelerated method over the vesting period of the applicable options, which is generally 60 months. Currently, we expect to recognize stock-based compensation expense related to employee, consultant and director options of approximately $600,000 and $200,000 during the years ended December 31, 2004 and 2005, respectively.

Significant Accounting Policies

Financial Reporting Release No. 60, which was recently issued 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 includes 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 the accrual of costs related to patient recruitment for our multi-center clinical study.

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 the related intellectual property is deemed to be no longer of value to us.

We accrued the estimated cost of patient recruitment associated with our large 5,500 patient multi-center clinical study, which was initiated in the third quarter of 2001, as patients were enrolled in the trial. These costs consisted primarily of payments made to the clinical centers, investigators and patients for participating in the Company's clinical study. The Company concluded its patient recruitment for the clinical study at the end of the first quarter of 2003 and essentially all patient recruitment costs have been paid.

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, 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. This 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 revenues. Cost of revenues increased to $22,000 for the year ended December 31, 2003 from $9,000 for the year ended December 31, 2002. Product cost of revenues includes the product costs of Effipure components sold to LabCorp as well as the estimated cost of performing commercial colorectal screening tests at our facilities while product royalty cost of revenues 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 with the completion of our 5,500 patient multi-center clinical trial 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 clinical 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.

Comparison of the years ended December 31, 2002 and 2001

Revenue. Revenue increased to $897,000 for the year ended December 31, 2002 from $51,000 for the year ended December 31, 2001. This 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 revenues. Cost of revenues for the year ended December 31, 2002 of $9,000 represents the estimated cost of performing colorectal screening tests at our facility.

Research and development expenses. Research and development expenses, excluding departmental allocations of stock-based compensation, increased to $20.0 million for the year ended December 31, 2002 from $13.3 million for the year ended December 31, 2001. This increase was primarily attributable to the initiation of our 5,500 patient multi-center clinical trial in October 2001 and included increases of $1.7 million in personnel-related expenses, $1.5 million in laboratory expenses, $1.8 million in trials and studies expenses and $1.6 million related to the leasing of additional laboratory space.

Selling, general and administrative expenses. Selling, general and administrative expenses, excluding departmental allocations of stock-based compensation, increased to $9.7 million for the year ended December 31, 2002 from $9.1 million for the year ended December 31, 2001. This increase was attributable primarily to additional personnel hired to build our infrastructure and the initiation of other corporate and marketing programs to support future growth and included increases of $162,000 in personnel-related expenses, $722,000 in professional fees and expenses, $62,000 in travel-related expenses partially offset by lower costs of $322,000 related to office space and related office expenses.

Stock-based compensation. Stock-based compensation, a non-cash expense, decreased to $2.0 million for the year ended December 31, 2002, of which $478,000 related to research and development personnel and $1.6 million related to general and administrative personnel from $3.8 million for the year ended December 31, 2001. The decrease in stock-based compensation in 2002 from 2001 is due to the accelerated method of amortization being used to record this expense.

Interest income. Interest income decreased to $962,000 for the year ended December 31, 2003 from $2.7 million for the year ended December 31, 2001. 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.

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 and cash received from LabCorp in connection with our strategic alliance. As of December 31, 2003, we had approximately $27.8 million in cash, cash equivalents and marketable securities available to fund our operations.

Net cash used in operating activities was $13.9 million for the year ended December 31, 2003, $11.9 million in 2002 and $15.8 million in 2001. Excluding the impact of the upfront deferred licensing fee of $15 million 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. This increase was primarily due to our increase in operating losses resulting from higher spending in research and development expenses as the we commenced our 5,500 patient multi-center clinical trial in October 2001. In addition, selling, general and administrative expenses increased as we initiated certain corporate, selling and marketing programs to support the commercial launch of PreGen-Plus. Accounts payable and accrued expenses decreased during the year ended December 31, 2003 due to the timing of payments primarily associated with the multi-center trial which successfully concluded during 2003.

Net cash provided by investing activities was $9.5 million for the year ended December 31, 2003 while investing activities used $28.1 million in 2002 and $4.6 million in 2001. Excluding the impact of the purchases and sales of marketable securities, net cash used in investing activities was $3.2 million for the year ended December 31, 2003, $1.8 million in 2002 and $4.6 million in 2001.

Cash used for purchasing property and equipment was $2.6 million for the year ended December 31, 2003, $1.3 million in 2002 and $2.6 million in 2001. This investment in property and equipment for 2003 was attributable to our relocation of our corporate headquarters and lab operations to Marlborough Massachusetts while the investment in 2002 and 2001 was primarily the result of the expansion of our laboratory operations to prepare for our multi-center clinical trial and the Mayo Clinic trial.

Cash used for the expansion of intellectual property portfolio was $608,000 for the year ended December 31, 2003, $417,000 in 2002 and $2.0 million in 2001. We also capitalized $102,000 of costs associated with its recent shelf filing for the year ended December 31, 2003. The investment for 2001 includes the purchase of intellectual property from MT Technologies relating to its Effipure technology, formerly known as Hybrigel™, which consisted of four issued patents and 40 pending patent applications for $1.3 million in cash. Patent costs, which historically consisted of related legal fees, are capitalized as incurred.

We purchased marketable securities of $11 million during 2003 utilizing a portion of the $15 million received from LabCorp in August 2003 upon commercialization of PreGen-Plus. For the year ended December 31, 2003, $23.7 million of marketable securities matured and were then re-invested in cash and cash equivalents or used to fund operations. For the year ended December 31, 2002, we purchased marketable securities of $26.3 million as we began to invest in longer-term securities in order to increase the return on our excess cash position consistent with our investment policy guidelines.

Net cash provided by financing activities was $1.2 million for the year ended December 31, 2003, $615,000 in 2002 and $50.8 million in 2001. Cash provided by financing for the year ended December 31, 2003 resulted from the issuance of $1.1 million of common stock under our stock option and stock purchase plans along with the repayment of $58,000 of stock subscription receivables. Cash provided by financing for the year ended December 31, 2002 resulted from issuance of $371,000 of common stock under our stock option and stock purchase plans along with the repayment of $248,000 of stock subscription receivables. Cash provided by financing for the year ended December 31, 2001 resulted primarily from the sale of our common stock from our initial public offering in 2001.

We expect that cash, cash equivalents and short-term investments currently on hand at December 31, 2003, will be sufficient to fund our operations for the next twelve to fifteen months. We

expect that payments from LabCorp under our strategic partnership agreement, when and if ultimately earned and paid, will supplement our liquidity position. These payments primarily take the form of royalty payments and milestone payments. 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, the timing of milestone 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 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 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.

On September 26, 2003, our shelf registration statement on Form S-3 filed with the SEC was declared effective 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 January 26, 2003, we filed a prospectus supplement pursuant to this shelf registration statement relating to an offering shares of our common stock. While we believe that we will be able to raise sufficient funds in this offering to provide additional liquidity for the foreseeable future, there can be no assurance that we will be successful in our capital raising efforts, or that we will be able raise the funds at an acceptable price level. With an effective shelf registration in place, we believe we are in a position to be able to maintain and maximize our financial flexibility for the foreseeable future.

Our future capital requirements include, but are not limited to, continued investment in our research and development programs, supporting our research and clinical study efforts and our 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. As of December 31, 2003, we had the following fixed obligations and commitments:

Year Ending December 31,	Operating Leases	Contractual Obligations	Purchase Commitments	Total
2004	$ 1,329	$ 695	$ 815	$ 2,839
2005	1,348	430	73	1,851
2006	1,357	220	330	1,907
2007	1,349	220	—	1,569
2008	1,377	220	—	1,597
Thereafter	2,235	2,840	—	5,075
Total payment obligations	$ 8,995	$ 4,625	$ 1,218	$ 14,838

Our future capital requirements will depend on many factors, including the following:

- the success of our clinical studies;
- the scope of and progress made in our research and development activities;
- the successful commercialization of Pre-Gen Plus; and
- the success of any proposed financing efforts.

Net Operating Loss Carryforwards

As of December 31, 2003, we had net operating loss carryforwards of approximately $66.9 million and tax credit carryforwards of approximately $2.1 million. The net operating loss and tax credit carryforwards

will expire at various dates through 2023, 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. You should carefully consider the risks described below and the other information in this report before deciding to invest in shares of our common stock. 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 products or services or become profitable.

We have incurred losses since we were formed. From our date of inception on February 10, 1995 through December 31, 2003, we have accumulated a total deficit of approximately $104.8 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. We cannot assure you that the revenue from any of our products or services will be sufficient to make us profitable.

Our ability to generate revenue substantially depends on the success of our strategic relationship with LabCorp.

We have a long-term, 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, or fail to meet its obligations under the agreement, our revenues would be materially adversely affected and the commercialization of PreGen-Plus would be interrupted. Further, we cannot guarantee that we would be able to enter into a similar agreement 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 total

milestone payments that we are eligible to receive under the agreement, the amendment may delay or make 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 we are unable to obtain clinical guideline acceptance and policy-level reimbursement approvals for PreGen-Plus. If we do not receive additional milestone payments under our agreement with LabCorp, we may be required to raise additional funds to continue the development and commercialization of PreGen-Plus or other technologies. Moreover, we cannot assure you that this amendment 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. If we and LabCorp are unsuccessful in managing our strategic relationship, 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.

Because our revenue will be substantially dependent upon LabCorp's commercial sales of PreGen-Plus, we are actively working together with LabCorp on initiatives designed to promote our joint success with regard to PreGen-Plus. Such initiatives include the following:

- test validation, technology transfer and licensing;
- contracting with manufacturers and suppliers;
- physician education and demand;
- broad-based reimbursement initiatives;
- advocacy development; and
- sales force training.

If we are unsuccessful in our efforts with respect to one or more of the foregoing initiatives, our revenues could be materially adversely affected.

Our business would suffer if we are unable to license certain technologies or obtain raw materials 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 supply of raw materials for which we, or LabCorp, have entered into certain licensing and supply agreements. While we believe that we, or LabCorp, entered into agreements for such technologies and raw materials on favorable terms and conditions, no assurances can be given that we, or LabCorp, will be able to maintain these relationships. Furthermore, the configuration of PreGen-Plus may require us, or LabCorp to enter into additional licenses with third parties for other technologies and raw materials, and there can be no assurance that we, or LabCorp, can obtain these technologies and raw materials on acceptable terms, or at all. Any such additional 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. While we believe such third parties will meet their contractual responsibilities under current and future agreements, there can be no assurance that this will be the case or that such future agreements will in fact be negotiated and entered into. There can be no assurance that any of our current contractual arrangements between us and third parties, us and LabCorp, or between our strategic partners and other third parties, will be continued, entered into, 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 commercial sale of PreGen-Plus or necessary to our realization of material revenues. This could require the PreGen-Plus test to be re-configured which could negatively impact its commercial sale and increase the costs associated with the PreGen-Plus test, which could have a material adverse effect on our revenues and gross margin, respectively.

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.

In the first quarter of 2003, we concluded patient enrollment in a multi-center clinical study of our PreGen-Plus technology that included approximately 5,500 asymptomatic, average-risk aged 50 and older patients from over 80 academic and community-based medical practices. The goal of this clinical 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 version of PreGen-Plus was four times more sensitive than Hemoccult II, the point sensitivity from our multi-center clinical study was lower than that seen in our previous research and clinical studies. Accordingly, despite the success of this study, 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 and, as a result, we may experience a decrease in our stock price.

In October 2001, we signed a Clinical Trial Agreement with Mayo Clinic in which the bead-based version of our PreGen-Plus test was made the subject of an independent study by Mayo Clinic, for which Mayo Clinic received a $4.9 million grant from the National Cancer Institute of the National Institutes of Health. This three-year study is expected to include approximately 4,000 patients at average risk for developing colorectal cancer and, similar to our multi-center clinical study, is designed to compare the results of our bead-based technologies with those of the Hemoccult II and Hemoccult Sensa®, two brands of FOBT, common first-line colorectal cancer screening options. The results of the Mayo clinical study may not show that tests using our technologies are sufficiently superior to Hemoccult II and Hemoccult Sensa. In that event, 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, the PreGen-Plus test.

