EXACT sciences

ANNUAL REPORT 2001

Applying Genomics to Eradicate Cancer™

EXACT Sciences is focused on a core belief: the early detection of cancer saves lives.

To that end, we have developed proprietary technologies using information from the human genome that may be used for the early detection of cancer. Our first target is colorectal cancer. Colorectal cancer is the most deadly cancer among non-smokers, yet is completely curable—*if* discovered early. Still, despite the long-standing availability of screening and diagnostic tests for colorectal cancer, the rate of early detection remains startlingly low. EXACT Sciences intends to change that by developing screening technologies that combine the accuracy of genomic information with the patient-friendly attributes of being safe, simple and easy to use.

Conquering the barriers associated with colorectal cancer screening is a formidable challenge—but we will not stop there. We believe our technologies may be extensible to other clinical problems—both in cancer and potentially in other disease areas. Although our primary focus remains bringing our PreGen™ technologies for colorectal cancer detection to market, we intend to explore these additional opportunities as well.

Ginger Bengochea
Patient

"Before a problem can be solved, it must be identified."

2001 Milestones

- **Successful IPO:** Completed just before the capital markets closed to IPOs; net proceeds of $51 million are supporting aggressive commercialization of proprietary technologies to detect colorectal cancer.
- **First commercial launch:** EXACT Sciences' first product, PreGen-26™, the first genomics-based test for the detection of cancer in patients with Hereditary Non-Polyposis Colon Cancer (HNPCC), was introduced nine months ahead of schedule.
- **First clinical reference laboratory alliance:** Partnership agreement enables Laboratory Corporation of America® Holdings (LabCorp®) to offer testing services based on PreGen-26 technology.
- **Major multi-center clinical study:** Fifteen to eighteen-month trial designed to validate the sensitivity and specificity of PreGen-Plus™ in an average-risk, asymptomatic population. The study involves five thousand patients in more than sixty centers nationwide.
- **Mayo Clinic study funded by National Cancer Institute:** Four thousand patient study, funded by $4.9 million grant from the National Cancer Institute of the National Institutes of Health, designed to further validate PreGen technology.

PreGen technology purifies and analyzes the DNA found in human stool and is designed to detect mutations that may be an indication of existing disease. Our first product—PreGen-26—detects mutations associated with an hereditary form of colorectal cancer; it is targeted for use by a small but very high-risk population. PreGen-Plus detects a broader range of mutations and will be used in the average-risk population.

Don M. Hardison
President and CEO

Stanley N. Lapidus
Chairman

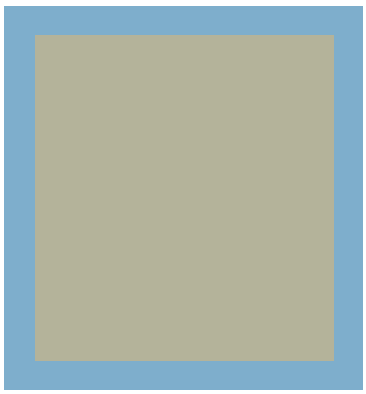
Letter to our Shareholders:

2001 was an important year for EXACT Sciences, as it marked our first year as a public company. It also marked a year of pivotal milestones along a clear path towards achieving our mission of eradicating the mortality associated with colorectal cancer. While this mission may seem audacious, we believe that we are developing the technologies and the business model that will allow us to work with the medical community to accomplish just that.

We believe—in fact, we know—that many of the lives lost to cancer do not have to be lost. Cancer, in many cases, is almost completely curable, *if caught at an early stage*. Colorectal cancer, our first target, is undeniably one of those cancers. There is virtually no argument among the medical community that detecting colorectal cancer at an early stage results in a cure rate of more than 90%. The tragedy is that most cases of colorectal cancer —approximately two-thirds of the 150,000 people who will be diagnosed with colorectal cancer this year— are diagnosed at a later stage, when the cure rate is less than 50%. Based on the hundreds of samples we have tested to date, we believe that our proprietary PreGen technology can be used to detect colorectal cancer at an early stage, and will do so accurately, safely, and non-invasively.

There were numerous accomplishments throughout the year, but let me highlight a few. To begin, we completed our initial public offering during a very difficult market. We believe that is an indication of how you, our investors, feel about what we are doing. In addition, we launched our first commercial product, PreGen-26, in June 2001, for those afflicted with Hereditary Non-Polyposis Colorectal Cancer, or HNPCC. The market for PreGen-26 is quite small, but the people afflicted with HNPCC have approximately an 80% lifetime risk of developing colorectal cancer. We thought it important that we get a product on the market that could help detect cancer in this population. PreGen-26 is an extremely sensitive and specific test, and we are proud to be doing our part to give physicians and patients a test that can aid in combating this disease. We also signed a strategic partnership agreement with Laboratory Corporation of America Holdings to distribute PreGen-26. This was an important step for us as it validated our technology and gave us access to LabCorp's distribution, processing, sales and billing organizations and set the stage for future collaborations.

We also made tremendous progress on the research side of our company. We had a number of abstracts presented at major medical meetings. We were also pleased to have six new patents issued during the year. We believe in the power of a DNA-based analysis for the early detection of cancer. We think the precision and elegance of DNA-based approaches—which directly probe the prime moving force that causes cells to turn cancerous—give us a distinct competitive and clinical advantage over other testing approaches. Using DNA offers us a



unique opportunity to continually increase the sensitivity (the ability to find disease if present) of our tests without negatively affecting specificity (the ability of our test to correctly identify a patient without disease). It also means that we will continually work to improve the performance characteristics of our assays.

At the same time, we continue to make significant advances in assay and process improvements. As part of this effort, we acquired a technology called *Hybrigel*™ and are making good progress toward implementing it into our sample preparation system. We are very optimistic about what this technology can do for us and for our partners. We believe it will allow us to continue our leadership role in extracting DNA from complex samples, which should make the subsequent task of DNA analysis all the more accurate and robust.

On the clinical front, we participated in numerous clinical studies through collaborations with prestigious investigators and institutions. To date, we have analyzed stool samples from over 150 patients with colorectal cancer. As we build a body of scientific evidence to support the performance characteristics of our PreGen technology, we are confident that we are indeed developing an important new tool in the fight against colorectal cancer.

One of our important clinical studies was initiated in the second half of 2001, with over sixty sites from around the country participating in the study. This five-thousand patient study for an average-risk, asymptomatic population is without precedent for a DNA diagnostic. We anticipate completing enrollment by the end of the first quarter of 2003, with data available in the second half of 2003. Additionally, Mayo Clinic and several other academic centers began a four-thousand patient study of our technology funded by a $4.9 million grant from the National Cancer Institute. We believe the results from these studies will provide supplemental information that will enhance PreGen's credibility with practitioners, payors, advocacy groups, those who set cancer screening guidelines, and the public. The studies also have the potential to develop advocates among the hundreds of gastroenterologists who are participating in them. I hope you will agree that 2001 was truly a year during which your company made great strides forward.

2002 promises even more. There are 80 million people over the age of 50 who, according to the American Cancer Society, should be screened regularly for colorectal cancer. Our objectives center around making PreGen-Plus, our assay to detect colorectal cancer in an average-risk, asymptomatic population, commercially available to as many people as possible, as soon as possible. Our business model and our strategy are designed to expedite this process. We believe we have developed a model that allows us to do what we do best—research and development and demand creation—while partnering with clinical laboratories to offer broad distribution.

We are in active partnership discussions with large clinical reference laboratories that will facilitate the commercialization of PreGen-Plus. Once we enter such a partnership, it should be a matter of months before PreGen-Plus will be on the market. We are also in preliminary negotiations with *in vitro* diagnostic partners for strategic relationships that should broaden the distribution of our technologies over the coming years. Because of the proprietary nature of our DNA-based technologies, the sheer size of the markets we are attacking, and the high margins and recurring revenue aspects of our business model, we believe we are a very attractive partner for both commercial laboratories and *in vitro* diagnostic companies.

In terms of demand creation, we are building a highly targeted, strategic accounts team which will work to educate medical thought leaders, managed care organizations and other payors about our technology. Our strategic marketing programs are designed to create broad-based demand for our PreGen-Plus assay with physicians, payors, employers and consumers.

Our research department will continue to be an area of differentiation, as it remains keenly focused on developing proprietary new technologies that aid in the detection of colorectal and other cancers. As an indication of the scientific progress we are making, we had eleven abstracts accepted at the Digestive Disease Week meeting to be held this month. Let me highlight three of the studies discussed in these abstracts, as they are indicative of the major progress we are making:

- Increasing the sensitivity of our assays without negatively affecting the specificity is a major research objective. One DDW abstract describes a study led by Tony Shuber, our Chief Technology Officer, and his team in collaboration with Dr. David Ahlquist of Mayo Clinic that uses hypermethylated DNA markers in a novel stool-based test for detection of colorectal cancer. Although more study is needed, the potential promise of this could be an increase in our ability to pick up cancers without a significant increase in false-positives. By adding new markers with a wary eye on the cost-benefit equation, we can optimize the ability of our assays to detect mutations associated with colorectal cancer.
- The second study illustrates our efforts to simplify the process for screening for mutations associated with colorectal cancer. It discusses a novel new scanning technology developed by Tony and his team that we call Digital Oligonucleotide Tiling, or DOT. This is a very simple and efficient method of screening for mutations. It will allow us to identify mutations within gene sequences without prior knowledge of the mutations. DOT could lead to a reduction of assay complexity while retaining or increasing clinical sensitivity. It will allow us to continue developing next generation assays for the detection of cancer and significant adenomas without changing the assay formulation.

- Finally, there is our constant effort to detect earlier and earlier stages of developing colorectal cancer. An obvious big win would be the detection of advanced colonic polyps, especially those with high-grade dysplasia or *carcinoma-in-situ* (CIS), which have the highest likelihood of progressing to invasive malignancy. We have a number of efforts underway to prove our ability to detect these advanced polyps in the pre-malignancy stage. One such study is described in an abstract co-authored by Dr. Barry Berger from EXACT Sciences with Dr. Jeremy Ditelberg of the Beth Israel Deaconess Medical Center in Boston. In it, we were able to identify mutations in tissue taken from advanced polyps. We have used a similar technique to identify these same mutations in stool samples. This presents the possibility of finding these same mutations in the stools of patients with high-grade dysplasia and CIS that are likely to be deadly if left undetected. If this continues to bear out, it truly could lead to early detection and would be an important step in saving lives.