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 such as 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 are cost-effective. While we and LabCorp have had some success in obtaining reimbursement from third-party payors for tests performed, to date, LabCorp has not secured any broad-based policy-level reimbursement approval from Medicare or enough third-party payors to ensure the long-term commercial success of PreGen-Plus.

Reimbursement by Medicare will require a review that may be lengthy and which may be performed under the provisions of a National Coverage Decision process. The Federal Balanced Budget Act of 1997 provides for adding new technologies to the colorectal cancer screening benefit, such as ours, with such frequency and payment limits as the Secretary of Health and Human Services, or HHS, determines appropriate. We cannot guarantee that the Secretary of HHS will act to approve tests based on our technologies on a timely basis, or at all.

Since policy-level reimbursement approval is required from each private payor individually, seeking such approvals is a time-consuming and costly process. If we, or LabCorp, are unable to obtain adequate reimbursement approval from Medicare and private payors for PreGen-Plus as a benefit, or if the amount reimbursed is inadequate, our ability to generate revenue from our PreGen-Plus tests will be limited.

If our Effipure technology and our or LabCorp's other technological advancements do not increase the performance of the PreGen-Plus test, the demand for PreGen-Plus may be negatively impacted.

We continue to work to improve the performance characteristics of PreGen-Plus through technical innovations such as our Effipure technology. However, there can be no assurance that future generations of our PreGen-Plus test, or the commercial version of the PreGen-Plus test currently offered by LabCorp, which incorporates Effipure and other technology improvements, will have significantly greater sensitivity that that of our original bead-based technology that was used in the multi-center study. We have conducted studies of the commercial version of PreGen-Plus, which includes our Effipure technology. These studies, which have consisted of cohorts from previously conducted clinical studies, including the multi-center study, have shown that the commercial version of the PreGen-Plus test, which includes Effipure, detected cancer in additional samples that the original bead-based PreGen-Plus version did not. Although this ability of the commercial version of PreGen-Plus to detect previously missed cancers has been a consistent outcome across all of our internal studies, 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 commercial test as compared to the original bead-based test. If future generations of our PreGen-Plus test, or the commercial version of the PreGen-Plus test, with Effipure, does not have significantly greater sensitivity than that of the original bead-based technology, 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.

The long-term commercial success of PreGen-Plus may be jeopardized if we, or LabCorp, are not able to lower costs through automating and simplifying key operational processes.

Currently, colorectal cancer screening tests using our technologies are more expensive than FOBT because they are labor-intensive and use highly complex processes and expensive reagents. In order to make our technologies less costly and more commercially attractive, we or LabCorp will need to reduce the costs of tests using our technologies through significant automation of key operational processes and other cost savings procedures. 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.

If we are unable to convince medical practitioners to order tests using our technologies, our revenue and profitability may be limited.

If we, or LabCorp, fail to convince 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. We and LabCorp will need to make thought-leading gastroenterologists and primary care physicians aware of the benefits of tests using our technologies through published papers, presentations at scientific conferences, favorable results from our clinical studies and obtaining reimbursement from insurers. Our failure to be successful in these efforts 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.

If PreGen-Plus is not included in colorectal cancer screening guidelines, physicians may not order PreGen-Plus and payors may not authorize reimbursement for PreGen-Plus.

An important element to market acceptance of PreGen-Plus and the test's successful commercialization involves the inclusion of PreGen-Plus in colorectal cancer screening guidelines. Guideline inclusion is in large part dependent upon the data from our multi-center study being accepted by, and published in, peer-reviewed journals. There can be no assurance that a peer-reviewed journal will accept or publish our multi-center study data, nor can there be any assurance that PreGen-Plus will be included within colorectal cancer screening guidelines any time soon, if at all. In the event PreGen-Plus is not included within colorectal cancer screening guidelines, our revenues, profits and results of operations would likely be materially and negatively affected.

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 alternative colorectal cancer screening technologies, adequate third-party reimbursement is obtained and medical practitioners 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 decide not to complete a colorectal cancer screening test. If only a small portion of the population 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 that 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 analyte specific reagent, 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 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 for 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 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 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.

Additionally, a third-party has asserted claims of patent infringement against certain entities that are anticipated suppliers of materials necessary to the PreGen-Plus test as it is currently configured. Although to date no legal proceedings have been initiated against us, if any third party, including the third party discussed above, is successful in challenging the supply of materials needed for the PreGen-Plus test as it is currently configured, commercialization of our technologies may be significantly delayed, sales of the PreGen-Plus test may become interrupted, and our revenue may become impacted.

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, 2003, we have 30 issued patents and 29 pending patent applications in the United States and we also have 33 issued foreign patents and 98 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.

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 50 million fail to follow the American Cancer Society's screening guidelines. As a result, the colorectal 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 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. 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 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 which could 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 materially 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, John A. McCarthy, Jr., our Executive Vice President, Chief Financial Officer and Treasurer, 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, McCarthy 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, McCarthy 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 and as we transition to a company with commercialized products and services. 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 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 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 benefits from our research and development activities.

We may not have the ability to support demand.

The demand for the PreGen-Plus test may require us and LabCorp to implement certain increases in scale and related manufacturing and process improvements, and to establish an internal quality assurance program to support commercial testing. No assurance can be given that these increases in scale, related improvements and quality assurance program will be successfully implemented, and failure to do so could result in higher cost of testing or an inability to meet market demand. Since PreGen-Plus was recently introduced commercially in August 2003, there can be no assurance that LabCorp will be able to perform tests on a timely basis at a level consistent with demand. If LabCorp encounters difficulty meeting market demand for PreGen-Plus, there could be substantial interruption in LabCorp's continued ability to offer PreGen-Plus commercially and our revenue could be materially and adversely affected.

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 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 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.

Our former independent public accountants, Arthur Andersen LLP, were found guilty of federal obstruction of justice charges, and you are unlikely to be able to exercise effective remedies against it in any legal action.

Prior to July 17, 2002, Arthur Andersen LLP served as the Company's independent auditors. On March 14, 2002, Arthur Andersen was indicted on federal obstruction of justice charges arising from the government's investigation of Enron Corporation and on June 15, 2002, Arthur Andersen was found guilty. Arthur Andersen informed the SEC that it would cease practicing before the SEC by August 31, 2002, unless the SEC determined that another date was appropriate. On May 7, 2002, the

Company dismissed Arthur Andersen and retained Ernst & Young LLP as its independent auditors for its fiscal year ended December 31, 2002. SEC rules require the Company to present historical audited financial statements in various SEC filings, such as registration statements, along with Arthur Andersen's consent to the Company's inclusion of Arthur Andersen's audit report in those filings. Since the Company's former engagement partner and audit manager have left Arthur Andersen and in light of the cessation of Arthur Andersen's SEC practice, the Company is not able to obtain the consent of Arthur Andersen to the inclusion of Arthur Andersen's audit report in the Company's relevant current and future filings. The SEC has provided regulatory relief designed to allow companies that file reports with the SEC to dispense with the requirement to file a consent of Arthur Andersen in certain circumstances, but purchasers of securities sold under the Company's registration statements, which were not filed with the consent of Arthur Andersen to the inclusion of Arthur Andersen's audit report, will not be able to sue Arthur Andersen pursuant to Section 11(a)(4) of the Securities Act and therefore the purchasers' right of recovery under that section may be limited as a result of the lack of the Company's ability to obtain Arthur Andersen's consent.

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 or 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. For example, between September 10, 2003 and December 19, 2003, the closing price of our common stock dropped from approximately $17.55 to $8.85 per share and from March 3, 2003 to July 31, 2003 the price of our common stock rose from $8.35 to $17.11 per share. Consequently, the current market price of our common stock may not be indicative of future market prices and we may be unable to sustain or increase the value of an investment in our common stock. Factors 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;
- 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;
- slow 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 one of these factors to be material.

Future sales by our existing stockholders could depress the market price of our common stock.

If our existing stockholders sell a large number of shares of our common stock, the market price of our common stock could decline significantly. Moreover, the perception in the public market that our existing stockholders might sell shares of common stock could adversely affect the market price of our common stock.

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;
- 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 Auditors

The Board of Directors and Stockholders
EXACT Sciences Corporation

We have audited the accompanying consolidated balance sheets of EXACT Sciences Corporation as of December 31, 2002 and 2003, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended. 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. The financial statements of EXACT Sciences Corporation for the years ended December 31, 2001 were audited by other auditors who have ceased operations and whose report dated January 28, 2002, expressed an unqualified opinion on those statements.

We conducted our audits in accordance with auditing standards generally accepted in the 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 consolidated financial statements referred to above present fairly, in all material respects the consolidated financial position of EXACT Sciences Corporation as of December 31, 2002 and 2003, and the consolidated results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Boston, Massachusetts
January 23, 2004

THE FOLLOWING REPORT IS A COPY OF THE ACCOUNTANT'S REPORT PREVIOUSLY ISSUED BY ARTHUR ANDERSEN LLP. THIS REPORT HAS NOT BEEN REISSUED BY ARTHUR ANDERSEN LLP.

Report of Independent Public Accountants

To EXACT Sciences Corporation:

We have audited the accompanying consolidated balance sheets of EXACT Sciences Corporation (a Delaware corporation in the development stage) and subsidiary as of December 31, 2000 and 2001, and the related consolidated statements of operations, stockholders' equity and cash flows for the three years in the period ended December 31, 2001 and the period from inception (February 10, 1995) to December 31, 2001. These financial statements are the responsibility of management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of EXACT Sciences Corporation and subsidiary as of December 31, 2000 and 2001, and the results of their operations and their cash flows for the three years in the period ended December 31, 2001 and the period from inception (February 10, 1995) to December 31, 2001, in conformity with accounting principles generally accepted in the United States.

Arthur Andersen LLP
Boston, Massachusetts
January 28, 2002

EXACT SCIENCES CORPORATION

Consolidated Balance Sheets

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

	December 31,	
	2002	2003
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 17,439	$ 14,200
Marketable securities	26,407	13,607
Prepaid expenses	1,110	1,283
Total current assets	44,956	29,090
Property and Equipment, at cost:		
Laboratory equipment	3,427	4,114
Office and computer equipment	1,278	1,360
Leasehold improvements	823	1,460
Furniture and fixtures	272	299
	5,800	7,233
Less—Accumulated depreciation and amortization	(3,544)	(4,314)
	2,256	2,919
Patent Costs and Other Assets, net of accumulated amortization of approximately $902 and $1,392 at December 31, 2002 and 2003, respectively	2,874	2,672
	$ 50,086	$ 34,681
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,157	$ 657
Accrued expenses	2,466	1,553
Deferred licensing fees, current portion	1,621	4,514
Total current liabilities	5,244	6,724
Deferred Licensing Fees, less current portion	6,493	15,729
Commitments and contingencies		
Stockholders' Equity:		
Common stock, $0.01 par value Authorized—100,000,000 shares Issued and outstanding—19,070,767 and 19,306,936 shares at December 31, 2002 and 2003, respectively	191	193
Additional paid-in capital	117,256	118,225
Treasury stock, 60,959 shares at December 31, 2002 and 2003, respectively	(12)	(12)
Notes receivable	(699)	(641)
Deferred compensation	(1,977)	(729)
Other comprehensive income (loss)	57	(1)
Accumulated deficit	(76,467)	(104,807)
Total stockholders' equity	38,349	12,228
	$ 50,086	$ 34,681

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,		
	2001	2002	2003
Revenue:			
License fees	$ 51	$ 886	$ 2,871
Royalty fees	—	—	8
Product	—	11	22
	51	897	2,901
Cost of revenues:			
Royalty fees	—	—	1
Product	—	9	21
	—	9	22
Gross profit	51	888	2,879
Operating Expenses:			
Research and development	13,335	19,989	17,084
Selling, general and administrative	9,078	9,701	13,515
Stock-based compensation (1)	3,788	2,043	1,118
	26,201	31,733	31,717
Loss from operations	(26,150)	(30,845)	(28,838)
Interest income	2,665	962	498
Net loss	$ (23,485)	$ (29,883)	$ (28,340)
Net loss per share—basic and diluted:	$ (1.42)	$ (1.62)	$ (1.50)
Weighted average common shares outstanding—basic and diluted	16,487	18,433	18,911

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

Research and development	$ 898	$ 478	$ 249
Selling, general and administrative	2,890	1,565	869
Total	$ 3,788	$ 2,043	$ 1,118

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

EXACT SCIENCES CORPORATION

Consolidated Statements of Stockholders' Equity

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

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Common Stock			Treasury Stock		
	Number of Shares	$0.01 Par Value	Number of Shares	$0.01 Par Value	Number of Shares	$0.01 Par Value	Number of Shares	$0.01 Par Value	Number of Shares	$0.01 Par Value	Additional Paid-In Capital	Number of Shares	Value	Notes Receivable
Balance, December 31, 2000	902,414	$ 9	996,196	$ 10	1,007,186	$ 10	1,417,534	$ 14	2,789,581	$ 28	$ 60,281	—	$ —	$
Repurchase of common stock	—	—	—	—	—	—	—	—	—	—	—	50,646	(8)	
Issuance shares under stock purchase plan	—	—	—	—	—	—	—	—	4,737	—	32	—	—	
Exercise of common stock options	—	—	—	—	—	—	—	—	107,354	1	164	—	—	
Sale of common stock at initial public offering, net of issuance costs of $5,442,264	—	—	—	—	—	—	—	—	4,000,000	40	50,518	—	—	
Repayment of subscription receivable	—	—	—	—	—	—	—	—	—	—	—	—	—	
Conversion of convertible preferred stock into common stock at initial public offering	(902,414)	(9)	(996,196)	(10)	(1,007,186)	(10)	(1,417,534)	(14)	11,889,135	119	(76)	—	—	
Compensation expense related to issuance of stock options	—	—	—	—	—	—	—	—	—	—	(610)	—	—	
Non-cash cost related to issuance of warrant	—	—	—	—	—	—	—	—	—	—	188	—	—	
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	
Balance, December 31, 2001	—	—	—	—	—	—	—	—	18,790,807	188	110,497	50,646	(8)	
Repurchase of common stock	—	—	—	—	—	—	—	—	—	—	—	10,313	(4)	
Issuance shares under stock purchase plan	—	—	—	—	—	—	—	—	17,840	—	137	—	—	
Exercise of common stock options	—	—	—	—	—	—	—	—	262,120	3	231	—	—	
Repayment of subscription receivable	—	—	—	—	—	—	—	—	—	—	—	—	—	
Compensation expense related to issuance (forfeitures) of stock options	—	—	—	—	—	—	—	—	—	—	(159)	—	—	
Non-cash cost related to issuance of warrant	—	—	—	—	—	—	—	—	—	—	6,550	—	—	
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	

Other comprehensive income	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	
Comprehensive loss																
Balance, December 31, 2002	—	$ —	—	$ —	—	$ —	—	$ —	$ —	19,070,767	$ 191	$ 117,256	60,959	$ (12)	$	
Issuance shares under stock purchase plan	—	—	—	—	—	—	—	—	28,621	—	216	—	—			
Exercise of common stock options	—	—	—	—	—	—	—	—	207,548	2	883	—	—			
Repayment of subscription receivable	—	—	—	—	—	—	—	—	—	—	—	—	—			
Compensation expense related to issuance (forfeitures) of stock options	—	—	—	—	—	—	—	—	—	—	(130)	—	—			
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—			
Other comprehensive income	—	—	—	—	—	—	—	—	—	—	—	—	—			
Comprehensive loss																
Balance, December 31, 2003	—	$ —	—	$ —	—	$ —	—	$ —	$ —	19,306,936	$ 193	$ 118,225	60,959	$ (12)	$	

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,		
	2001	2002	2003
Cash Flows from Operating Activities:			
Net loss	$ (23,485)	$ (29,883)	$ (28,340)
Adjustments to reconcile net loss to net cash used in operating activities—			
Depreciation	895	1,663	1,897
Amortization	173	495	912
Stock-based compensation expense	3,788	2,043	1,118
Amortization of deferred licensing fees	(50)	(886)	(2,871)
Changes in assets and liabilities:			
Prepaid expenses	17	(389)	(172)
Accounts payable	594	(19)	(501)
Deferred license fees	600	15,000	15,000
Accrued expenses	1,631	59	(913)
Net cash used in operating activities	(15,837)	(11,917)	(13,870)
Cash Flows from Investing Activities:			
Purchase of marketable securities	—	(26,350)	(11,009)
Maturity of marketable securities	—	—	23,751
Purchases of property and equipment	(2,615)	(1,335)	(2,560)
Increase in patent costs and other assets	(1,951)	(417)	(710)
Net cash provided by (used in) investing activities	(4,566)	(28,102)	9,472
Cash Flows from Financing Activities:			
Proceeds from exercise of common stock options and stock purchase plan	147	371	1,101
Repayment of notes receivable	79	248	58
Repurchase of treasury shares	(8)	(4)	—
Net proceeds from sale of common stock	50,558	—	—
Net cash provided by financing activities	50,776	615	1,159
Net Increase (Decrease) in Cash and Cash Equivalents	30,373	(39,404)	(3,239)
Cash and Cash Equivalents, beginning of year	26,470	56,843	17,439
Cash and Cash Equivalents, end of year	$ 56,843	$ 17,439	$ 14,200
Supplemental Disclosure of Non-Cash Investing and Financing Activities:			
Sale of restricted stock through issuance of notes receivable	$ 50	$ —	$ —
Issuance of warrants	$ 188	$ 6,550	$ —

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

EXACT SCIENCES CORPORATION

Notes to Consolidated Financial Statements December 31, 2003

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

(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 by Laboratory Corporation of America® Holdings ("LabCorp®").

On February 5, 2001, the Company completed an initial public offering of 4,000,000 shares of its common stock at $14.00 per share. The Company received net proceeds of approximately $50,558 after deducting the underwriters' commission and issuance costs. Upon consummation of the initial public offering, all previously issued shares of preferred stock outstanding automatically converted into 11,889,135 shares of common stock.

(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, 2003, approximately $1,000 of the Company's cash has been pledged as collateral for an outstanding letter of credit. Cash equivalents primarily consist of money market funds at December 31, 2002 and 2003.

Marketable Securities

The Company accounts for its investments in marketable securities in accordance with Statement of Financial Accounting Standards ("SFAS") No. 115, " *Accounting for Certain Investments in Debt and Equity Securities* ". Management determines the appropriate classification of debt securities at the time of purchase and re-evaluates such designation as of each balance sheet date. Debt securities are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to maturity. Marketable equity securities and debt securities not classified as held-to-maturity are classified as available-for-sale. Available-for-sale securities are carried at fair value, with the unrealized gains and losses, net of tax, reported in other comprehensive income. The amortized cost of

debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity computed under the effective interest method. Such amortization is included in investment income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in investment income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in investment income.

All of the Company's investments are comprised of fixed income investments and all are deemed available-for-sale. The objectives of this portfolio are to provide liquidity and safety of principal while 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. Available-for-sale securities consist of corporate debt securities as of December 31, 2002 and 2003 all of which mature in 2004.

For the year ended December 31, 2003, the gross unrealized gains on available-for-sale securities totaled approximately $58 while there were no realized gains or losses on the sales of available-for sale securities.

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 life or useful life
Furniture and fixtures	3 years

Repair and maintenance costs are charged to operations when incurred.

Patent Costs

Patent costs, which 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 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, 2003 over the next five years is as follows:

Year	Amount
2004	$ 465
2005	441
2006	378
2007	61
2008	20
Total	$ 1,365

The Company has approximately $1.1 million of additional intangible assets as of December 31, 2003 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 Asset*, 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. All shares issuable upon exercise of stock options to purchase 2,228,077; 2,892,291; and 3,591,603 common shares, unvested restricted common shares of 649,963; 342,391; and 132,482, and outstanding warrants to purchase common shares of 88,125; 1,000,000; and 1,000,000, have therefore been excluded from the computations of diluted weighted average shares outstanding for the years ended December 31, 2001, 2002 and 2003, respectively.

In accordance with the Securities Exchange Commission ("SEC") Staff Accounting Bulletin ("SAB") No. 98, *Earnings Per Share in an Initial Public Offering,* the Company has determined that there were no nominal issuances of the Company's common stock prior to the Company's initial public offering.

Pro Forma Net Loss

The Company's historical capital structure is not indicative of its capital structure subsequent to its initial public offering due to the automatic conversion of all shares of preferred stock into 11,889,135 shares of common stock concurrent with the closing of the Company's initial public offering on February 5, 2001. Accordingly, pro forma net loss per share is presented below for the year ended December 31, 2001, assuming the conversion of all outstanding shares of preferred stock into common

stock upon the closing of the Company's initial public offering using the if-converted method from the respective dates of issuance.

	Year Ended December 31, 2001
Net loss	$ (23,485)
Weighted average shares outstanding	16,487
Weighted conversion of preferred stock to common stock	1,024
Pro forma weighted average shares outstanding	17,511
Pro forma basic and diluted net loss per share	$ (1.34)

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* . SFAS No. 123, *Accounting for Stock-Based Compensation*, 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, computed using the Black-Scholes option pricing model, of $167, $68 and $87 was recorded in the accompanying consolidated statements of operations for the years ended December 31, 2001, 2002, and 2003, 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, 2001, 2002, and 2003, using the Black-Scholes option pricing model prescribed by SFAS No. 123.

The assumptions used for the years ended December 31, 2001, 2002, and 2003 are as follows:

	December 31,		
	2001	2002	2003
Risk-free interest rates	2.86%–4.98%	1.71%–3.71%	1.23%–1.91%
Expected lives	7 years	7 years	7 years
Expected volatility	100%	100%	100%
Dividend yield	0%	0%	0%
Weighted average fair value of grants	$9.43	$7.41	$6.43

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

	December 31,		
	2001	2002	2003
Net loss as reported	$ (23,485)	$ (29,883)	$ (28,340)
Add: Stock-based compensation included in reported net loss	3,788	2,043	1,118
Deduct: Total stock based employee compensation determined under SFAS 123 for all awards	(6,918)	(5,524)	(6,540)
Pro forma net loss—SFAS 123	$ (26,615)	$ (33,364)	$ (33,762)
Basic and diluted net loss per share:			
As reported	$ (1.42)	$ (1.62)	$ (1.50)
Pro forma—SFAS 123	$ (1.61)	$ (1.81)	$ (1.79)

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, not the amount billed. In accordance with the general principles, 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.

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.

Clinical Trial Accrual

The Company accrued the estimated cost of patient recruitment associated with its large multi-center clinical study as patients enrolled in the trial. These patient recruitment costs consisted primarily of payments made to the clinical centers, investigators and patients for participating in the Company's clinical study. The Company concluded its patient recruitment for the clinical study during 2003 and essentially all patient recruitment costs have been paid as of the end of 2003.

Advertising Costs

The Company expenses the costs of media advertising at the time the advertising take place. The Company expensed $213, $201 and $1,338 of media advertising for the years ended December 31, 2001, 2002 and 2003, 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. Prior to December 31, 2002, the Company's net loss equaled its comprehensive loss.

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, accounts payable and capital lease obligations. 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 November 2002, the Financial Accounting Standards Board issued Financial Accounting Standards Board Interpretation No. 45 (FIN 45), "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." FIN 45 requires that upon issuance of a guarantee, the guarantor must disclose and recognize a liability for the fair value of the obligation it assumes under that guarantee. The initial recognition and measurement requirement of FIN 45 is effective for guarantees issued or modified after December 31, 2002. As of December 31, 2003, the fair value of the Company's guarantees that were issued or modified after December 31, 2002 was not material. The disclosure requirements of FIN 45 were effective for interim and annual periods ending after December 15, 2002. In connection with various other agreements, the Company may provide routine guarantees. Generally, because a maximum obligation is not explicitly stated, the potential amount of future maximum payments cannot be reasonably estimated, and

therefore, the Company has not recorded any liability for these indemnities in the consolidated financial statements. The duration of the indemnities varies, and in many cases is indefinite.