We've also had three publications highlighting our technology in peer-reviewed journals thus far this year. One of them is a wonderful example of the power of our focused approach on DNA that was published in the January 31, 2002, *New England Journal of Medicine*. EXACT Sciences' Chief Technology Officer, Tony Shuber, and one of his fine scientists, Kevin Boynton, were among the co-authors of the article entitled "Detections of APC Mutations in Fecal DNA from Patients with Colorectal Tumors." This study, which was the result of a collaboration with the Howard Hughes Medical Institute, the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins School of Medicine, M.D. Anderson, the Lahey Clinic, and others, describes a scanning method called Digital Protein Truncation that has been exclusively licensed to EXACT Sciences and should be a valuable addition to other methodologies that scan for unknown mutations that we are in the process of optimizing.

In closing, we believe it is not often that a corporation finds its mission so perfectly aligned with that of groups such as the American Cancer Society or the National Colorectal Cancer Research Alliance, or even with the interests of the United States Congress, where so many members have gotten behind colorectal cancer screening. It is, however, the case for EXACT Sciences. There is no controversy about whether early detection saves lives with this cancer. It is a cancer that no one should die from and yet every year, 57,000 Americans do. Often, they die because their cancer was detected at too late a stage. They die because they were not part of a regular screening program, because the tests currently available are inaccurate or invasive and not adequately complied with by the patient. This year, another 150,000 Americans will be diagnosed with colorectal cancer and two-thirds of those Americans, or 100,000 people, will have less than a 50% chance of surviving more than five years. If those cancers were detected at an earlier stage, those survival rates would be a lot closer to 90%.

We at EXACT Sciences believe that our technology will increase the rate of early detection of colorectal cancer and will save people's lives. We are proud to be at the absolute forefront of this great effort and look forward to doing our part in eradicating mortality from this terrible disease.

We thank you for your support in this important effort.

Don M. Hardison
President and CEO

The Physician Perspective
Henry T. Lynch, MD

Creighton University is home to cancer expert Dr. Henry T. Lynch. Dr. Lynch's groundbreaking study of Hereditary Non-Polyposis Colorectal Cancer (HNPCC) has made early detection—and thus timely treatment—possible; indeed, the disease is commonly referred to as Lynch Syndrome. One key to his studies: A registry that tracks patients with HNPCC and their families, thus documenting patterns in cancer genetics. Dr. Lynch collaborated with EXACT Sciences in a pilot study dealing with the efficacy of PreGen-26.

Below, both Dr. Lynch and Ginger Bengochea, a participant in the registry, comment on the disease, the registry and the importance of concrete information.

The usefulness of disease monitoring tools is enhanced by the availability of thorough, detailed family histories.

Colorectal cancer is so common that a person may have two or more relatives affected due to chance alone. However, colorectal cancer can be inherited. Hereditary Non-Polyposis Colorectal Cancer, one type of hereditary colorectal cancer, accounts for 3% to 6% of all colorectal cancer cases. In families afflicted with HNPCC, multiple members are affected, often at a young age—the average age of onset of the cancer being about 45. Other cancers, such as endometrial and ovarian, also occur more frequently in these families.

Since I first began working with hereditary colorectal cancer patients, I have seen hundreds of HNPCC families all across the United States and the world. I have traveled extensively throughout Europe and the Orient, lecturing about hereditary colorectal cancer. Over the years, we have acquired over 30,000 patients in our registry.

The patients in the registry are either physician- or self-referred. They come to us because they have symptoms or because they know they have a family history of colon cancer and want to know its significance. Many of them are concerned about being at higher-than-average risk for developing the disease.

Once someone is identified as likely to have HNPCC, the most important thing they can do is to undergo regular screening for colorectal cancer. They should have an annual colonoscopy due to the rapid evolution of cancer of the colon in these high-risk patients. PreGen-26 fits into this regimen by providing an opportunity to screen for disease during the intervals between colonoscopies.

Rigorous informs

The Patient Perspective
Ginger Bengochea

Life is all about choice. And to make the best choices you need as much information as possible.

In 1992, I experienced some symptoms. Although I knew something was wrong, I had to wait to seek treatment because I was between jobs. When I finally went in, they immediately told me I had rectal cancer—and they called in the surgeon.

In my preop and during my surgery, they found additional cancers. At that time, I made certain choices about my treatment based on what I knew, which wasn't as much as I know now. If I had gone to Creighton University before that surgery and learned about the hereditary aspect of my cancers, I might have made a different choice.

I firmly believe people should be aware of their total health situation—because there is information that enables you to take control. And now there are even more options.

Although we had no previous knowledge of a genetic predisposition to colon cancer in my family, upon reflection it is obvious that the cancer that my mother and grandmother had was due to this disease.

My brother has been confirmed to have the mutated gene. Approximately five years ago, before DNA testing, he was given six months to live due to the seriousness of multiple cancers; he is now cancer-free. So my whole family went up to Creighton to be tested. The people there have been so kind in following my family, taking blood and doing research.

As a result, my children know more about their health and can make better, more informed decisions.

Now I am in a regular monitoring program. If you catch this cancer early, you don't have to bring in the sledge hammer. I took the PreGen-26 test at Dr. Lynch's request—and I was glad to do it. It is another resource that I can use to make decisions about my healthcare.

I look at myself as healthy and happy. That is my choice.

Technological advancements underpin true change

For companies whose mission is to fundamentally change medical practice, the key challenge lies in technology. No matter what the ideas, no matter how profound the discoveries, without the critical enabling technology, products will never enter the clinic—and so any improvements to healthcare will be incremental.

To that end, EXACT Sciences is dedicated to developing breakthrough technologies that isolate and analyze DNA from bodily fluids for the early detection and management of sporadic cancers.

Selected Ongoing Areas of Research

Product/Process Development:

- **Hybrigel incorporation:** Hybrigel technology should significantly improve the purity and yield of DNA from bodily fluids such as stool.
- **Auto digital-PCR:** Migrating digital PCR technology from a research to a commercial-scale process will facilitate commercialization of next generation PreGen products.

Applied and Translational Research:

- **Digital oligonucleotide tiling (DOT):** DOT is a novel mutation scanning technique that allows for the scanning of a gene without knowing the specific point mutations; this should be a valuable addition to current analytical methodologies and support the development of improved PreGen products.
- **Monitoring and staging:** The quantification of informative molecular markers present at diagnosis may prove to be a valuable strategy for improving cancer staging and/or monitoring.
- **Hypermethylation:** Molecular tools that detect the hypermethylation of cancer-related genes are being developed to provide more powerful assays for the detection of cancer.
- **DNA Integrity Assay (DIA™):** Earlier insights into the potential prognostic value of DNA integrity analysis in cancer detection are being further validated and extended on clinical samples.
- **Additional cancer initiatives:** The technologies associated with DIA used in colorectal cancer are being studied for their applicability to other cancers.
- ***H. pylori:*** The molecular analysis of *H. pylori* correlating to disease incidence will provide improved detection and monitoring during treatment.

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, 2001

☐ **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.)
63 Great Road, Maynard, Massachusetts	**01754**
(Address of principal executive offices)	(zip code)

Registrant's telephone number, including area code: (978) 897-2800

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. ☐

The aggregate market value of the voting stock held by non-affiliates of the Registrant, as of March 22, 2002 was approximately $117,894,000 (based on the closing price of the Registrant's Common Stock on March 22, 2002, of $10.12 per share).

The number of shares outstanding of the Registrant's $.01 par value Common Stock as of March 22, 2002 was 18,766,669.

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, 2001. 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, 2001

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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

EXACT Sciences Corporation (Nasdaq: EXAS) has developed proprietary technologies in applied genomics that we believe will revolutionize the early detection of colorectal cancer and several other types of common cancers. We believe that medical practitioners will order tests based on our technologies as part of a regular screening program for the early detection of such cancers and pre-cancerous lesions. We also believe that the widespread and periodic application of these tests will reduce mortality, morbidity and the costs associated with these cancers.

We have selected colorectal cancer as the first application of our technology platform because it is the most deadly cancer among non-smokers, curable if detected early and well understood from a genomics point of view. There are an estimated 80 million Americans age 50 and above for whom the American Cancer Society and National Cancer Institute recommend regular colorectal cancer screening. Current detection methods for colorectal cancer have proven to be inadequate screening tools due to the invasiveness of the procedures, the relative lack of accuracy or poor patient compliance.

We have developed proprietary technologies that isolate the minute amounts of human DNA shed from the colon into stool. From that DNA, we then identify mutations in the DNA that is shed from abnormal cells associated with colorectal cancer and pre-cancerous lesions. We have conducted blinded clinical studies at the Mayo Clinic and other institutions that we believe indicate that our tests are able to detect colorectal cancer more accurately in patients who have the disease at an earlier stage than existing non-invasive methods available for mass screening for colorectal cancer. Early detection results in less expensive and more effective treatment of patients. We believe that the benefits of early detection and the ease of use and accuracy of our test will convince medical practitioners and patients to use tests based on our technologies. We are currently conducting additional clinical studies of our technologies to detect colorectal cancer in average risk patients and plan to develop commercial products and services based on these technologies.

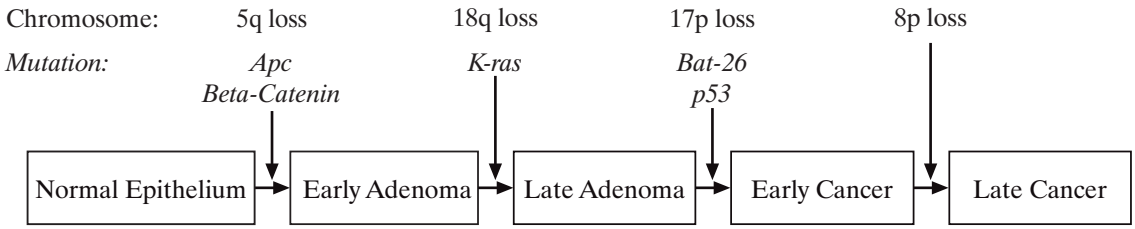
We were incorporated in the State of Delaware on February 10, 1995 as Lapidus Medical Systems, Inc. We changed our corporate name to EXACT Laboratories, Inc. on December 11, 1996, to EXACT Corporation on September 12, 2000 and to EXACT Sciences Corporation on December 1, 2000. Our executive offices are located at 63 Great Road, Maynard, Massachusetts 01754. Our telephone number is (978) 897-2800. Our web address is www.exactsciences.com.