In May 2003, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 150 (FAS 150), "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." FAS 150 establishes standards for how an issuer classifies and measures in its statement of financial position certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances) because that financial instrument embodies an obligation of the issuer. FAS 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of FAS 150 did not have a material effect on the Company's financial position or results of operations.

In January 2003, the Financial Accounting Standards Board issued Financial Accounting Standards Board Interpretation No. 46 (FIN 46), "Consolidation of Variable Interest Entities." FIN 46 requires that if an entity has a controlling financial interest in a variable interest entity, the assets, liabilities and results of activities of the variable interest entity should be included in the consolidated financial statements of the entity. FIN 46 was effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied to the first interim or annual period beginning after December 15, 2003. The Company is required to adopt the provisions of FIN 46 in the first quarter of fiscal 2004 and does not expect the adoption to have a material impact on its financial position or results of operations.

(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. As amended, the Company is also 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, and up to $30 million based upon the achievement of certain significant LabCorp revenue thresholds. Additionally, the amendment to the license agreement 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.

(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, 2003, the Company had net operating loss and research tax credit carryforwards of approximately $66,921 and $2,132, respectively, for financial reporting purposes, which may be used to offset future taxable income. The carryforwards expire through 2023 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,	
	2002	2003
Deferred tax assets:		
Operating loss carryforwards	$ 18,329	$ 26,508
Tax credit carryforwards	1,326	2,132
Deferred revenue	3,214	10,455
Other temporary differences	3,522	2,723
Tax assets before valuation allowance	26,391	41,818
Less—Valuation allowance	(26,391)	(41,818)
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 had 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, 2003, 132,482 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.

(6) 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 and $218 to the Mayo Clinic for the years ended December 31, 2001, 2002 and 2003, respectively, related to this study and recorded these as research and development expense as incurred.

In March 2001, the Company entered into a consulting agreement with a member of its Board of Directors. The Company paid approximately $37, $55 and $55 for services provided under the agreement for the years ended December 31, 2001, 2002 and 2003, respectively.

(7) 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, 2003.

(8) EMPLOYEE STOCK PURCHASE PLAN

The 2000 Employee Stock Purchase Plan (the "2000 Purchase Plan") provides for the issuance of up to an aggregate of 583,962 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, of one share of common stock on either the first or last day of the offering period, whichever is lower. No employee may be granted an option that would permit the employee's rights to purchase common stock to accrue in excess of $25,000 in any calendar year. The first offering period under the 2000 Purchase Plan commenced on the date at which shares were issued in connection with the Company's initial public

offering of its common stock (January 30, 2001) and continued through July 31, 2001. Thereafter, the offering periods will begin on each February 1 and August 1. Options 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

(9) 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.

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

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 terminated by vote of the Board of Directors. At December 31, 2003, 1,180,802 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, 2003, a total of 2,952,690 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.

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, 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, 2003, options to purchase 2,410,801 were outstanding under the 2000 Option Plan and 465,194 shares were available for future grant under the 2000 Option Plan.

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

	Number of Shares	Weighted Exercise Price
Outstanding, December 31, 2000	1,771,621	$ 3.16
Granted	690,500	11.21
Exercised	(107,354)	1.54
Canceled	(126,690)	5.84
Outstanding, December 31, 2001	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
Exercisable, December 31, 2001	819,174	$ 3.90
Exercisable, December 31, 2002	1,071,983	$ 5.65
Exercisable, December 31, 2003	1,698,315	$ 7.40

The following table summarizes information relating to currently outstanding and exercisable stock options as of December 31, 2003:

	Outstanding			Exercisable	
Exercise Price	Number of Shares	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
$0.04–$0.38	325,954	5.53	$ 0.35	290,285	$ 0.35
$2.05–$2.05	397,015	6.42	2.05	217,541	2.05
$5.50–$6.95	733,000	9.12	6.78	667	5.93
$7.27–$9.90	1,225,009	7.85	8.03	592,541	7.90
$10.05–$12.89	587,125	7.66	11.45	370,635	11.51
$13.00–$14.33	323,500	8.52	13.57	226,646	13.54
	3,591,603	7.77	$ 7.48	1,698,315	$ 7.40

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, including all outstanding stock option grants noted above, and outstanding warrants at December 31, 2003:

Plan	Shares Reserved
2000 Stock Purchase Plan	532,794
1995 Option Plan	1,180,802
2000 Option Plan	2,875,995
Outstanding warrants	1,000,000
Total	5,589,591

(10) COMMITMENTS

Operating Lease

The Company leases certain equipment and conducts its operations in leased facilities under noncancelable operating leases expiring through July 2010. Future minimum payments under operating leases as of December 31, 2003 are as follows:

Year Ending December 31,	
2004	$ 1,329
2005	1,348
2006	1,357
2007	1,349
2008	1,377
Thereafter	2,235
Total lease obligations	$ 8,995

Rent expense included in the accompanying consolidated statements of operations was approximately $301, $348 and $871 for the years ended December 31, 2001, 2002, and 2003, 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 with Johns Hopkins University ("JHU") for an exclusive long-term license to certain patents relating to the digital-PCR technology developed by Dr. Bert Vogelstein's laboratory at the Johns Hopkins Kimmel Cancer Center. Pursuant to the terms of this license agreement, the Company has agreed to pay JHU a license fee based on a percentage of the Company's net revenues, including an annual minimum license fee of $200, over the life of the licensed patents, or 2022. The Company has recorded research and development expense associated with license

agreements of $50, $50 and $250 for each of the years ended December 31, 2001, 2002 and 2003, 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 and as such, has remaining purchase obligations of approximately $1.2 million associated with these agreements to be satisfied over the next several years. 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. The Company has and will continue to take steps to mitigate these risks.

(11) ACCRUED EXPENSES

Accrued expenses at December 31, 2002 and 2003 consisted of the following:

	December 31,	
	2002	2003
Payroll and payroll-related	$ 864	$ 535
Occupancy costs	246	250
Professional fees	179	244
Research and trial-related expenses	940	200
Consulting	98	48
Other	139	276
	$ 2,466	$ 1,553

(12) 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, 2003. In the opinion of management, this information has been prepared on the same basis as the audited financial statements appearing elsewhere in this Form 10-K, and all necessary adjustments, consisting only of normal recurring adjustments, have been included in the amounts stated below to present fairly the unaudited quarterly results of operations. The quarterly

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

	Quarter ended			
	March 31,	June 30,	September 30,	December 31,
	(Amounts in thousands, except per share data)			
2003				
Revenue	$ 408	$ 406	$ 918	$ 1,169
Cost of revenues	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 common 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
2002				
Revenue	$ 39	$ 40	$ 410	$ 408

Cost of revenues	—	2	4	3
Research and development	5,043	5,066	5,131	4,749
Selling, general and administrative	2,289	2,534	2,396	2,482
Stock-based compensation	568	544	544	387
Loss from operations	(7,861)	(8,106)	(7,665)	(7,213)
Interest income	275	231	251	205
Net loss	$ (7,586)	$ (7,875)	$ (7,414)	$ (7,008)
Net loss per common share—basic and diluted	$ (0.42)	$ (0.43)	$ (0.40)	$ (0.38)
Weighted average common shares outstanding—basic and diluted	18,165	18,376	18,551	18,642

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

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

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's President and Chief Executive Officer and Executive Vice President, Chief Financial Officer and Treasurer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures, as defined in Exchange Act Rule 15d-15(e). Based upon that evaluation, subject to the limitations inherent in such controls noted below, the Company's President and Chief Executive Officer and Executive Vice President, Chief Financial Officer and Treasurer concluded that the Company's disclosure controls and procedures are effective in enabling the Company to record, process, summarize and report information required to be included in the Company's periodic SEC filings within the required time period. The Company is presently engaged in a broad review of its internal control procedures in anticipation of the need for the Company's independent auditors to certify as to the adequacy of those controls in connection with the filing of the Company's Annual Report on Form 10-K for its 2004 fiscal year.

Limitations Inherent in All Controls. The Company's management, including the President and Chief Executive Officer and Executive Vice President, Chief Financial Officer and Treasurer, recognize that our disclosure controls and our internal controls (discussed below) cannot prevent all error or all attempts at fraud. Any controls system, no matter how well crafted and operated, can only provide reasonable, and not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints that affect the operation of any such system and that the benefits of controls must be considered relative to their costs. Because of the inherent limitations in any control system, no evaluation or implementation of a control system can provide complete assurance that all control issues and all possible instances of fraud have been or will be detected.

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 June 9, 2004, 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, 2003, 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 and Other Information

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 June 9, 2004, 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, 2003, is hereby incorporated by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The Company maintains the following three equity compensation plans under which our equity securities are authorized for issuance to our employees and/or directors; the 1995 Stock Option Plan, the 2000 Stock Option and Incentive Plan and the 2000 Employee Stock Purchase Plan. Each of the foregoing equity compensation plans was approved by our stockholders. The following table presents information about these plans as of December 31, 2003.

EQUITY COMPENSATION PLAN INFORMATION

Plan Category	Number Of Securities To Be Issued Upon Exercise Of Outstanding Options, Warrants, And Rights	Weighted Average Exercise Price Of Outstanding Options, Warrants And Rights	Number Of Securities Remaining Available For Future Issuance Under Equity Compensation Plans (Excluding Securities Outstanding)
Equity compensation plans approved by security holders	3,591,603	$ 7.48	997,988
Equity compensation plans not approved by security holders	None	None	None
Total	3,591,603	$ 7.48	997,988

No further grants will be made under the 1995 Stock Option Plan.

The balance of the information required by this Item 12 is hereby incorporated by reference to the Section "Securities Ownership of Certain Beneficial Owners and Management" from the registrant's definitive proxy statement for the annual meeting of stockholders to be held on June 9, 2004, 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, 2003.

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 June 9, 2004, 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, 2003, 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 June 9, 2004, 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, 2003, is hereby incorporated by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedule and Reports on Form 8-K.

(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)
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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)
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10.8*	Secured Promissory Note between the Registrant and Don M. Hardison dated as of June 23, 2000 (previously filed as Exhibit 10.10 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)

10.9	Lease Agreement, dated December 10, 1996, between C.B. Realty Limited Partnership and the Registrant, as amended (previously filed as Exhibit 10.11 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.10	Fourth Amendment to Lease Agreement, dated February 7, 2001, between C.B. Realty Limited Partnership and the Registrant
10.11	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)
10.12	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)
10.13	Mayo Foundation for Medical Education and Research (the "Foundation") Technology License Contract between the Registrant and the Foundation dated as of July 7, 1998, as amended (previously filed as Exhibit 10.14 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.14	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)
10.15	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)
10.16*	Restricted Stock Purchase Agreement between the Registrant and John A. McCarthy, Jr. dated as of November 28, 2000 (previously filed as Exhibit 10.17 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.17*	Full Recourse Promissory Note between the Registrant and John A. McCarthy, Jr. dated as of November 28, 2000 (previously filed as Exhibit 10.18 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.18*	Pledge Agreement between the Registrant and John A. McCarthy, Jr. dated as of November 30, 2000 (previously filed as Exhibit 10.19 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.19*	Severance Agreement between the Registrant and Stanley N. Lapidus dated January 4, 2001 (previously filed as Exhibit 10.20 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.20*	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)
10.21*	Severance Agreement between the Registrant and John A. McCarthy, Jr. dated January 4, 2001 (previously filed as Exhibit 10.22 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.22*	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)
10.23	Warrant Agreement between the Registrant and The Mayo Foundation for Medical Research dated December 28, 2000 (previously filed as Exhibit 10.26 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)

10.24*	Amendment No 1. to Full Recourse Promissory Note between the Registrant and Stanley N. Lapidus dated as of November 30, 2001 (previously filed as Exhibit 10.26 to our Annual Report on Form 10-K for the period ended December 31, 2002 (File No. 000-32179) which is incorporated herein by reference)
10.25*	Amendment No 1. to Full Recourse Promissory Note between the Registrant Don M. Hardison dated as of November 30, 2001 (previously filed as Exhibit 10.27 to our Annual Report on Form 10-K for the period ended December 31, 2002 (File No. 000-32179) which is incorporated herein by reference)
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	filed as Exhibit 10.28 to our Annual Report on Form 10-K for the period ended December 31, 2002 (File No. 000-32179) which is incorporated herein by reference)
10.27*	Executive Cash Incentive Plan dated October 15, 2001 (previously filed as Exhibit 10.29 to our Annual Report on Form 10-K for the period ended December 31, 2002 (File No. 000-32179) which is incorporated herein by reference)
10.28**	Agreement between the Registrant and Laboratory Corporation of America Holdings, Inc. dated June 26, 2002 (previously filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 000-32179) which is incorporated herein by reference)
10.29	Lease Agreement, dated January 23, 2003, between Marlborough Campus Limited Partnership and the Registrant
10.30**	Exclusive License Agreement between Matrix Technologies Corporation, d/b/a Apogent Discoveries, and the Registrant dated as of November 26, 2002
10.31**	Services, Manufacturing and Supply Agreement dated as of April 7, 2003, by and between the Company and Discovery Labware, Inc.
10.32**+	First Amendment to License Agreement by and between the Company and Laboratory Corporation of America Holdings, Inc. dated January 19, 2004
10.33**+	Sublicense Agreement between the Company and Beckman Coulter dated July 28, 2003
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
23.1 (A)	Information regarding Arthur Andersen LLP
24.1	Power of Attorney (included on signature page)
31.1	Certification Pursuant to 18 U.S.C Section 1350, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification Pursuant to 18 U.S.C Section 1350, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
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* Indicates a management contract or any compensatory plan, contract or arrangement.

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

\+ Filed herewith.

(b) Reports on Form 8-K.

During the quarter ended December 31, 2003, we furnished five reports on Form 8-K. The first report, dated October 9, 2003, announced that top-line data from the Company's multi-center study of

PreGen-Plus versus fecal occult blood testing would be presented as part of a symposium in conjunction with the American College of Gastroenterology 2003 Annual Conference being held in Baltimore, MD and that the Company would host a conference call to discuss the data presented at the ACG symposium. The second report, dated October 14, 2003, furnish a press release announcing the top-line results of the Company's multi-center study of PreGen-Plus versus fecal occult blood. The third report dated October 28, 2003 furnished our third quarter results press release as an exhibit. Our fourth, dated November 26, 2003, announced that the Company was hosting an analyst and institutional investor day on Monday, December 1, 2003, in Boston, Massachusetts and that the presentations were being webcast. The fifth report, dated December 11, 2003, announced that the Company's presentation at the Harris Nesbitt Gerard "Focus on Healthcare" Conference would be webcast live. We also filed a report on Form 8-K, dated October 22, 2003, announcing that the Company was hosting a conference call for its third quarter financial and operating results. We filed no other reports on Form 8-K during the quarter ended December 31, 2003.

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: January 29, 2004

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 John A. McCarthy, Jr., and each of them singly, our true and lawful attorneys, with full power to them and each of them singly, to sign for us and in our names in the capacities indicated below, any amendments to this Annual Report on Form 10-K, and generally to do all things in our names and on our behalf in such capacities to enable EXACT Sciences Corporation to comply with the provisions of the Securities Exchange Act of 1934, as amended, and all the requirements of the Securities Exchange Commission.

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

SIGNATURE	TITLE	DATE
/s/ STANLEY N. LAPIDUS Stanley N. Lapidus	Chairman of the Board and Director	January 29, 2004
/s/ DON M. HARDISON Don M. Hardison	President, Chief Executive Officer and Director (Principal Executive Officer)	January 29, 2004
/s/ JOHN A. MCCARTHY, JR. John A. McCarthy, Jr.	Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)	January 29, 2004
/s/ RICHARD W. BARKER Richard W. Barker	Director	January 29, 2004
/s/ SALLY W. CRAWFORD Sally W. Crawford	Director	January 29, 2004
/s/ EDWIN M. KANIA, JR.		

Edwin M. Kania, Jr.	Director	January 29, 2004
/s/ CONNIE MACK, III Connie Mack, III	Director	January 29, 2004
/s/ LANCE WILLSEY Lance Willsey	Director	January 29, 2004
/s/ PATRICK J. ZENNER Patrick J. Zenner	Director	January 29, 2004

Exhibit Index to Annual Report on Form 10-K
for Fiscal Year Ended December 31, 2002

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

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

\+ Filed herewith.

EXHIBIT 10.32

**FIRST AMENDMENT TO AGREEMENT BETWEEN
EXACT SCIENCES CORPORATION
AND
LABORATORY CORPORATION OF AMERICA HOLDINGS**

This First Amendment (this "Amendment") is made and effective as of January 19, 2004, by and between LABORATORY CORPORATION OF AMERICA HOLDINGS ("LABCORP") and EXACT SCIENCES CORPORATION ("EXACT").

WHEREAS, LabCorp and EXACT entered into an Agreement dated June 26, 2002 (the "Agreement"); and

WHEREAS, the parties desire to amend certain provisions of the Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, the parties agree to the following amendments to the Agreement, to be effective as of the date of execution of this Amendment:

1. Section 1.8 of the Agreement shall be deleted in its entirety and replaced with the following:

1.8 "Exclusive Period" shall mean the period beginning on August 13, 2003, and ending on August 13, 2008, unless sooner terminated in accordance with Section 8.1, 11.2, or 11.6.

2. Milestones 1, 2 and 3 (and the associated Milestone License Fees) on Schedule 4 of the Agreement and Sections 1.4, 1.6 and 3.5 of the Agreement shall be deemed eliminated for all purposes, except that Milestone 1 shall continue to apply solely for purposes of Section 6.2.2.b.

3. Section 6.1.4 of the Agreement shall be deemed eliminated and replaced with the following:

6.1.4 Performance-Based License Fees. If (and only if) the First Trigger Date occurs on or before /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/, then LABCORP shall pay EXACT a non-refundable license fee of /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ to be paid within 30 days of the First Trigger Date. If (and only if) the Second Trigger Date occurs on or before /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/, then LABCORP shall pay EXACT a non-refundable license fee of /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ within 30 days of the Second Trigger Date.

4. EXACT hereby agrees to purchase LabCorp's /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ as of the date of this Amendment at /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ for such /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/, in amount not to exceed /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/. All such /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ is sold "AS IS" and LabCorp disclaims any and all warranties and representations with regard to such /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/. NO EXPRESS AND NO IMPLIED WARRANTIES OF ANY TYPE, WHETHER OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR OTHERWISE, SHALL APPLY TO THE /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/.

5. EXACT hereby agrees that LabCorp has no obligations or other liabilities to EXACT for /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ for all /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ and EXACT agrees that any /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ are hereby deemed canceled and LabCorp shall assume no responsibility for such items.

6. Each party agrees to meet, either in person or by telephone, no less frequently than semi-monthly to the extent reasonable under the circumstances, to evaluate /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ relating to the commercialization of PreGen-Plus ("Sales/Marketing Steering Committee".) The Sales/Marketing Steering Committee shall meet on at least a quarterly basis to review progress of the commercialization of PreGen-Plus.

7. LabCorp agrees that it will notify EXACT, at least once every two months, of the Assay's current configuration and composition as of the date of each notification. More frequent notifications will be made to EXACT upon material changes to the Assay by LabCorp from time to time. The parties agree to use reasonable efforts to collaborate and develop an Assay notification process (the "Notification Process") within sixty (60) days after the effective date of this Amendment that (i) defines the specific areas of Assay configuration and composition for which notification to EXACT will be provided, and (ii) outlines the process by which the parties will regularly communicate on issues of Assay evolution and development.

8. LabCorp and EXACT hereby agree that any /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ paid by LabCorp to /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ related to LabCorp's /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ from a third party for use in performing the Assay (the "/*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ Fees") will be considered a "third party royalty" under Section 6.2.2.c of the Agreement and such cost will be deducted from the Assay payments due EXACT under Article 6 of the Agreement; provided, however, that (i) if LabCorp does not use its best efforts to /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ for such license, then with respect to the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ Fees, only up to /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ of LABCORP, its Affiliates and

sublicensees /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ from performance of Assays may be deducted from the Assay payments due EXACT under Article 6 of the Agreement; and (ii) the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ Fees shall not be deducted from the Assay payments to EXACT to the extent:

LabCorp enters into a relationship with /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ that makes the above-referenced license duplicative or unnecessary for LabCorp and has the net effect of eliminating or reducing the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ payable by LabCorp of the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ Fees. For the avoidance of confusion, for every /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ net reduction of /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ payable by LabCorp relating to the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ Fees, the amount that qualifies as a "third party royalty" under
Section 6.2.2.c. which LabCorp may deduct from the Assay payments due to EXACT will be decreased by /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/

9. For the purposes of this Amendment, the "/*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ Agreement" shall mean that /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ dated /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/, whereby "/*/[CONFIDENTIAL TREATMENT REQUESTED]/*/. For the purposes of this Amendment, /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ shall have the same meaning as in the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ Agreement. For the purposes of this Amendment, the "/*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ Effective Royalty Rate" shall mean /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ actually paid by LabCorp to /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ during the Preliminary Measuring Period or Full Measuring Period, as applicable, pursuant to the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ Agreement divided by the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ during the same period. For purposes of this Amendment, the "Preliminary Measuring Period" shall mean the period from /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ through /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/. For purposes of this Amendment, the "Full Measuring Period" shall mean the period from /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ through /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/. For the purposes of this Amendment, the "Excess" shall mean the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ Effective Royalty Rate minus /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/

In the event that, following the Preliminary Measuring Period, the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ Effective Royalty Rate is /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ then LabCorp may request that /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ to LabCorp an amount equal to the Excess times /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/, and if so requested, EXACT agrees to pay LabCorp such amount within thirty (30) days (the "Preliminary Payment

Amount"). In the event that, following the Preliminary Measuring Period, the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ Effective Royalty Rate is /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ then the "Preliminary Payment Amount" shall be /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/

In the event that, following the Full Measuring Period, the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ Effective Royalty Rate is /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ then the "Full Payment Amount" shall be an amount equal to the Excess times the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/. In the event that, following the Full Measuring Period, the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ Effective Royalty Rate is /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ then the "Full Payment Amount shall be /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/

In the event that following the Full Measuring Period, the Full Payment Amount is /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ the Preliminary Payment Amount, then LabCorp will notify EXACT and EXACT will pay LabCorp the amount equal to /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ within 30 days after such notice.

In the event that following the Full Measuring Period, the Preliminary Payment Amount is /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ the Full Payment Amount, then LabCorp will notify EXACT and LabCorp will pay EXACT the amount equal to /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ within 30 days after such notice.

Notwithstanding the foregoing, in the event that LabCorp enters into a relationship with /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/, at any time during the Measuring Period, that provides LabCorp with /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ Rights") that effectively render the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ (with respect to LabCorp's performing of the Assay), then /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ shall be due from EXACT to LabCorp relating to the Excess described above.

10. The parties recognize and agree that /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ all amounts paid to EXACT to date from LabCorp have been effectively earned.

11. The parties agree that /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ and /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ on Schedule 4 of the Agreement will remain unmodified by this Amendment and will continue in full force and effect, as written.

12. Except as expressly modified herein, the Agreement and all of its terms and conditions shall continue in full force and effect.

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Amendment as of the date first above written.

LABORATORY CORPORATION OF AMERICA HOLDINGS	*EXACT SCIENCES CORPORATION*
By: /s/ Bradford Smith	*By: /s/ Don Hardison*
Printed Name: Bradford Smith	*Printed Name: Don Hardison*
Title: Executive Vice President	*Title: President, CEO*

Exhibit 10.33

SUBLICENSE AGREEMENT

This Sublicense Agreement (the "Agreement") is entered into as of July 28th, 2003 (the "Effective Date") by and between Beckman Coulter, a Delaware corporation, having a principal place of business at 4300 North Harbor Boulevard, Fullerton, California 92835 ("BECKMAN"), and EXACT Sciences Corporation, a Delaware corporation having a principal place of business at 100 Campus Drive, Marlborough, Massachusetts 01754 ("EXACT").