Genomics and Colorectal Cancer

Genomics, broadly defined, is the study of the genome and its importance in human physiology and disease. Initial efforts in genomics centered on identifying the definitive sequence of every gene in the human genome. Scientists are now focusing on applied genomics—the development of novel technologies for the application of genomics to the detection and management of disease.

Cancer develops when the DNA in a single normal cell mutates or changes to encourage uncontrolled 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, and that it arises from alterations in multiple genes in an individual cell, 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 arms, such as 5q, 18q, 17p and 8p, are deleted; or
- deletions in DNA regions such as *Bat-26*.

The multi-step process provides genomic targets for the early detection of cancer. The detection of genetic alterations associated with cancer allows for the direct, early detection of cancer before the onset of symptoms.

Colorectal Cancer

Colorectal cancer is the most deadly cancer in the U.S. among non-smokers and the second most deadly cancer overall. Only lung cancer kills more people each year. The American Cancer Society estimates that in the U.S. there will be approximately 148,000 new cases and approximately 57,000 deaths in the year 2002 from colorectal cancer. Almost 50% of the patients with a new diagnosis of colorectal cancer will die within five years.

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		85%	
Late	Dukes' C	Lymph node involvement	63%	50%-60%	Surgery and chemotherapy
	Dukes' D	Metastatic disease		10%	

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 and National Cancer Institute recommend that the 80 million Americans age 50 and above undergo regular colorectal cancer screening tests.

Our Solution

Many non-invasive cancer screening methods are not effective early detection methods. For example, PSA for prostrate cancer screening, mammography for breast cancer and fecal occult blood testing (FOBT) for colorectal cancer find only indirect evidence of cancer and suffer from lack of sensitivity or specificity. As a result, mortality, morbidity and the cost of treatment of many cancers remain high. We have made significant scientific advances that we believe will allow for the direct early detection of several types of common cancers. Our primary business opportunity is to use our technologies to lower mortality, morbidity and the costs associated with these cancers by developing tests for early detection.

The first application of our technologies is colorectal cancer screening. We believe medical practitioners will order tests using our technologies every one to three years to screen for the presence of colorectal cancer. Using our proprietary genomic technologies, a laboratory will isolate the human DNA shed into the stool from the colon. The laboratory will then use our technologies to identify mutations in the genome shed from abnormal cells associated with adenomas and colorectal cancer. When individuals test positive in these tests, the ordering physician should refer the patient referral for a colonoscopy follow-up or indicate other diagnostic testing. Through regular screening, we believe that tests using our technologies will enable the detection of colorectal cancer and adenomas earlier so that patients can be treated more effectively.

We believe colorectal cancer screening tests using our technologies will become a widely-accepted and regularly-used screening tool as a result of the following features and benefits:

- ***Earlier Detection.*** Early detection saves lives. We believe colorectal cancer screening tests using our technologies will detect Dukes' A and B cancers, as well as some pre-cancerous lesions. We believe that this will represent a marked improvement over current colorectal cancer screening methods.
- ***Higher Sensitivity.*** Since the fall of 1998, we have conducted a series of blinded clinical studies at the Mayo Clinic and with other institutions using our colorectal cancer screening tests. In these clinical studies, the sensitivity of our tests for colorectal cancer substantially exceeded the sensitivity reported for FOBT and flexible sigmoidoscopy.
- ***Higher Compliance.*** We designed our technologies to detect colorectal cancer from a single whole stool sample obtained non-invasively. Patients are not required to touch their stool, modify their diet or undergo bowel preparation. Moreover, we believe that, based on the results of our clinical studies and trials, we will be able to educate physicians about the potential for improving detection of colorectal cancer with our technologies. We also believe that this will lead to many primary care physicians including regular testing based on our technologies as a part of their periodic physical examinations of patients aged 50 and above who, upon learning of the benefits, will likely agree to such testing.
- ***Cost-effective Prevention and Treatment.*** We believe that colorectal cancer screening tests using our technologies will detect early stage lesions more effectively than current screening methods. As a result of this early detection, medical practitioners will have the ability to treat early stage colorectal cancer and pre-cancerous lesions which is less expensive and more effective than treating late stage cancer.

- ***Scalability.*** Screening 80 million Americans age 50 and above requires a process that is able to efficiently test a large population. Procedures such as flexible sigmoidoscopy and colonoscopy suffer problems of scalability because of the short supply of skilled clinicians. We believe tests using our technologies will enable mass screening on a regular basis.

Our Testing Process

Diagnostic tests typically require sample collection and preparation procedures as well as detection methods. We have overcome significant technical challenges in the development of a three-step sample collection and preparation process and four detection methods that apply genomics to the early detection of colorectal cancer. We currently have 19 issued U.S. patents and 36 pending U.S. patent applications relating to our testing process.

Specimen Collection and Transportation. We have based our tests on collecting a single whole stool in an easy non-invasive manner. Samples can be forwarded directly to the laboratory performing the colorectal cancer-screening test by the patient.

Representative Sampling. In the past, DNA testing using stool samples lacked sensitivity. We believe that this was due to the non-uniform distribution of abnormal DNA in stool. We have invented proprietary methods to assure that the portion of stool that is processed at the laboratory is representative of the entire stool. Based upon our data to date, we believe these methods lead to increased sensitivity.

DNA Extraction, Purification and Amplification. The isolation and amplification of human DNA found in stool is technically challenging because over 99% of DNA is not human DNA, but is 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 simplify the isolation and amplification of human DNA found in stool.

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

Our Proprietary Cancer Detection Methods

Our technology platform consists of the proprietary cancer detection methods set forth in the table below. Each of these methods enables the early detection of cancer in a minute amount of altered DNA obtained from a sample that is composed of DNA largely from normal human cells.

Name	Role in Detection	Our Scientific Advance
Multiple Mutation Detection (MuMu)	• Each element of MuMu detects a single mutation of a cancer-related gene	• Sensitive and specific detection of single DNA mutations
Deletion Technology	• Detects short deletions and insertions in the Bat-26 region of a specific gene	• Distinguishes between deletions and insertions resulting from the testing itself, and those associated with mismatch-repair cancers
DNA Integrity Assay (DIA)	• Detects abnormally longer human DNA fragments associated with abnormality	• Proprietary marker associated with cancer that does not require knowledge of which specific genes cause cancer
Enumerated Loss of Heterozygosity (e-LOH)	• Enumerates ratio of paternal DNA as compared to maternal DNA at a given genomic site to identify chromosomal loss that is characteristic of many cancers	• Statistical method that applies a commonly used analytical technique to indicate a large portion of a chromosome is missing and does not require knowledge of which specific genes cause cancer

Multiple Mutation. Multiple Mutation, or MuMu, identifies DNA mutations at specific sites. We have currently selected 21 sites that are commonly mutated in the colorectal cancer-related genes *Apc*, *p53* and *K-ras*. We have designed our proprietary MuMu method to allow simultaneous probing of different DNA sequences and to allow analysis even though only a small amount of DNA in the sample is derived from abnormal cells while the vast majority is derived from normal human cells or bacteria.

Deletion Technology. Deletion Technology detects short deletions and insertions in segments of DNA that are indications of defects in cellular mechanisms for DNA repair. Approximately 15% of sporadic colorectal cancers, referred to as mismatch-repair cancers, result from inactivation of the proteins that normally repair errors in DNA after DNA replication. We have developed a proprietary method for identifying this condition by detecting the presence of short deletions and insertions in a DNA segment known as *Bat-26*. This altered gene segment appears in virtually all colorectal cancers resulting from defects in the mismatch repair mechanism.

DNA Integrity Assay. DNA recovered from the stool of many cancer patients contains a small but detectable population of DNA that is longer than DNA recovered from individuals who are normal and have never had cancer or an adenoma. Use of this proprietary detection method does not require knowledge of which genes cause cancer. In addition to its utility for our colorectal cancer tests, we believe that this discovery may lead us to the development of a marker for other cancers, including lung, pancreatic, gall bladder and bile duct cancers.

Enumerated Loss of Heterozygosity. In normal cells, the quantity of DNA inherited from each parent is generally equal. This is not true for cells from many different types of cancers, including virtually all non-mismatch repair colorectal cancers. This condition, which is an imbalance of maternal and paternal chromosomal fragments, is called loss of heterozygosity, or LOH. Prior to our development efforts, we believe that scientists were unable to detect LOH in stool samples. We have developed proprietary methods for detecting LOH in a highly heterogeneous DNA sample such as stool by enumerating the ratio of fragments of DNA that are inherited from each parent at defined locations in the genome. We call this detection method e-LOH. Use of this detection method does not require knowledge of which genes cause cancer. We believe that our novel e-LOH detection method may be broadly applicable to early cancer detection using a variety of bodily fluids as the sample source.

Sales and Marketing

We are building our organization and programs to support our commercialization strategy—applying our proprietary technologies to the early detection of colorectal cancer initially and then extending our technologies to several other types of cancers. We believe that opinion leaders in genomics, gastroenterology and primary care are key to establishing tests using our technologies as a standard of care for colorectal cancer screening. We have worked closely with leading researchers at academic institutions, including the Mayo Clinic and Johns Hopkins University, since our inception, to evaluate our technologies and our colorectal cancer screening tests, and to gain support for our clinical studies. We have recently entered into a Clinical Trial Agreement with the Mayo Clinic in which our genomics-based colorectal cancer technology will be the subject of an independent study by the Mayo Clinic for which the Mayo Clinic received a $4.9 million grant from the National Cancer Institute of the National Institutes of Health. Dr. David Ahlquist, a member of our scientific advisory board and a director of the Colorectal Neoplasia Clinic at Mayo, is the principal investigator of this clinical trial and has assisted us in our clinical trials and the use of our technologies in the detection of colorectal cancer. We participate in conferences and scientific meetings. The journal *Gastroenterology* published our first full-length peer-reviewed article in November 2000. We believe our continuing efforts will make our products and services attractive to third-party payors, medical practitioners and patients.

In addition, we intend to build upon public awareness about colorectal cancer. Several stories of high profile individuals with colorectal cancer have increased public awareness about colorectal cancer and the need for effective early detection. We believe that this publicity has a heightened effect on the public given an increasing perception that people wish to take more control over decisions relating to their medical care.

We intend to commercialize our products and services through a staged market entry. Initially, we intend to offer colorectal cancer screening services ourselves to establish the market. We then intend to license our proprietary technologies to leading clinical reference laboratories to enable them to develop their own tests. We may also package our technologies and seek approval for diagnostic test kits with which any clinical laboratory could conduct tests using our technologies.