In consideration of the mutual promises and conditions contained in this Agreement, BECKMAN and EXACT agree as follows:

ARTICLE 1 - DEFINITIONS

1.1 "Affiliate" shall mean any company, corporation or other business entity that is controlled by, controlling, or under common control with the subject company, corporation or other business. For this purpose "control" means direct or indirect beneficial ownership of at least fifty percent (50%) interest in the voting stock (or the equivalent) of the company, corporation or other business or having the right to direct, appoint or remove a majority of members of its board of directors (or their equivalents) or having the power to control the general management of the company, corporation or other business, by law or contract.

1.2 "EXACT Net Revenues" shall mean:

(i) gross royalties received by EXACT from its Sublicensee relating to the Third Party's sale or provision of Licensed Services, and

(ii) gross revenues received by EXACT relating to EXACT's direct provision of Licensed Services, less the following deductions:

(a) Trade, quantity, cash or other discounts, if any, actually allowed and taken;

(b) Credits or allowances, not to exceed two percent of EXACT Net Revenues, made or given on account of defective services or

disputed services that are specifically identifiable to Licensed Services sold to a Third Party; and

(c) Any tax or governmental charge received by EXACT from its customer with respect to the sale, use or delivery of Licensed Services to the customer and paid by EXACT to a governmental entity.

1.3 "Field" shall mean /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ used for /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/

Notwithstanding the foregoing, the "Field" shall not include:

the provision of /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ or the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ for the provision of /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/

/*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ that consist of /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ for the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ of samples of /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ to produce /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/

For the sake of clarity, the parties confirm that the limitation set forth in paragraph (b) of this definition in conjunction with the definition of Specialty Testing operates within the Field to:

(i) INCLUDE within the scope of this license the ability of EXACT and its Sublicensee to provide to /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ for which the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ does not require a /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ or a /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ (including those laboratory services performed as /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ or that are based on /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/), and

(ii) EXCLUDE from the scope of this license the ability of EXACT and its Sublicensee to sell products or services for which /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ requires a /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/

1.4 "Licensed Patents" shall mean, individually and collectively, (i) the U.S. patent(s) identified on Exhibit 1, attached hereto, and any reissues, reexaminations, and extensions thereof, and all Canadian patents or applications corresponding to any of the foregoing; (ii) the U.S. patent applications identified on Exhibit 1, and all Canadian patents or applications corresponding thereto; (iii) all non-provisional, continuation, continuation-in part, divisional and Canadian applications that claim the priority, either directly or indirectly, to any Licensed Patents described in subsection (i) or (ii) above; and (iv) all United States and Canadian patents issued on the Licensed Patents described in subsection (ii) or (iii) above, and all reissues, reexaminations and extensions thereof.

1.5 "Licensed Services" shall mean services that but for this Agreement would infringe a valid and enforceable claim in the Licensed Patents.

1.6 "Intellectual Property" shall mean rights to patents, copyrights, trademarks, trade secrets, proprietary information, know-how and technical data (whether or not patentable) and all other intellectual property rights, in each case whether registered or unregistered and including applications for the grant of any of the foregoing and all rights or forms of protection having equivalent or similar effect to any of the foregoing which may subsist anywhere in the world.

1.7 "License Term" shall mean the period of time from the Effective Date of the Agreement through expiration of the last to expire of the Licensed Patents.

1.8 "Party" or "Parties" shall mean BECKMAN and/or EXACT, as the context requires.

1.9 "Sublicensee" shall mean any entity to which EXACT has granted a sublicense of some or all of the rights conveyed to EXACT under this Agreement.

1.10 "Territory" shall mean the United States and Canada.

1.11 "Test" shall mean a test result per single patient derived from the provision of Licensed Services.

1.12 "Third Party" means any person or entity other than EXACT or BECKMAN.

1.13 /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ means that patent license agreement signed by BECKMAN and /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ on /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/

1.14 "Fluorescence Polarization" means the process by which a fluorescent sample is irradiated with plane-polarized excitation radiation and components of a resultant fluorescent signal are separately detected from the sample which are polarized respectively parallel to and perpendicular to the plane of polarization of the excitation radiation, either on a steady state or time resolved basis relative to the excitation radiation, as and to the extent claimed in any valid, maintained and enforceable U.S. or foreign patent issuing from or claiming priority from U.S. Patent Application Serial No. 09/137,826 entitled Fluorescence Polarization in Nucleic Acid Analysis, filed August 20, 1998, owned or licensed by NEN Life Science Products, Inc.

1.15 "Fluorescence Resonance Energy Transfer" means the process by which a fluorescent sample containing two distinct dyes wherein the sample is irradiated with light energy optimal to excite the first of the two dyes and wherein that first dye upon excitation transfers the energy to the second dye specifically when both dyes are attached to the same primer through a process whereby a nucleic acid template-dependent primer extension reaction determines the identity of a single nucleotide base at a specific position in a nucleic acid of interest, which process is covered by U.S. Patent No. 5,888,819 and 6,004,744 and any divisionals, continuation, reissues and foreign counterparts thereof, and the fluorescence emission of the second dye is detected at second wavelength, as and to the extent claimed in U.S. Patent No. 5,945,283 entitled Methods and Kits for Nucleic Acid Analysis Using Fluorescence Resonance Energy Transfer, issued on December

17, 1996 and owned or licensed by NEN Life Science Products, Inc., and any divisionals, continuations, reissues and foreign counterparts thereof and as and to the extent such NEN patents are valid, maintained and enforceable.

1.16 "Specialty Testing" means:

(a) products and processes for the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ of samples of human, animal or vegetable origin, and

(b) /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ specific receptor proteins, ligands, nucleic acid sequences, and similar reagents which /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ are intended for use in a diagnostic application for /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/

1.17 /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ means:

(a) in the case of the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ and

(b) in the case of countries outside of the United States, /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ with similar responsibilities.

1.18 "Colorectal Cancer Assay" means any /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ (including but not limited to /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ testing).

ARTICLE 2 - GRANT OF LICENSES; OWNERSHIP

2.1 LICENSE GRANT. Subject to the terms and conditions of this Agreement, BECKMAN grants to EXACT a non-exclusive, royalty-bearing license under the Licensed Patents in the Field in the Territory during the License Term, to make, have made, use, offer to sell, sell and import Licensed Services. This license

granted hereunder shall include a limited right to sublicense as herein provided. Nothing in this Agreement will be construed to grant to EXACT any license or rights except under the Licensed Patents and within the Field.

2.2 SUBORDINATION TO /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/. This Agreement will not be construed to grant EXACT (i) any rights that are broader then the rights granted to BECKMAN under the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ with regard to /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ (as that term is defined in the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/; or (ii) a term of license that is longer than the term of the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/

2.3 SUBLICENSING. EXACT shall have the right to sublicense the rights granted in Paragraph 2.1 above only to Laboratory Corporation of America Holdings ("LabCorp"), provided however, that no such sublicense shall be effective until LabCorp executes a written sublicense agreement (the "Sublicense Agreement") with EXACT with respect to the Licensed Services and provided that the terms of the Sublicense Agreement are not inconsistent with and are subordinate to the rights afforded EXACT hereunder. The Sublicense Agreement will include the following provisions of this Agreement: Article 4 - Royalty Reports; Records; Article 7 - Indemnification and Insurance; and, Article 8 - Disclaimer of Warranties; and, Section 10.12 - References to BECKMAN; and further will provide that those provisions are for the benefit of and may be enforced by BECKMAN. EXACT will provide BECKMAN with a copy of the Sublicense Agreement within sixty (60) days after it is executed.

2.4 NO IMPLIED LICENSES. Nothing in this Agreement shall be construed as granting any Party any right or license under any Intellectual Property of the other Party by implication, estoppel or otherwise, except as expressly provided otherwise in this Agreement.

2.5 EXCLUDED FIELD. Notwithstanding anything to the contrary in this Agreement, the licenses granted therein shall not extend to /*/[CONFIDENTIAL TREATMENT

REQUESTED]/*/ or to /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ provided that the foregoing limitation shall (i) only be in force during the shorter of the term of the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ specified in the definitions thereof, or during such time as such /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ are valid, enforceable and maintained and (ii) not limit or restrict EXACT's right to use the Licensed Patents in connection with /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ and /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ to the extent EXACT has obtained license rights to /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ and /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ from an appropriate Third Party.

ARTICLE 3 - ROYALTIES

3.1 ROYALTIES. During the License Term, EXACT shall pay BECKMAN a
/*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ percent /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ royalty on EXACT Net Revenues. EXACT shall pay royalties due with respect to each calendar quarter hereunder within forty-five (45) days after the last day of such calendar quarter.

ARTICLE 4 - ROYALTY REPORTS; RECORDS

4.1 ROYALTY REPORTS. Within forty-five (45) days after March 31, June 30, September 30 and December 31 of each year during the Term, EXACT shall deliver to BECKMAN the royalty payment due pursuant to Section 3.1 hereof and a corresponding royalty report relating to the calendar quarter to which the royalty paid relates. If EXACT Net Revenue includes revenue denominated in a currency other than the currency of the United States of America, those foreign currency sales for each calendar quarter will be converted to the currency of the United States of America at the prevailing rate for the last business day of the quarter as quoted by THE WALL STREET JOURNAL (or if THE WALL STREET JOURNAL is not available

then a comparable publication) or such conversion shall be accomplished by a procedure mutually agreed upon by EXACT and BECKMAN.

4.2 REPORTS. Each royalty report shall include the following:

(a) Identification of the Licensed Services performed by EXACT during the relevant calendar quarter;

(b) The quantity of each Licensed Services performed by EXACT during the relevant calendar quarter;

(c) The Exact Net Revenues for each of the Licensed Services performed by EXACT during the relevant calendar quarter;

(d) Deductions applicable to determining EXACT Net Revenues during the relevant calendar quarter;

(e) Identification of the Licensed Services performed by Sublicensee during the relevant calendar quarter;

(f) The quantity of each Licensed Services performed by Sublicensee during the relevant calendar quarter;

(g) The Exact Net Revenues for each of the Licensed Services performed by Sublicensee during the relevant calendar quarter;

(h) Total royalties due to EXACT from Sublicensee under the sublicense granted under this Agreement during the relevant calendar quarter; and

(i) Total royalties due to BECKMAN for the calendar quarter.

With each report, EXACT shall pay to BECKMAN the royalties due and payable for such calendar quarter in accordance with paragraph 3.1.

4.3 RECORD KEEPING.

4.3.1 BOOKS AND RECORDS. EXACT shall keep complete and accurate records for the latest five (5) years as necessary to establish from source documents and data the EXACT Net Revenues for each Licensed Service. EXACT will maintain such records in sufficient detail and in a manner and context to enable the determination of the amount of royalties due hereunder to BECKMAN.

4.3.2 INSPECTIONS. Upon thirty (30) days' written notice, EXACT agrees to permit one or more auditors appointed by BECKMAN (except any to whom EXACT has a reasonable objection) to enter upon the premises of EXACT during usual business hours of EXACT in order to examine records pertaining to this Agreement for previous quarter(s) and to make on EXACT's premises and retain copies of any and all parts of the records and accounts kept by EXACT pursuant to this Article 4, including invoices and Sublicense payment records and reports which are relevant to any report required to be rendered by EXACT. Said copies shall be provided to the auditor(s) at no expense to the auditor(s) or to BECKMAN. Said auditor(s) shall provide BECKMAN with the amount of the EXACT Net Revenue and the application of the appropriate royalty rate so that royalties due BECKMAN may be calculated for each Licensed Service. In the event such audit establishes that EXACT has underpaid its royalty obligations by /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ or more during any calendar quarter, any amounts found to have been owed but not paid shall be paid to BECKMAN promptly with nine percent (9%) interest per annum. In the event such audit establishes that EXACT has underpaid its royalty obligations by /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ or more during any calendar quarter, EXACT shall reimburse BECKMAN for the out-of-pocket expense of such audit. BECKMAN shall not make more than one audit request annually.

4.4 FORM OF PAYMENTS. EXACT shall make all payments due under this Agreement by check or wire transfer in United States funds.

4.5 LATE PAYMENT. If EXACT does not make any payment under this Agreement when due, the payment will accrue interest from the date due at the rate of one percent 0.75% per month; PROVIDED, HOWEVER, that in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit BECKMAN from exercising any other rights it may have as a consequence of the lateness of such payment.