In support of our staged market entry strategy, we plan to execute a multi-channel sales approach. Initially, we intend to create our own dedicated business development team made up of senior members of our organization, including a strategic sales team, whose efforts will focus on securing adequate reimbursement for our products and services and also will educate senior staff of the Centers for Medicare and Medicaid Services (formerly known as the Health Care Financing Administration), large managed care organizations, insurance companies, large employers and large physician groups about the cost effectiveness of using our products and services. In parallel with this effort, we intend to enter into business relationships with leading clinical reference laboratories that will market their own tests utilizing our technologies through their dedicated sales forces. In addition, we may enter into

business relationships with distributors of other medical products to distribute our products and services.

We believe that our business relationships with leading clinical reference laboratories will support the strategies of these laboratories to expand their molecular diagnostic businesses. We established our first relationship with Laboratory Corporation of America Holdings (LabCorp) in July 2001. Under this agreement we granted LabCorp a license to certain of our proprietary genomics-based technologies for use in connection with clinical research, clinical trials testing and the performance of commercial diagnostic services which relate to the detection of colorectal cancer. LabCorp will offer testing services based on these technologies for the detection of colorectal cancer. We received an upfront payment from LabCorp at the execution of this agreement and will receive licensing fees in the future based on the number of tests that LabCorp performs using our technologies.

We believe that tests utilizing our technologies will be attractive to clinical reference laboratories because such tests:

- enable laboratories to perform higher volumes of testing with their existing infrastructure;
- enable the laboratories to differentiate themselves technologically; and
- offer potentially higher gross margins than other non-genomics based tests.

While we have executed a strategic alliance agreement with LabCorp, we have limited experience in establishing these business relationships and there can be no assurance that we will enter into additional agreements with other leading clinical reference laboratories on favorable terms, if at all.

Clinical Studies

Colorectal Cancer

In conjunction with the Mayo Clinic, we have conducted three blinded clinical studies since the fall of 1998. These clinical studies included stool samples from 219 patients of the Mayo Clinic, 58 of whom had cancer. Each patient participating in our clinical studies received a colonoscopy at the Mayo Clinic to determine whether cancer was present. The first two clinical studies were conducted using frozen, partial stool samples. The Mayo Clinic sent stool samples to us for testing and we analyzed the testing results jointly with the Mayo Clinic. The sensitivity for each of these two clinical studies was 91% and 67%, respectively. When excluding the data from patients who began bowel preparation before their stool samples were collected, which we believe may have lowered sensitivity, sensitivity was 91% and 72%, respectively. In the spring of 2000, we conducted a third clinical study at the Mayo Clinic in which we collected fresh, whole stool. The sensitivity for this clinical study was 78%. These sensitivity rates are superior to the 25%-30% sensitivity of FOBT and the approximately 48% sensitivity of flexible sigmoidoscopy for colorectal cancers located throughout the colon. Specificity ranged from 95% to 100% across all three clinical studies. These specificity rates are comparable or superior to rates reported for FOBT and flexible sigmoidoscopy.

The results of these three blinded clinical studies are set forth in the table below:

Study	Completion Date	Number of Patients	Sample Type	Sensitivity	Specificity
Mayo Clinic I Pilot Study . . .	November 1999	61	Frozen partial stool	91%	95-100%
Mayo Clinic II Study	April 2000	129	Frozen partial stool	67-72%	95%
Mayo Clinic III Study	June 2000	29	Fresh whole stool	78%	100%

We initiated a blinded multi-center clinical trial in the third quarter of 2001 that is expected to include an estimated 5,000 patients age 50 and older with average-risk profiles from at least 40 academic and community-based practices. The goal of this clinical trial will be to provide additional

validation of the sensitivity and specificity of our tests for colorectal cancer in average-risk individuals. We are conducting this clinical trial in accordance with the applicable guidelines of the United States Food and Drug Administration, or FDA, so that the results may be used in any application that we may make to the FDA.

In October 2001, we signed a Clinical Trial Agreement with the Mayo Clinic in which our genomics-based colorectal cancer technology will be 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 will involve approximately 4,000 patients at average risk for developing colorectal cancer, and will compare the results of our non-invasive, genomics-based screening technology with those of FOBT, a common first-line colorectal cancer screening option.

Adenomas

While most adenomas do not progress to cancer in a patient's lifetime, those that do are more likely to have villous features characterized by an irregular surface and associated with more rapid growth. In the Mayo Clinic II study, there were 24 patients with adenomas greater than one centimeter. The sensitivity of our screening tests in detecting these adenomas with villous features was 56%. The sensitivity results for villous adenomas are much better than those obtained with FOBT and are comparable to those obtained by flexible sigmoidoscopy. We believe that by detecting adenomas more likely to progress to cancer during a patient's lifetime through a non-invasive screening procedure we will provide additional medical value for our technologies. We intend to test for adenomas in our planned 5,000-patient clinical trial.

Reimbursement

We intend to obtain reimbursement for tests using our technologies from Medicare, major national and regional managed care organizations and insurance carriers. We currently do not have reimbursement approval from any organization. Medicare and other third-party payors will independently evaluate our technologies by reviewing the published literature with respect to the results obtained from our clinical studies. We intend to assist them in evaluating our technologies by providing scientific and clinical data to support our claims regarding the superiority of our technologies. In addition, we intend to present analysis showing the benefits of early disease detection and the resulting cost-effectiveness of our technologies. We also intend to apply for current procedural terminology codes which facilitate Medicare reimbursement.

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 and flexible sigmoidoscopy. Based on evidence provided by the Black Caucus and the Black Caucus Health Brain Trust, 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 sigmoidoscopy. We believe these actions provide evidence of the public interest in new 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 the Centers for Medicare and Medicaid Services (formerly known as the Health Care Financing Administration) 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 Centers for Medicare and Medicaid Services 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

departure from the Centers for Medicare and Medicaid Services' policy of not reimbursing for these costs at the time.

In addition, we 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, sponsored by Senators Edward Kennedy and Jesse Helms. 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. In addition, we have worked with the Black Caucus and the Black Caucus Health Brain Trust.

We are also meeting with senior executives, medical directors and chiefs of service in gastroenterology and primary care at managed care organizations, insurance companies, large employers and large physician groups. These individuals will play a key role in the reimbursement determination for tests using our technologies.

We believe that colorectal cancer screening tests based on our technologies will add a lifesaving, cost-effective alternative to currently available colorectal cancer screening methods. Reimbursement for FOBT tests ranges from $5 to $30, but FOBT is most effective in detecting later stage cancers where survival rates are low and treatment costs are high. Reimbursement for flexible sigmoidoscopy ranges from $280 to $500, but flexible sigmoidoscopy at best can directly detect no more than half of all colorectal cancers and adenomas. Medicare currently reimburses 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 has been limited.

Research and Development

Our research and development efforts aim to develop multiple genomics methods for the early detection of cancer and pre-cancerous lesions. We believe that the evaluation of these methods in a clinical setting will determine the best approaches for commercialization. Finally, we believe it is necessary to develop methods to automate and simplify the collection, preparation and analysis of samples to produce cost-effective commercial tests.

Process Development. We have undertaken a multi-year effort to automate our testing process and reduce the cost of processing stool samples. Our objectives include eliminating many of the manual steps, reducing the use of expensive reagents and increasing screening throughput. This effort is important so that we will be able to offer our products and services at commercially reasonable prices in our own laboratory and with leading clinical reference laboratories.

Extensions to Other Cancers. Our proprietary DIA detection method uses a marker that may be broadly applicable to the detection of cancers other than colorectal cancer. In the course of our blinded clinical studies at the Mayo Clinic, we tested 50 stool samples from patients diagnosed with aero-digestive cancers at sites other than the colon, such as cancer in the lung, pancreas, esophagus, stomach and duodenum, gall bladder and bile ducts. The results are shown in the table below:

Location of Cancer	Number Detected/ Number with Cancer	Percent Detected
Lung, non-adenocarcinoma	7/8	88%
Lung, adenocarcinoma	3/13	23%
Pancreas	10/11	91%
Esophagus	3/7	43%
Stomach/Duodenum	1/5	20%
Gall Bladder/Bile Ducts	6/6	100%

Combined, these cancers kill more people than colorectal cancer. Data will be collected on these aero-digestive cancers in the approximately 4,000 patient clinical trial with the Mayo Clinic. If the results are promising, we intend to develop methods and technologies to detect these cancers.

Adenomas. While our research focus has been the detection of cancer, we intend to conduct research on improved methods for adenoma detection as well, particularly those adenomas with villous features. As part of this effort, we have invented a new method for scanning regions of DNA at which mutations associated with adenoma development are often found.

New Technology Platform. We are also conducting research on new technologies that may enable us to develop new instrumentation and methods for life sciences research. If successful, we believe this technology may be used in both clinical and research laboratories for detecting abnormalities in DNA, identifying single nucleotide polymorphisms in populations of individuals and for high throughput screening in the pharmaceutical industry.

Government Regulation

We are subject to regulatory oversight by the FDA under provisions of the Federal Food, Drug and Cosmetic Act and regulations thereunder, including regulations governing the development, marketing, labeling, promotion, manufacturing and export of 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.

Initially, we intend to offer colorectal cancer screening services, as an in-house developed test performed in our own laboratories. We then intend to license our intellectual property to leading clinical reference laboratories to enable them to perform their own colorectal cancer screening services, using their own test methods, equipment and additional reagents. We may also package our technologies in the form of diagnostic test kits with which clinical laboratories could conduct colorectal cancer screening tests.

Generally, medical devices, a category that includes our products, 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, pre-market clearance or approval is not currently required for this category of products. The FDA does regulate the sale of certain reagents, including 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. They generally do not require FDA pre-market approval or clearance if they are used in in-house laboratories or are sold to clinical laboratories certified by the government to perform high complexity testing and are 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 ours. Laboratories also are subject to restrictions on the labeling and marketing of tests that have been developed using analyte specific reagents. The analyte specific reagent regulatory category is relatively new and its regulatory boundaries are not well defined. We believe that our in-house testing 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 our test, or one or more of our 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.

Any diagnostic test kits that we may sell would require FDA approval or clearance before they could be marketed. There are two 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) procedure, in which 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 that the product is substantially equivalent to a legally marketed product. 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 when the FDA issues a clearance letter determining the product to be substantially equivalent.

If a medical device does not qualify for the 510(k) procedure, the FDA must approve 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 typically a more complex submission then a 510(k) submission, resulting in longer review and approval timeframes and usually includes the results of pre-clinical and extensive clinical studies and detailed information on the product and manufacturing. Before the FDA will approve a PMA, the manufacturer must pass an inspection of its compliance with the requirements of the FDA's quality system regulations.

We believe our products sold in diagnostic test kit form would likely require PMA approval. The PMA process is lengthy and costly, and we cannot be sure that the FDA will approve PMAs for our products in a timely fashion, or at all. 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, changes to the product, its indication, or its labeling would be likely to require additional approvals.

Physicians who order colorectal cancer screening tests based on our technologies will need to provide patients a specimen container to collect stool. Specimen transport and storage containers are also medical devices regulated by the FDA although they generally have been exempted by regulation from the FDA's pre-market clearance or approval requirement. We believe that our specimen container falls within the 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.

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 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 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 money penalties. If we fail to meet the requirements of CLIA or state law, it could cause us to incur significant expense.

Intellectual Property

In order to protect our proprietary technologies, we rely on combinations of patent, trademark, copyright, and trade secret protection, as well as confidentiality agreements with employees, consultants, and third parties.

We have pursued an aggressive 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, including lung, pancreas, gall bladder and bile duct 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 and that provide barriers to entry for our competition. In November 2001, we purchased intellectual property of MT Technologies (formerly known as Mosaic Technologies, Inc.) relating to its Hybrigel technology which consisted of 4 issued patents and 40 pending patent applications. The purchase price for the assets included $1.3 million in cash and warrants to purchase an aggregate of 40,000 shares of our common stock, exercisable over three years, at an exercise price of $7.33 per share.

As of December 31, 2001, including those patents purchased from MT Technologies, we had 19 patents issued and 36 pending patent applications in the United States and, in foreign jurisdictions, 5 patents issued and 92 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 has a term of 20 years from its respective priority filing dates. Consequently, our first patents are set to expire in 2016. We have filed terminal disclaimers in certain later-filed patents, which means that such later-filed patents will expire earlier than the twentieth anniversary of their priority filing dates.

A third-party institution has asserted 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. To date, no legal proceedings have been initiated by this third party. If any third party, including the third party discussed above, asserting co-inventorship rights with respect to any patent 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 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 under the Patent Cooperation Treaty. This patent application designates the United States, Japan, Europe and Canada.

We license on a non-exclusive basis the 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. In exchange for the license, we have agreed to pay Roche a royalty based on net revenues we receive from tests using our technologies. 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.

We license on a non-exclusive basis technology for performing a step in our testing methods from Genzyme Corporation, the exclusive 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 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 performing our tests and the sale of 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.

Competition

To our knowledge, none of the large genomics or diagnostics companies is developing tests to conduct stool-based DNA testing. However, companies may be working on such tests that have not yet been announced. In addition, other companies may succeed in developing or improving 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.

We face potential competition from alternative procedures-based detection technologies such as sigmoidoscopy, colonoscopy and virtual colonoscopy as well as traditional screening tests such as the FOBT marketed by Beckman Coulter, Inc. Virtual colonoscopy involves a new and experimental approach being developed at research institutions that requires patients to undergo bowel preparation similar to a colonoscopy after which they are scanned by a spiral CT scanner. Three-dimensional images are constructed to allow a radiologist to virtually travel through the colon.

In addition, our competitors, including Bayer Corporation, diaDexus, Inc., Matritech, Inc., and Millennium Predictive Medicine, Inc., are developing serum-based tests, an alternative cancer-screening approach that is based on detection of proteins or nucleic acids that are produced by colon cancers and may be found circulating in 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:

- improved sensitivity;
- non-invasiveness;
- acceptance by the medical community and primary care medical practitioners;
- adequate reimbursement from Medicare and other third-party payors;
- cost-effectiveness; and
- patent protection.

Employees

As of December 31, 2001, we had sixty-eight employees, eight of whom have PhDs. Forty-six persons are engaged in research and development, five persons in sales and marketing and seventeen persons in general and administration. None of our employees is represented by a labor union. We consider our relationship with our employees to be good.

Item 2. Properties

We lease approximately 20,000 square feet of space in our headquarters located in Maynard, Massachusetts under various leases which expire on June 30, 2003 and November 30, 2003. We have an option to extend the lease for an additional three-year term and have a right of first refusal on approximately 9,000 square feet of space as it becomes available in the building. We believe that this facility is adequate to meet our current and foreseeable requirements and that suitable additional or substitute space will be available on commercially reasonable terms if needed.

Item 3. Legal Proceedings

From time to time we are a party to various legal proceedings arising in the ordinary course of our business. We are not currently a party to any 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 2001.

PART II

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

Our common stock has been listed for trading on the Nasdaq National Market under the symbol "EXAS" since the effective date of our initial public offering on January 30, 2001. Prior to that time, there was no public market for our common stock. On March 22, 2002, the last reported price of our common stock on the Nasdaq National Market was $10.12 per share. Based upon information supplied to us by the registrar and transfer agent for our common stock, the number of common stockholders of record on March 22, 2002 was approximately 200, not including beneficial owners in nominee or street name. We believe that a significant number of shares of our common stock are held in nominee name for beneficial owners. The high and low common stock prices per share subsequent to our initial public offering on January 2001 were as follows:

Fiscal 2001 Quarter Ended:	High	Low
March 31,	$15.38	$7.50
June 30,	$14.15	$5.30
September 30,	$15.57	$7.75
December 31,	$11.75	$6.75

We have not paid any cash dividends on our common stock and we currently intend to retain any future earnings for use in our business. Accordingly, we do not anticipate that any cash dividends will be declared or paid on the common stock in the foreseeable future.

Recent Sales of Unregistered Securities

In November 2001, we issued two warrants to purchase an aggregate of 40,000 shares of common stock at an exercise price of $7.33 per share to two investors. These warrants were issued in connection with the purchase of intellectual property of MT Technologies relating to its Hybrigel technology.

No underwriters were involved in the foregoing sales of securities. Such sales were made in reliance upon an exemption from the registration provisions of the Act set forth in Section 4(2) thereof relative to sales by an issuer not involving any public offering or the rules and regulations thereunder. All of the foregoing securities are deemed restricted securities for the purposes of the Securities Act.

Use of Proceeds from Registered Securities

We sold 4,000,000 shares of common stock, $.01 par value per share, pursuant to our final U.S. prospectus and our final international prospectus, dated January 30, 2001. These prospectuses were contained in our Registration Statement on Form S-1, which was declared effective by the Securities and Exchange Commission (SEC File No. 333-48812) on January 30, 2001. All shares covered by the Registration Statement were sold. The initial public offering closed on February 5, 2001. Our net proceeds from the offering were approximately $50.6 million after deducting underwriting discounts and commissions and offering expenses. None of the net proceeds from the initial public offering were used to pay, directly or indirectly, directors, officers, persons owning ten percent or more of our equity securities, or our affiliates. We currently expect to use the net proceeds from the offering to fund clinical studies and trials, other research and development, working capital and other general corporate purposes. As of December 31, 2001, we had not used any of the proceeds of this offering which are invested primarily in all highly liquid investments with maturities of 90 days or less at the time of acquisition.

Item 6. Selected Financial Data

The selected historical financial data set forth below as of December 31, 2000 and 2001 and for the years ended December 31, 1999, 2000 and 2001, are derived from our financial statements, which have been audited by Arthur Andersen LLP, independent public accountants, and which are included elsewhere in this Form 10-K. The selected historical financial data as of December 31, 1997, 1998 and 1999 and for the years ended December 31, 1997 and 1998 are derived from our financial statements, which have been audited by Arthur Andersen LLP, 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 accountants included elsewhere in this Form 10-K.

	1997	1998	1999	2000	2001
	(Dollars in thousands, except share and per share data)				
Statement of Operations Data:					
Revenue	$ —	$ —	$ —	$ —	$ 51
Research and development	1,222	2,849	3,689	5,332	13,335
Selling, general and administrative	814	1,170	1,560	4,814	9,078
Stock-based compensation (1)	1	2	14	3,184	3,788
Loss from operations	(2,037)	(4,021)	(5,263)	(13,330)	(26,150)
Interest income	154	443	299	1,447	2,665
Net loss	$ (1,883)	$ (3,578)	$ (4,964)	$ (11,883)	$ (23,485)
Net loss per common share:					
Basic and diluted (2)	$ (10.70)	$ (6.08)	$ (5.32)	$ (8.13)	$ (1.42)
Weighted average common shares outstanding:					
Basic and diluted	175,953	588,143	932,593	1,461,726	16,487,499
Balance Sheet Data:					
Cash and cash equivalents	$ 1,792	$ 8,826	$ 3,553	$ 26,470	$ 56,843
Total assets	2,417	9,708	4,754	29,059	63,100
Stockholders' equity	2,305	9,298	4,410	27,700	58,967

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

	1997	1998	1999	2000	2001
Research and development	$ 1	$ 2	$ 9	$ 810	$ 898
General and administrative	—	—	5	2,374	2,890
Total	$ 1	$ 2	$ 14	$ 3,184	$ 3,788

(2) Computed as described in Note 2 to the financial statements included elsewhere in this Form 10-K.

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

Except for the historical information contained or incorporated by reference herein, this following discussion contains forward-looking statements that involve risks and uncertainties, certain of which are beyond our control. Actual results could differ materially from these forward-looking statements as a result of a number of factors including, but not limited to, those factors described in "Factors That May Affect Future Results" and elsewhere in this Form 10-K.

Overview

We apply proprietary genomics technologies to the early detection of common cancers. We have selected colorectal cancer screening as the first application of our technology platform. 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 incorporated into our technologies;
- developing relationships with opinion leaders in the scientific and medical communities;
- conducting market studies and analyzing potential approaches for commercializing our technologies;
- hiring research and clinical personnel;
- hiring management and other support personnel; and
- raising capital.

Initially, we intend to offer colorectal cancer screening services ourselves to establish the market. We then intend to license our proprietary technologies to leading clinical reference laboratories to enable them to develop tests. We may also package our technologies and seek approval for diagnostic test kits with which any clinical laboratory could conduct our tests.

We have generated no material operating revenues since our inception, and do not expect any material operating revenues for the foreseeable future. As of December 31, 2001, we had an accumulated deficit of approximately $46.6 million. Our losses have resulted principally from costs incurred in conjunction with our research and development initiatives.

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 that the cost of our research and development activities will increase substantially as we continue activities relating to the development of our colorectal cancer screening tests and the extension of our technologies to several other forms of common cancers and pre-cancerous lesions. We are currently conducting a clinical trial that will include an estimated 5,000 average-risk patients from at least 40 academic and community-based practices, the costs of which will be borne by us, together with other smaller clinical studies.