ARTICLE 5 - CONFIDENTIALITY

5.1 CONFIDENTIAL INFORMATION. During the Term, the Parties may exchange information from time to time that they consider to be confidential. "Confidential Information" hereunder shall, subject to Article 5.3, mean the substance of this Agreement, the Sublicense Agreement and any information or materials that are disclosed by EXACT to BECKMAN or auditors for BECKMAN under Article 4, Royalty Reports; Records, whether orally, visually, or in tangible form, and all copies thereof. Tangible materials that disclose or embody Confidential Information shall be marked by the disclosing party as "Confidential," "Proprietary" or the substantial equivalent thereof. Confidential Information that is disclosed orally or visually shall be identified by the disclosing Party as confidential at the time of disclosure and reduced to a written summary by the disclosing Party, which shall mark such summary as "Confidential," "Proprietary" or the substantial equivalent thereof, and deliver it to the receiving Party by the end of the month following the month in which disclosure occurs. Such information shall be treated as Confidential Information pending receipt of such summary.

5.2 TREATMENT OF CONFIDENTIAL INFORMATION. The Party receiving Confidential Information shall employ all reasonable efforts to maintain the secrecy and confidentiality of such Confidential Information, such efforts to be no less than the degree of care employed by the receiving Party to preserve and safeguard its

own Confidential Information. The information shall not be disclosed or revealed to anyone except employees of the recipient who have a need to know the information and who are required to maintain confidential the proprietary information of the receiving Party and such employees shall be advised by the receiving Party of the confidential nature of the Confidential Information and that the Confidential Information shall be treated accordingly. Each Sublicensee shall be bound, as a receiving Party, not to disclose the Confidential Information of BECKMAN, whether such Confidential Information is provided by BECKMAN or by EXACT; and both the Sublicensee and EXACT shall be jointly and severally liable for any breach of such obligation by the Sublicensee.

5.3 EXCEPTIONS. The receiving party's obligations under this Article 5 shall not extend to any part of the information that:

(i) can be demonstrated to have been in the public domain or publicly known prior to the date of the disclosure; or

(ii) can be demonstrated from written records to have been in the possession of the receiving Party or readily available to the receiving Party from another source not under obligation of secrecy to the disclosing Party prior to the disclosure; or

(iii) becomes part of the public domain or publicly known other than as a result of any unauthorized act by the receiving Party; or

(iv) is demonstrated from contemporaneous written records to have been developed by or for the receiving Party without reference to confidential information disclosed by the disclosing Party; or

(v) is required to be disclosed by law, government regulation or court order.

However, the exception set forth in Section 5.3(v) shall only apply if, prior to making any legally required disclosure of the disclosing Party's Confidential Information, the receiving Party notifies the disclosing Party and affords the

disclosing Party a reasonable opportunity to defend against or limit such required disclosure.

5.4 INJUNCTION. In view of the difficulties of placing a monetary value on the Confidential Information, the disclosing Party shall be entitled to a preliminary and final injunction without the necessity of posting any bond or undertaking in connection therewith to prevent further breach of this Article 5 or further unauthorized use of its Confidential Information. This remedy is separate from any other remedy the disclosing Party may have.

5.5 TREATMENT UPON TERMINATION OF THE AGREEMENT. Upon the expiration or termination, for any reason, of this Agreement, or upon the demand of the disclosing Party at any time, the receiving Party shall return promptly to the disclosing Party or destroy, at option of the disclosing Party, all tangible materials that disclose or embody Confidential Information of the disclosing Party, unless otherwise prohibited by law. Notwithstanding the foregoing, BECKMAN may retain all EXACT royalty reports, royalty payment records and communications concerning royalties paid or payable by EXACT or Sublicensee.

ARTICLE 6 - REPRESENTATIONS AND WARRANTIES

6.1 BECKMAN REPRESENTATIONS AND WARRANTIES. BECKMAN hereby represents and warrants to EXACT that:

6.1.1 BECKMAN is a corporation duly organized and validly existing in the State of Delaware, and has all requisite power and authority to execute, deliver and perform its obligations under this Agreement and to consummate the transactions contemplated hereby;

6.1.2 This Agreement does not contravene or constitute a default under or violation of any provision of applicable law binding upon BECKMAN or any agreement, commitment, instrument or other arrangement to which BECKMAN is a party;

6.1.3 To the knowledge of BECKMAN, all necessary consents, approvals and authorizations of all governmental authorities and other persons required to be obtained in connection with entry into this Agreement have been obtained;

6.1.4 The /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ has been fully executed, is in effect as of the date that BECKMAN signs this Agreement and includes the right for BECKMAN to convey the rights provided in this Agreement herein, and;

6.1.5 BECKMAN has no actual knowledge of any claim brought by a Third Party in a federal court or before the U.S. Patent Office that asserts that the Licensed Patents are invalid.

6.2 EXACT REPRESENTATIONS AND WARRANTIES. EXACT hereby represents and warrants to BECKMAN that:

6.2.1 EXACT is a corporation duly organized and validly existing under the laws of the State of Delaware and has all requisite corporate power and authority to execute, deliver and perform its obligations under this Agreement and to consummate the transactions contemplated hereby;

6.2.2 This Agreement does not contravene or constitute a default or violation of any provision of applicable law binding upon EXACT or any agreement, commitment or instrument to which EXACT is a party; and,

6.2.3 EXACT has conducted its own analysis of the Licensed Patents and the Licensed Services in assessing whether any product or process made, used, sold or imported under any Licensed Patents will be free from infringement of patents, copyrights or other rights not licensed hereunder or patents, copyrights or other rights of any Third Party and has obtained such legal opinions as necessary or appropriate.

ARTICLE 7 - INDEMNIFICATION & INSURANCE

7.1 INDEMNIFICATION OF BECKMAN. EXACT will save, defend, indemnify and hold harmless BECKMAN and its Affiliates, and the officers, directors and employees of any of them ("BECKMAN INDEMNITEES") from and against any and all losses, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys' fees, ("LOSSES") to which any of them may become subject as a result of any claim, demand, action or proceeding by any Third Party to the extent such Losses arise out of
(i) the research, development, manufacture, production, supply, promotion, import, sale or use by EXACT or its sublicensees, contractors or customers of any products or services, (ii) the conduct of any research and development by EXACT or its sublicensees, including, without limitation, clinical trials, conducted with respect to the products, processes or services licensed under this Agreement, or (iii) a breach by EXACT of any of its representations and warranties contained in this agreement, except to the extent such Losses result from the gross negligence or willful misconduct of Beckman Indemnitees or the breach of this Agreement by BECKMAN. If BECKMAN seeks indemnification hereunder, it will inform EXACT of the claim as soon as reasonably practicable after it receives notice of the claim, will permit EXACT to assume direction and control of the defense of the claim (including the right to settle the claim solely for monetary consideration), and will cooperate as requested (at the expense of EXACT) in the defense of the claim.

7.2 INSURANCE. During the term of this Agreement, EXACT, at its own expense, will maintain commercial general liability insurance, including products liability and, if necessary, commercial umbrella insurance, related to and covering the development, production, use, and sale of the Licensed Services. The limits of insurance maintained by EXACT for bodily injury and/or death and property damage for any one occurrence shall be at least Four Million U.S. Dollars (U.S. $4,000,000), and for the products and completed operations aggregate, shall be at least Two Million U.S. Dollars (U.S.$2,000,000). Such insurance will be written by companies having an A.M. Best rating of no lower than A - "X". BECKMAN

and its Affiliates will be named as additional insureds under such insurance policies. Such insurance shall be written to cover claims incurred, discovered, manifested, or made during or after the expiration of this Agreement. EXACT will provide a certificate of insurance evidencing such coverage as primary coverage and requiring thirty (30) days prior written notice to BECKMAN of cancellation or material change. All such insurance of BECKMAN and its Affiliates shall be noncontributory.

7.3 INDEMNIFICATION OF EXACT. BECKMAN will save, defend, indemnify and hold harmless EXACT and its officers, directors and employees ("EXACT INDEMNITEES") from and against Losses to which any of them may become subject as a result of any claim, demand, action or proceeding by any Third Party to the extent such Losses arise from the breach by BECKMAN of the warranty and representations made by BECKMAN in section 6.1, "BECKMAN Warranties and Representations." Without limiting the foregoing, BECKMAN will not be obligated under this paragraph to the extent such Losses result from the acts or omissions of Exact Indemnitees or the breach of this Agreement, including the representations and warranties made by EXACT within it, by EXACT.

7.4 INDEMNIFICATION OF EXACT IF /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ this Sublicense. BECKMAN will save, defend, indemnify and hold harmless Exact Indemnitees from and against Losses to which any of them may become subject as a result of a action or proceeding by /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/, a corporation organized under the laws of the State of Delaware and having a place of business located at /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ to the extent relating to (i) BECKMAN's rights to grant sublicenses under /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ or (ii) the right of BECKMAN to enter this Agreement with EXACT, and seeking to invalidate this Agreement on that basis, except to the extent such Losses result from the acts or omissions of Exact Indemnitees or the breach of this Agreement, including the representations and warranties made by EXACT within it, by EXACT.

7.5 EXACT INDEMNIFICATION PROCESS. If EXACT seeks indemnification under paragraph 7.3 or 7.4 above, it will inform BECKMAN of the claim as soon as reasonably practicable after it receives notice of the claim, will permit BECKMAN to assume direction and control of the defense of the claim (including the right to settle the claim solely for monetary consideration), and will cooperate as requested (at the expense of BECKMAN) in the defense of the claim.

ARTICLE 8 - DISCLAIMERS

8.1 DISCLAIMERS. Nothing in this Agreement will be construed as:

(i) a warranty or representation by BECKMAN as to the validity or scope of Licensed Patents;

(ii) a warranty or representation by BECKMAN that the Licensed Services or any product or process made, used, sold or imported under any Licensed Patents is or will be free from infringement of patents, copyrights or other rights not licensed hereunder or patents, copyrights or other rights of any Third Party;

(iii) conferring by implication, estoppel or otherwise any license or rights under any Intellectual Property belonging to BECKMAN other than the Licensed Patents as defined in this Agreement; or

(iv) an obligation by BECKMAN to furnish know-how or any other information to EXACT not provided in the Licensed Patents.

8.2 NO OTHER WARRANTIES. EXCEPT AS EXPRESSLY PROVIDED HEREIN, NEITHER PARTY MAKES ANY WARRANTIES WITH RESPECT TO THE LICENSED SERVICES AND DISCLAIMS ALL OTHER WARRANTIES AND CONDITIONS, EXPRESS OR IMPLIED, INCLUDING THOSE OF MERCHANTABILITY, AND FITNESS FOR A PARTICULAR PURPOSE, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICE, TO THE EXTENT PERMITTED BY APPLICABLE LAW.

8.3 THIRD PARTY INFRINGEMENTS. Neither Party shall have any obligation with respect to the abatement of infringement of the Licensed Patents by third parties. However, if at any time a Third Party shall infringe any unexpired Licensed Patents and if such infringement shall come to the attention of a Party, that Party will give notice in writing to the other Party of the existence of such infringement. BECKMAN will decide on an appropriate course of action to take with respect to the infringement in view of all of the circumstances then existing.

ARTICLE 9 - TERM AND TERMINATION

9.1 TERM. This Agreement shall commence on the Effective Date and shall remain effective for the period of the License Term, unless earlier terminated as provided by this Agreement.

9.2 TERMINATION FOR BREACH. Either Party may terminate this Agreement if the other Party materially breaches its obligations hereunder, and such breach is not cured within sixty (60) days after written noticed thereof to such other Party.