Selling, general and administrative expenses consist primarily of non-research personnel salaries, office expenses and professional fees. We expect general and administrative expenses to increase as we hire additional personnel and build our infrastructure to support future growth.

Stock-based compensation expense, a non-cash expense, represents the difference between the exercise price and fair value of common stock on the date of grant. The stock compensation is being amortized 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 $2.1 million, $1.3 million, $600,000 and $200,000 during the years ended December 31, 2002, 2003, 2004 and 2005, respectively.

Significant Accounting Policies

Financial Reporting Release No. 60, which was recently issued by the Securities and Exchange Commission ("SEC"), 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 include a summary of the significant accounting policies and methods used in the preparation of our consolidated financial statements.

Further, we have made a number of estimates and assumptions that affect reported amounts of assets, liabilities, revenues and expenses, and actual results may differ from those estimates. As we are a development stage company, the areas that require the greatest degree of management judgment is the assessment of the recoverability of long lived assets, primarily intellectual property, and the realization, if any, of our net deferred tax assets.

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 years presented.

Results of Operations

Comparison of the years ended December 31, 2001 and 2000

Revenue. Revenue was $51,000 for the year ended December 31, 2001. This revenue is primarily composed of amortization of up-front technology license fees associated with an agreement signed in July 2001 with Laboratory Corporation of America Holdings, Inc. that is being amortized on a straight-line basis over the license period.

Research and development expenses. Research and development expenses, excluding departmental allocations of stock-based compensation, increased to $13.3 million for the year ended December 31, 2001 from $5.3 million for the year ended December 31, 2000. This increase was primarily attributable with the initiation of our blinded multi-center clinical trial and included increases of $1.1 million in personnel-related expenses, $808,000 in professional fees and expenses, $821,000 in laboratory expenses, $4.5 million in trials and studies expenses and $642,000 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 $9.1 million for the year ended December 31, 2001 from $4.8 million for the year ended December 31, 2000. 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 $1.8 million in personnel-related expenses, $1.9 million in professional fees and expenses, $81,000 in travel-related expenses and $503,000 related to the leasing of additional office space and related office expenses.

Stock-based compensation. Stock-based compensation, a non-cash expense, increased to $3.8 million for the year ended December 31, 2001, of which $898,000 related to research and development personnel and $2.9 million related to general and administrative personnel. Stock-based compensation was $3.2 million for the year ended December 31, 2000, of which $810,000 related to research and development personnel and $2.4 million related to general and administrative personnel.

Interest income. Interest income increased to $2.7 million for the year ended December 31, 2001 from $1.4 million for the year ended December 31, 2000. This increase was primarily due to an

increase in our cash and cash equivalents balances resulting from the issuance of common stock in February 2001.

Comparison of the years ended December 31, 2000 and 1999

Research and development expenses. Research and development expenses, excluding departmental allocations of stock-based compensation, increased to $5.3 million for the year ended December 31, 2000 from $3.7 million for the year ended December 31, 1999. This increase was attributable primarily to an increase of $285,000 in personnel-related expenses, an increase of $168,000 in professional fees and expenses, an increase of $505,000 in laboratory expenses, an increase of $579,000 in trials and studies expenses and an additional $63,000 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 $4.8 million for the year ended December 31, 2000 from $1.6 million for the year ended December 31, 1999. This increase was attributable primarily to an increase of $1.2 million in personnel-related expenses, an increase of $1.8 million in professional fees and expenses, an increase of $114,000 in travel-related expenses and an additional $47,000 related to the leasing of additional office space.

Stock-based compensation. Stock-based compensation increased to $3.2 million for the year ended December 31, 2000, of which $810,000 related to research and development personnel and $2.4 million related to general and administrative personnel. Stock-based compensation was $14,000 for the year ended December 31, 1999, of which $9,000 related to research and development personnel and $5,000 related to general and administrative personnel.

Interest income. Interest income increased to $1,447,000 for the year ended December 31, 2000 from $299,000 for the year ended December 31, 1999. This increase was primarily due to an increase in our cash and cash equivalents balances resulting from the issuance of preferred stock in April 2000.

Quarterly Results of Operations

The following table sets forth unaudited quarterly statement of operations data for each the eight quarters ended December 31, 2001. 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,	Year
2001					
Revenue	$ —	$ —	$ 13	$ 38	$ 51
Research and development	2,543	2,849	3,535	4,408	13,335
Selling, general and administrative	2,583	2,607	1,965	1,923	9,078
Stock-based compensation	1,052	1,055	865	816	3,788
Loss from operations	(6,178)	(6,511)	(6,352)	(7,109)	(26,150)
Interest income	778	800	623	464	2,665
Net loss	$ (5,400)	$ (5,711)	$ (5,729)	$ (6,645)	(23,485)
Net loss per common share — basic and diluted (1)	$ (0.44)	$ (0.32)	$ (0.32)	$ (0.37)	$ (1.42)
Weighted average common shares outstanding:					
Basic and diluted	12,190,643	17,817,844	17,886,920	18,054,587	16,487,499
2000					
Research and development	$ 1,154	$ 1,145	$ 1,516	$ 1,517	$ 5,332
Selling, general and administrative	483	824	1,135	2,372	4,814
Stock-based compensation	242	505	772	1,665	3,184
Loss from operations	(1,879)	(2,474)	(3,423)	(5,554)	(13,330)
Interest income	41	451	500	455	1,447
Net loss	$ (1,838)	$ (2,023)	$ (2,923)	$ (5,099)	$ (11,883)
Net loss per common share — basic and diluted (1)	$ (1.54)	$ (1.41)	$ (1.91)	$ (3.03)	$ (8.13)
Weighted average common shares outstanding:					
Basic and diluted	1,194,025	1,434,267	1,534,010	1,684,602	1,461,726

(1) Computed as described in Note 2 to the financial statements included elsewhere in this Form 10-K.

Liquidity and Capital Resources

We have financed our operations since inception primarily through private sales of preferred stock, as well as the completion of an initial public offering of our common stock in January 2001. As of December 31, 2001, we had approximately $56.8 million in cash and cash equivalents.

Net cash used in operating activities was $15.8 million for the year ended December 31, 2001, $8.0 million in 2000 and $4.6 million in 1999. This increase was primarily due to our increase in operating losses resulting from higher spending in research and development expenses as the Company commenced its blinded multi-center clinical trial. In addition, selling, general and administrative expenses increased as we built our infrastructure and initiated certain corporate and marketing programs to support future growth.

Net cash used in investing activities was $4.6 million for the year ended December 31, 2001, $1.1 million in 2000 and $722,000 in 1999. For each of these periods, cash used in investing activities

reflected increased investment in our intellectual property portfolio and the expansion of our laboratory and office space. 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.

Net cash provided by financing activities was $50.8 million for the year ended December 31, 2001, $32.0 million in 2000 and $57,000 in 1999. Cash provided by financing for the years ended December 31, 2001 resulted from the sale of our common stock from our initial public offering in 2001 and the sale of preferred stock in 1999 and 2000, respectively.

We expect that cash on hand at December 31, 2001 will be sufficient to fund our operations through at least 2003. Our future capital requirements include, but are not limited to, continuing our research and development programs, supporting our clinical study efforts, and launching our marketing efforts. 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; and
- the successful commercialization of colorectal cancer screening tests based on our technologies.

Net Operating Loss Carryforwards

As of December 31, 2001, we had net operating loss carryforwards of approximately $37 million and research and development tax credit carryforwards of approximately $943,000. The net operating loss and tax credit carryforwards will expire at various dates through 2021, 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.

Recent Accounting Pronouncements

In June 1998, the Financial Accounting Standards Board (FASB) issued Statements of Financial Accounting Standard (SFAS) No. 133, *Accounting for Derivative Instruments and Hedging Activities.* As amended in June 1999, the statement is effective for all fiscal quarters of all fiscal years beginning after June 15, 2000. In June 2000, the FASB issued statement No. 138, which is a significant amendment to SFAS No. 133. SFAS No. 133 and its amendments establish accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts (collectively, the derivatives) and for hedging activities. The Emerging Issues Task Force (EITF) has also issued a number of derivative-related tentative and final consensuses. We do not expect the adoption of these statements to have a material impact on our consolidated position or results of operations.

In July 2001, the FASB issued SFAS No. 141, *Business Combinations,* and SFAS No. 142, *Goodwill and Other Intangible Assets.* SFAS 141 requires the purchase method of accounting for business combinations initiated after June 30, 2001 and eliminates the pooling-of-interests method. The Company does not believe that the adoption of SFAS 141 will have a significant impact on its financial statements. SFAS 142 is effective January 1, 2002 and requires, among other things, the discontinuance of goodwill amortization. In addition, the standard includes provisions for the reclassification of certain existing recognized intangibles as goodwill, the reassessment of the useful lives of existing recognized intangibles, the reclassification of certain intangibles out of previously reported goodwill and the identification of reporting units for purposes of assessing potential future impairments of goodwill. We do not expect the adoption of these statements to have a material impact on our consolidated position or results of operations.

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.

We are a development stage company and may never successfully commercialize any of our products or services or earn a profit.

We are a development stage company and have incurred losses since we were formed. From our date of inception on February 10, 1995 through December 31, 2001, we have accumulated a total deficit of approximately $46.6 million. Since our colorectal cancer screening tests are still in development, we do not expect to have any material revenue from the sale of our products and services until the second half of 2003. Even after we begin selling our products and services, we expect that our losses will continue and increase as a result of continuing high 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.

If our clinical studies do not prove the superiority of our technologies, we may never sell our products and services.

In the third quarter of 2001, we initiated a blinded multi-center clinical study that will include approximately 5,000 patients with average-risk profiles. In October 2001, we also signed a Clinical Trial Agreement with the Mayo Clinic in which our genomics-based colorectal cancer technology will be 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 will involve approximately 4,000 patients at average risk for developing colorectal cancer, and compare the results of our non-invasive, genomics-based screening technology with those of the fecal occult blood test, a common first-line colorectal cancer screening option. The results of these clinical studies may not show that tests using our technologies are superior to existing screening methods. In that event, we will have to devote significant financial and other resources to further research and development. In addition, we may experience delays in the commercialization of tests using our technologies or commercialization may never occur. Our earlier clinical studies were small and included samples from high-risk patients. The results from these earlier studies may not be representative of the results we obtain from any future studies, including our planned clinical study, which will include substantially more samples and average-risk patients.