9.3 EFFECT OF TERMINATION ON SUBLICENSE. Upon early termination of this Agreement for any reason, all sublicenses granted under it shall terminate. EXACT shall notify each Sublicensee of the termination and each Sublicensee shall have the rights to request BECKMAN to continue the sublicense. The request by the Sublicensee must be received by BECKMAN no later than thirty days after the termination date of this Agreement. Upon receipt of such request and receipt of proof from the Sublicensee, if reasonably requested by BECKMAN, of the Sublicensee's ability to pay BECKMAN royalties when due, BECKMAN will continue the Sublicensee's sublicense for the period equal to the shorter of the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ of this Agreement or the unexpired term of /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ on condition that /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ remains in /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ and continues its /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ In the event of continuation of the sublicense, Sublicensee shall pay BECKMAN

/*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ received by Sublicensee (less the deductions described in 1.2(ii) above) relating to Sublicensee's direct provision of Licensed Services. For the avoidance of confusion, Sublicensee's Licensed Services under such circumstances shall mean the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ received by Sublicensee for the particular test being provided (of which the Licensed Service is comprised). Unless BECKMAN expressly elects to assume obligations of EXACT to Sublicense arising under the sublicense agreement, those obligations will remain the responsibility of EXACT to satisfy and EXACT will defend, indemnify and hold BECKMAN harmless from any claim arising with regard to those obligations.

9.4 SUBLICENSEE DUTIES AT TERMINATION. Except if termination resulted from expiration of the License Term, upon termination of this Agreement:

9.4.1 EXACT immediately will cease and then shall not engage in any activity that would infringe the Licensed Patents;

9.4.2 Subject to Section 9.3, Effect of Termination on Sublicense, Sublicensee immediately will cease and then shall not engage in any activity that would infringe the Licensed Patents.

9.5 OUTSTANDING PAYMENTS AND REPORTS AT TERMINATION. Termination of this Agreement for any reason shall be without prejudice to BCI's right to receive all payments and reports that may be or become due under Article 3 - Royalties, and Article 4 - Royalty Reports; Records.

9.6 SURVIVAL. The following Articles shall survive the termination of this Agreement for any reason: Article 1 - Definitions; Article 4 - Royalty Reports; Records; Article 5 - Confidentiality; Article 7 - Indemnification; and, Article 10 - Miscellaneous.

ARTICLE 10 - MISCELLANEOUS

10.1 NOTICES TO BECKMAN. Unless otherwise specified in this Agreement, reports, notices and other communications from EXACT to BECKMAN as provided hereunder must be sent to:

Beckman Coulter, Inc.
President, Biomedical Research Division
4300 N. Harbor Boulevard,
Fullerton, California 92835

Telephone: (714) 871-4848
Facsimile: (714) 773-8543

WITH A COPY TO:

Beckman Coulter, Inc.
General Counsel
4300 N. Harbor Boulevard,
Fullerton, California 92835

Telephone: (714) 773-6973
Facsimile: (714) 773-7936

or other individuals or addresses as BECKMAN subsequently furnish by written notice to EXACT.

10.2 NOTICES TO EXACT. Unless otherwise specified in this Agreement, reports, notices and other communications from BECKMAN to EXACT as provided hereunder must be sent to:

EXACT Sciences Corporation
100 Campus Drive
Marlborough, MA 01752

Attention: President

WITH A COPY TO:

EXACT Sciences Corporation
100 Campus Drive
Marlborough, MA 01752

Attention: General Counsel

or other individuals or addresses as EXACT subsequently furnish by written notice to BECKMAN.

10.3 INDEPENDENT CONTRACTORS. The Parties agree that, in the performance of this Agreement, they are and shall be independent contractors. Nothing herein shall be construed to constitute a partnership or joint venture between the Parties nor shall any Party be construed as the agent of any other Party for any purpose whatsoever, and no Party shall bind or attempt to bind any other Party to any contract or the performance of any obligation, or represent to any third party that it has any right to enter into any binding obligation on the other Party's behalf.

10.4 SEVERABILITY. If any one or more of the provisions of this Agreement is held to be invalid, illegal or unenforceable, the validity, legality or enforceability of the remaining provisions of this Agreement will not in any way be affected or impaired thereby.

10.5 NON-ASSIGNABILITY.

10.5.1 PERMITTED ASSIGNMENTS. Either Party may assign this Agreement and its rights and obligations hereunder to an acquirer of all or substantially all of such Party's business or assets, whether by merger, sale, acquisition or other change of control transaction, but only if it has notified the other party of the proposed permitted assignment not less than thirty (30) days prior to the effective date of the assignment. In the case of a permitted assignment by EXACT, BECKMAN may require EXACT to provide

BECKMAN with a written agreement that the assignee accepts and will comply with all terms and conditions of this Agreement and with reasonable evidence of the capability of the assignee to satisfy the obligations of EXACT under this Agreement. In addition, BECKMAN may require that any breach by EXACT be cured prior to the assignment. For the avoidance of confusion and for the purposes of calculating EXACT Net Revenues following an assignment, Licensed Services shall mean the /*/[CONFIDENTIAL TREATMENT REQUESTED]/*/ received by a Third Party assignee (under section 1.2(i) above) or received by the assignee (under section 1.2(ii) above) for the particular test being provided (of which the Licensed Service is comprised).

10.5.2 RESTRICTED ASSIGNMENTS. Except as allowed in the paragraph 10.5.1, "Permitted Assignments," neither this Agreement nor any part of the Agreement is assignable or in any way transferable by either Party without the express written consent of the other Party, which shall not be unreasonably withheld, delayed or conditioned, and any attempted or purported assignment or other transfer made without consent will be void and without effect.

10.5.3 BINDING EFFECT. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and assigns.

10.6 ENTIRE AGREEMENT. This instrument contains the entire Agreement between the Parties. No verbal agreement, conversation or representation between any officers, agents, or employees of the Parties either before or after the execution of this Agreement may affect or modify any of the terms or obligations herein contained.

10.7 MODIFICATIONS IN WRITING. No change, modification, extension, or waiver of this Agreement, or any of the provisions herein contained is valid unless made in writing and signed by a duly authorized representative of each Party.

10.8 GOVERNING LAW. The validity and interpretation of this Agreement and the legal relations of the Parties to it are governed by the laws of the State of Delaware without regard to any choice of law principal that would dictate the application of the law of another jurisdiction. The Parties agree that any legal action arising out of or in connection with this Agreement shall be brought in the federal or state courts for the Orange County, California, and the Parties irrevocably submit for all purposes to the jurisdiction of each such court.

10.9 CAPTIONS. The captions are provided for convenience and are not to be used in construing this Agreement.

10.10 COUNTERPARTS. This Agreement may be executed in counterparts, each of which shall be deemed an original and all of which when taken together shall be deemed but one instrument.

10.11 FORCE MAJEURE. If either Party fails to fulfill its obligations hereunder (other than an obligation for the payment of money), when such failure is due to an act of God, or other circumstances beyond its reasonable control, including but not limited to fire, flood, civil commotion, riot, war (declared and undeclared), acts of terrorism, revolution, or embargoes, then said failure shall be excused for the duration of such event and for such a time thereafter as is reasonable to enable the Parties to resume performance under this Agreement.

10.12 REFERENCES TO BECKMAN. EXACT agrees not to identify BECKMAN or its Affiliates in any promotional advertising or other promotional materials to be disseminated to the public or any portion thereof or to use the name of BECKMAN or any of its Affiliates, or any trademark, service mark, trade name or symbol of BECKMAN or its Affiliates, without BECKMAN's prior written consent, unless otherwise required by law.

10.13 NONDISCLOSURE OF AGREEMENT & PRESS RELEASES. EXACT may disclose this Agreement to its Sublicensee under a requirement to maintain it in confidence. Except as required by law, neither Party otherwise shall disclose the terms of this Agreement to any Third Party without the written consent of the other Party. Neither Party shall issue any press release or other statement to the media concerning the existence of this Agreement.

IN WITNESS WHEREOF, the Parties hereto have caused this agreement to be executed in quadruplicate by their duly authorized representatives as of the date first above written.

BECKMAN COULTER, INC.	*EXACT SCIENCES CORPORATION*
By: /s/ Elias Caro	*By: /s/ Don Hardison*
Name: Elias Caro	*Name: Don Hardison*
Title: President, BMR Division	*Title: President, CEO*
Date: July 31, 2003	*Date: July 28, 2003*

EXHIBIT 1

LICENSED PATENTS

/*/[CONFIDENTIAL TREATMENT REQUESTED]/*/

EXHIBIT 12.1

COMPUTATION OF RATIOS OF EARNINGS TO FIXED CHARGES AND EARNINGS TO COMBINED FIXED CHARGES AND PREFERRED STOCK DIVIDENDS
(IN THOUSANDS, EXCEPT RATIO DATA)

	FISCAL YEAR ENDED DECEMBER 31,				
	2003	2002	2001	2000	1999
Loss before benefit for taxes on loss	$(28,340)	$(29,883)	$(23,485)	$(11,883)	$(4,964)
Add-fixed charges	174	70	60	43	29
Income before taxes and fixed charges	(28,166)	(29,813)	(23,425)	(11,840)	(4,935)
Fixed charges:					
Estimated interest component of rental expense	174	70	60	43	29
Ratio of earnings before taxes and fixed charges To fixed charges	(1)	(1)	(1)	(1)(2)	(1)(2)

(1) During each of these periods, our earnings were less than our fixed charges. The amount of such deficiency was approximately $15.8 million for the six months ended June 30, 2003, and $29.9 million, $23.5 million, $11.9 million, $5.0 million and $3.6 million for fiscal years 2002, 2001, 2000, 1999 and 1998, respectively.

(2) During each of these periods, our earnings were less than our combined fixed charges and preferred dividends. The amount of such deficiency was approximately $11.9 million, $5.0 million and $3.6 million for fiscal years 2000, 1999 and 1998, as dividends were at the discretion of the board of directors none of which were declared.

EXHIBIT 23.1

CONSENT OF INDEPENDENT AUDITORS

We consent to the incorporation by reference in the Registration Statements (Form S-3 No. 333-108679, Form S-8 No. 333-107840 and Form S-8 No. 333-54618) of EXACT Sciences Corporation and in the related Prospectuses of our report dated January 23, 2004, with respect to the consolidated financial statements of EXACT Sciences Corporation included in this Annual Report (Form 10-K) for the year ended December 31, 2003.

/s/ Ernst & Young LLP

Boston, Massachusetts
January 28, 2004

EXHIBIT 23.1(A)

INFORMATION REGARDING CONSENT OF ARTHUR ANDERSEN LLP

As previously disclosed in the Company's Form 8-K filed on May 7, 2002, the Company replaced Arthur Andersen LLP as its independent public accountants and announced that the Company had appointed Ernst & Young LLP as its independent auditors.

After reasonable efforts, the Company was unable to obtain the written consent of Arthur Andersen LLP to incorporate by reference its report dated July 31, 2002.

The absence of this consent may limit recovery against Arthur Andersen LLP under Section 11 of the Securities Act. In addition, as a practical matter, the ability of Andersen to satisfy any claims (including claims arising from Arthur Andersen LLP's provision of auditing and other services to the Company and Arthur Andersen LLP's other clients) may be limited due to recent events regarding Arthur Andersen LLP, including without limitation its conviction on federal obstruction of justice charges arising from the federal government's investigation of Enron Corp.

EXHIBIT 31.1

CERTIFICATIONS

I, Don M. Hardison, certify that:

1. I have reviewed this annual report on Form 10-K of EXACT Sciences Corporation;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report on Form 10-K, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: January 29, 2004

By: /s/ Don M. Hardison

Don M. Hardison
President, Chief Executive Officer and Director
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATIONS

I, John A. McCarthy, Jr., certify that:

1) I have reviewed this annual report on Form 10-K of EXACT Sciences Corporation;

2) Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3) Based on my knowledge, the financial statements, and other financial information included in this annual report on Form 10-K, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4) The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5) The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6) The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: January 29, 2004

By: /s/ John A. McCarthy, Jr.

John A. McCarthy, Jr.
Executive Vice President, Chief Financial Officer and Treasurer
(Duly Authorized Officer and Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of EXACT Sciences Corporation (the "Company") on Form 10-K for the period ending December 31, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Don M. Hardison, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Don M. Hardison

Don M. Hardison
Chief Executive Officer
January 29, 2004

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of EXACT Sciences Corporation (the "Company") on Form 10-K for the period ending December 31, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John A. McCarthy, Jr., Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ John A. McCarthy, Jr.

John A. McCarthy, Jr.
Chief Financial Officer
January 29, 2004