We may be unable to recruit a sufficient number of patients for our planned average-risk clinical study.

We initiated a blinded multi-center clinical study of approximately 5,000 average-risk patients in the third quarter of 2001. If we are unable to enroll the required number of average risk patients, we will be unable to validate the superiority of our technologies, which would make it difficult to sell our products and services. Despite the availability of colorectal cancer screening methods today, most Americans who are recommended for colorectal cancer screening do not get screened. Participants in our clinical study will only have an average risk of developing colorectal cancer, yet will have to undergo a colonoscopy. This procedure requires sedation and causes patient discomfort. We cannot guarantee that we will be able to recruit patients on a timely basis, if at all.

If Medicare and other third-party payors, including managed care organizations, do not provide adequate reimbursement for our products and services, most clinical reference laboratories will not use our products or license our technologies to perform cancer screening tests.

Most clinical reference laboratories will not perform colorectal cancer screening tests using our products and licensing our technologies unless they are adequately reimbursed by third-party payors such as Medicare and 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 products and technologies are sensitive for colorectal cancer, not experimental or investigational, medically necessary, appropriate for the specific patient and cost-effective. To date, we have not secured any reimbursement approval for tests using our products and technologies from any third-party payor, nor do we expect any such approvals in the near future.

Reimbursement by Medicare will require approval by the Secretary of Health and Human Services, or HHS. The Federal Balanced Budget Act of 1997 provides for reimbursement of new technologies such as ours, but only with action of the Secretary of HHS. We cannot guarantee that the Secretary of HHS will act to approve tests based on our technologies on a timely basis, or at all. In addition, the assignment of a current procedural terminology code facilitates Medicare reimbursement. The process to obtain this code is lengthy and we cannot guarantee that we will receive a current procedural terminology code on a timely basis, or at all.

Since reimbursement approval is required from each payor individually, seeking such approvals is a time-consuming and costly process. If we are unable to obtain adequate reimbursement by Medicare and managed care organizations, our ability to generate revenue and earnings from the sale of our products or licenses to our technologies will be limited.

We will not be able to commercialize our technologies if we are not able to lower costs through automating and simplifying key operational processes.

Currently, colorectal cancer screening tests using our technologies are very expensive because they are labor-intensive and use highly complex and expensive reagents. In order to generate significant profits and make our technologies attractive to potential partners, we will need to reduce substantially the costs of tests using our technologies through significant automation of key operational processes and other cost savings procedures. If we fail to sufficiently reduce costs, tests using our technologies either may not be commercially viable or may generate little, if any, profitability.

Our inability to establish strong business relationships with leading clinical reference laboratories to perform colorectal cancer screening tests using our technologies will limit our revenue growth.

A key step in our strategy is to license our proprietary technologies to leading clinical reference laboratories that will perform colorectal cancer screening tests. While we have executed a strategic alliance agreement with Laboratory Corporation of America Holdings, we have limited experience in establishing these business relationships. If we are unable to establish additional business relationships with leading clinical reference laboratories, we may have limited ability to generate significant revenue.

Our failure to convince medical practitioners to order tests using our technologies will limit our revenue and profitability.

If we fail to convince medical practitioners to order tests using our technologies, we will not be able to sell our products or license our technologies in sufficient volume for us to become profitable. We will need to make leading gastroenterologists aware of the benefits of tests using our technologies through published papers, presentations at scientific conferences and favorable results from our clinical

studies. Our failure to be successful in these efforts would make it difficult for us to convince medical practitioners to order colorectal cancer screening tests using our technologies for their patients.

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 institutions, such as the Mayo Clinic, that we believe are key to establishing tests using our technologies as a standard of care for colorectal cancer screening. We have consulting agreements with all but one member of our scientific advisory board, each of which may be terminated by us or the scientific advisory board member with 30 or 60 days notice. Our existing collaboration agreement with the Mayo Clinic expired on December 31, 2001. If any of 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 difficulty establishing tests using our technologies as a standard of care for colorectal cancer screening, which would limit our revenue growth and profitability.

We may experience limits on our revenue and profitability if only an insignificant number of people decide to be screened for colorectal cancer.

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, an insignificant 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 and the National Cancer Institute that all Americans age 50 and above be screened for colorectal cancer, most of these individuals decide not to complete a colorectal cancer screening test. If only an insignificant portion of the population decides to complete colorectal cancer screening tests, we may experience limits on our revenue 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. As a result, we intend to devote significant personnel and financial resources in the future to extending our technology platform to the development of screening tests for these common cancers and pre-cancerous lesions. To do so, we may need to overcome technological challenges to develop reliable screening tests for these cancers. We may never realize any benefits from these research and development activities.

If we fail to obtain the approval of the U.S. Food and Drug Administration, or FDA, or comply with other FDA requirements, we may not be able to market our products and services and may be subject to stringent penalties.

The FDA does not actively regulate laboratory tests that have been developed and used by the laboratory to conduct in-house testing. The FDA does regulate specific reagents, such as ours, that react with a biological substance including those designed to identify a specific DNA sequence or protein. Its regulations provide that most such reagents, which the FDA refers to as analyte specific reagents, are exempt from the FDA's pre-market review requirements. If the FDA were to decide to regulate in-house developed laboratory tests or decide to require pre-market approval or clearance of any analyte specific reagents, the commercialization of our products and services could be delayed,

halted or prevented. If the FDA were to view any of our actions as non-compliant it could result in regulatory warning, an imposition penalties or other enforcement actions. Similarly, if the FDA were to determine that our specimen container requires pre-market approval or clearance, the sale of our products and services could be delayed, halted or prevented and the FDA could impose penalties on us or seek other enforcement action. Finally, our analyte specific reagents will be subject to a number of FDA requirements, including a requirement to comply with the FDA's quality system regulation which establishes extensive regulations for quality control and manufacturing procedures. Failure to comply with these regulations could subject us to enforcement action. Adverse FDA action in any of these areas could significantly increase our expenses and limit our revenue and profitability.

If we fail to comply with regulations relating to clinical laboratories, we may be prohibited from processing our own tests in-house, be required to incur significant expense to correct non-compliance, or be subject to other requirements or penalties.

We are subject to U.S. and state laws and regulations regarding the operation of clinical laboratories. For example, the federal Clinical Laboratory Improvement Amendments impose certification requirements for clinical laboratories, and establishes 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 include prohibiting a laboratory from running tests, requiring a laboratory to implement a corrective plan, and imposing civil money or criminal penalties. In May 2000, we received a clinical laboratory certificate of compliance. However, if we fail to meet the requirements of the Clinical Laboratory Improvement Amendments in the future, we could be required to halt providing services and incur significant expense, thereby limiting our revenue and profitability.

Other companies may develop and market 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, and has attracted competitors, some of which have significantly greater resources than we have.

Currently, we face competition from alternative procedures-based detection technologies such as flexible sigmoidoscopy and colonoscopy, as well as traditional screening tests such as the fecal occult blood test. Other entities are developing new colorectal screening methods such as virtual colonoscopy, an experimental procedure being developed at research institutions in which a radiologist views the inside of the colon through a scanner. In addition, competitors, including Bayer Corporation, diaDexus, Inc., Matritech, Inc. and Millennium Predictive Medicine, Inc., are developing serum-based tests, or screening tests based on the detection of proteins or nucleic acids produced by colon cancer. These and other companies may also be working on additional methods of detecting colon cancer that have not yet been announced. We may be unable to compete effectively against these competitors either because their test is superior or because they may have more expertise, experience, financial resources and business relationships.

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; Don M. Hardison, our President and Chief Executive Officer, John A. McCarthy, Jr., our Executive Vice President, Chief Operating Officer, Chief Financial Officer and Treasurer, and Anthony P. Shuber, our Senior Vice President and Chief Technology Officer. Anthony P. Shuber, together with Stanley N. Lapidus, our Chairman, have been critical to the development of our technologies and business. Mr. Hardison, who joined us in May 2000, and Mr. McCarthy, who joined us in October 2000, are key additions to our management team and will be critical to directing and

managing our growth and development in the future. We have no employment agreements with any of Messrs. Lapidus, Hardison, McCarthy or Shuber, however, each has signed a non-disclosure and assignment of intellectual property agreement and non-compete agreement. We also have a severance agreement with each of Messrs. Lapidus, 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 our testing process and as we attempt to transition from a development company 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 are unable to protect our intellectual property effectively, we may be unable to prevent third parties from using our technologies, 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, 2001, we had 19 issued patents and 36 pending patent applications in the United States. We also had 5 issued foreign patents and 92 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 has asserted co-inventorship rights with respect to 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 this or other 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 will be 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 also 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.

We may incur substantial costs to protect and enforce our patents.

We have pursued an aggressive patent strategy designed to maximize our patent protection against third parties in the U.S. and in foreign countries. We have filed patent applications that cover the methods we have designed to detect colorectal cancer and other cancers, as well as patent applications that cover our testing process. In order to protect or enforce our patent rights, we may 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.

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 or us. We pursue an aggressive patent strategy that we believe provides us with a competitive advantage in the early detection of colorectal cancer and other common cancers. We currently have 19 issued U.S. patents and 36 pending patent applications in the United States. Because the U.S. Patent & Trademark Office maintains patent applications in secrecy until a patent issues, others may have filed patent applications for technology covered by our pending applications. There may be third-party patents, patent applications and other intellectual property relevant to our potential products that may block or compete with our products or processes. 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 assure you 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 us to 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 use of our technology, 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 or rights under a patent or patent application subject to such a proceeding.

Our business would suffer if certain licenses were terminated.

We license certain technologies from Roche Molecular Systems, Inc. and Genzyme Corporation that are key to our technologies. The Roche license for the polymerase chain reaction (PCR) technology, which relates to a gene amplification process used in almost all genetic testing, is a non-exclusive license through 2004, the date on which the patent that we utilize expires. Roche may terminate the license upon notice if we fail to pay royalties, submit certain reports or breach any other material term of the license agreement. The Genzyme license is a non-exclusive license to use the *Apc* and *p53* genes and methodologies relating to the genes in connection with our products and services through 2013, the date on which the term of the patent that we utilize expires. Genzyme may terminate the license upon notice if we fail to pay milestone payments and royalties, achieve a certain level of sales, or submit certain reports. In addition, if we fail to use reasonable efforts to make products and services based on these patents available to the public or fail to request FDA clearance for a diagnostic test kit as required by the agreement, Genzyme may terminate the license. If either Roche or Genzyme were to terminate the licenses, we would incur significant delays and expense to change a portion of our testing methods and we cannot guarantee that we would be able to change our testing methods without affecting the sensitivity of our tests.

Changes in healthcare policy could subject us to additional regulatory requirements that may delay the commercialization of our tests and increase our costs.

Healthcare policy has been a subject of discussion in the executive and legislative branches of the federal and many state governments. We developed a staged commercialization strategy for our colorectal cancer screening tests based on existing healthcare policies. Changes in healthcare policy, if implemented, could substantially delay the use of our tests, 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.

We may need to raise additional funds to execute our business strategy. 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. 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.

We currently have no credit facility or committed sources of capital. If our capital resources are insufficient to meet future requirements, we will have to raise additional funds to continue the development and commercialization of our technologies. 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.

Our executive officers, directors and principal stockholders own a significant percentage of our Company and could exert significant influence over matters requiring stockholder approval.

As of March 22, 2002, our executive officers, directors and principal stockholders and their affiliates together control approximately 37.9% of our outstanding common stock, without giving effect to the exercise of outstanding options under our stock plans. As a result, these stockholders, if they act together, will have significant influence over matters requiring stockholder approval, such as the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying, preventing or deterring a change in control, could deprive you of the opportunity to receive a premium for your common stock as part of a sale and could adversely affect the market price of our common stock.

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 stock is likely to be highly volatile and could fluctuate widely in price in response to various factors, many of which are beyond our control, including:

- technological innovations or new products and services by us or our competitors;
- clinical trial results relating to our tests or those of our competitors;
- reimbursement decisions by Medicare and other managed care organizations;
- FDA regulation of our products and services;
- the establishment of partnerships with clinical reference laboratories;
- health care legislation;
- intellectual property disputes;
- additions or departures of key personnel; and
- sales of our common stock.

Because we are a development stage company with no material revenue expected until the second half of 2003, you may consider one of these factors to be material. Our stock price may fluctuate widely as a result of any of the above.

In addition, the Nasdaq National Market and the market for applied genomics companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the performance of those companies.

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.

Item 7a. Quantitative and Qualitative Disclosures About Market Risk

We have no derivative financial instruments. We invest our cash and cash equivalents 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.

Item 8. Financial Statements and Supplementary Data

EXACT SCIENCES CORPORATION
(A Development Stage Company)
Index to Financial Statements

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.

/s/ ARTHUR ANDERSEN LLP

Boston, Massachusetts
January 28, 2002

EXACT SCIENCES CORPORATION

(A Development Stage Company)

Consolidated Balance Sheets

	December 31, 2000	December 31, 2001
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 26,469,866	$ 56,842,722
Prepaid expenses	738,475	721,179
Total current assets	27,208,341	57,563,901
Property and Equipment, at cost:		
Laboratory equipment	1,011,052	2,497,113
Office and computer equipment	429,014	1,178,153
Leasehold improvements	236,437	581,102
Furniture and fixtures	175,996	211,530
	1,852,499	4,467,898
Less—Accumulated depreciation and amortization	(988,967)	(1,883,783)
	863,532	2,584,115
Patent Costs and Other Assets, net of accumulated amortization of approximately $223,000 and $397,000 at December 31, 2000 and 2001, respectively (Note 2)	986,629	2,952,221
	$ 29,058,502	$ 63,100,237
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 582,298	$ 1,176,440
Accrued expenses (Note 12)	776,396	2,407,367
Deferred licensing fees (Note 2)	—	549,625
Total current liabilities	1,358,694	4,133,432
Commitments (Note 10)		
Stockholders' Equity:		
Series A convertible preferred stock, $0.01 par value- Authorized—1,000,000 shares Issued and outstanding—902,414 shares at December 31, 2000	9,024	—
Series B convertible preferred stock, $0.01 par value Authorized—1,250,000 shares Issued and outstanding—996,196 shares at December 31, 2000	9,962	—
Series C convertible preferred stock, $0.01 par value Authorized—1,015,000 shares Issued and outstanding—1,007,186 shares at December 31, 2000	10,072	—
Series D convertible preferred stock, $0.01 par value Authorized—1,435,373 shares Issued and outstanding—1,417,534 shares at December 31, 2000	14,175	—
Common stock, $0.01 par value Authorized—100,000,000 shares Issued and outstanding—2,789,581 and 18,790,807 shares at December 31, 2000 and 2001, respectively	27,896	187,908
Additional paid-in capital	60,281,143	110,497,193
Treasury stock, 50,646 shares at December 31, 2001	—	(8,353)
Subscriptions receivable	(975,443)	(946,433)
Deferred compensation	(8,578,341)	(4,179,405)
Deficit accumulated during the development stage	(23,098,680)	(46,584,105)
Total stockholders' equity	27,699,808	58,966,805
	$ 29,058,502	$ 63,100,237

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

EXACT SCIENCES CORPORATION

(A Development Stage Company)

Consolidated Statements of Operations

	Year Ended December 31,			Period from Inception (February 10, 1995) to December 31, 2001
	1999	2000	2001	
Revenue	$ —	$ —	$ 50,870	$ 50,870
Operating Expenses:				
Research and development	3,688,796	5,332,055	13,335,265	26,792,187
Selling, general and administrative	1,560,368	4,813,715	9,077,564	17,892,256
Stock-based compensation (1)	13,780	3,184,053	3,788,498	6,989,078
Loss from operations	(5,262,944)	(13,329,823)	(26,150,457)	(51,622,651)
Interest Income	299,019	1,446,704	2,665,032	5,038,546
Net loss	$(4,963,925)	$(11,883,119)	$(23,485,425)	$(46,584,105)
Net Loss Per Share:				
Basic and diluted	$ (5.32)	$ (8.13)	$ (1.42)	
Weighted Average Common Shares Outstanding:				
Basic and diluted	932,593	1,461,726	16,487,499	

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

Research and development	$ 8,819	$ 809,880	$ 897,760	$ 1,718,469
General and administrative	4,961	2,374,173	2,890,738	5,270,609
Total	$ 13,780	$ 3,184,053	$ 3,788,498	$ 6,989,078

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

EXACT SCIENCES CORPORATION
(A Development Stage Company)
Consolidated Statements of Stockholders' Equity

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Treasury Stock		Subscriptions Receivable	Deferred Compensation	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
	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		Number of Shares	$0.01 Par Value				
Inception, February 10, 1995	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	$ —	—	$ —	$ —	$ —	$ —	$ —
Sales of Series A convertible preferred stock, net of issuance costs of $6,665	159,308	1,593	—	—	—	—	—	—	—	—	176,574	—	—	—	—	—	178,167
Sale of common stock	—	—	—	—	—	—	—	—	96,250	963	(613)	—	—	—	—	—	350
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(138,163)	(138,163)
Balance, December 31, 1995	159,308	1,593	—	—	—	—	—	—	96,250	963	175,961	—	—	—	—	(138,163)	40,354
Sale of Series A convertible preferred stock, net of issuance costs of $12,321	743,106	7,431	—	—	—	—	—	—	—	—	842,617	—	—	(25,000)	—	—	825,048
Sale of Series B convertible preferred stock, net of issuance costs of $36,892	—	—	964,551	9,646	—	—	—	—	—	—	3,763,444	—	—	—	—	—	3,773,090
Sale of common stock	—	—	—	—	—	—	—	—	550,000	5,500	18,500	—	—	—	—	—	24,000
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(652,020)	(652,020)
Balance, December 31, 1996	902,414	9,024	964,551	9,646	—	—	—	—	646,250	6,463	4,800,522	—	—	(25,000)	—	(790,183)	4,010,472
Sale of Series B convertible preferred stock, net of issuance costs of $4,138	—	—	31,645	316	—	—	—	—	—	—	120,500	—	—	—	—	—	120,816
Sale of common stock	—	—	—	—	—	—	—	—	203,607	2,036	27,580	—	—	—	—	—	29,616
Exercise of common stock options	—	—	—	—	—	—	—	—	23,375	233	787	—	—	—	—	—	1,020
Compensation expense related to issuance of stock options	—	—	—	—	—	—	—	—	—	—	10,155	—	—	—	(9,310)	—	845
Repayment of subscription receivable	—	—	—	—	—	—	—	—	—	—	—	—	—	25,000	—	—	25,000
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(1,883,073)	(1,883,073)
Balance, December 31, 1997	902,414	9,024	996,196	9,962	—	—	—	—	873,232	8,732	4,959,544	—	—	—	(9,310)	(2,673,256)	2,304,696
Sale of Series C convertible preferred stock, net of issuance costs of $37,414	—	—	—	—	1,007,186	10,072	—	—	—	—	10,527,979	—	—	—	—	—	10,538,051
Sale of common stock	—	—	—	—	—	—	—	—	55,000	550	7,450	—	—	—	—	—	8,000
Exercise of common stock options	—	—	—	—	—	—	—	—	517,000	5,170	64,010	—	—	(47,580)	—	—	21,600
Repayment of subscription receivable	—	—	—	—	—	—	—	—	—	—	—	—	—	3,802	—	—	3,802
Compensation expense related to issuance of stock options	—	—	—	—	—	—	—	—	—	—	8,583	—	—	—	(6,681)	—	1,902
Repurchase of common stock	—	—	—	—	—	—	—	—	—	—	—	8,250	(1,200)	—	—	—	(1,200)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(3,578,380)	(3,578,380)
Balance, December 31, 1998	902,414	$9,024	996,196	$9,962	1,007,186	$10,072	—	$ —	1,445,232	$14,452	$15,567,566	8,250	$(1,200)	$(43,778)	$(15,991)	$(6,251,636)	$ 9,298,471

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

EXACT SCIENCES CORPORATION
(A Development Stage Company)
Consolidated Statements of Stockholders' Equity

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Treasury Stock		Subscriptions Receivable	Deferred Compensation	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
	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		Number of Shares	$0.01 Par Value				
Balance, December 31, 1998	902,414	$ 9,024	996,196	$ 9,962	1,007,186	$10,072	—	$ —	1,445,232	$ 14,452	$ 15,567,566	8,250	$(1,200)	$ (43,778)	$ (15,991)	$ (6,251,636)	$ 9,298,471
Exercise of common stock options	—	—	—	—	—	—	—	—	155,491	1,555	57,462	—	—	—	—	—	59,017
Repayment of subscription receivable	—	—	—	—	—	—	—	—	—	—	—	—	—	4,072	—	—	4,072
Compensation expense related to issuance of stock options	—	—	—	—	—	—	—	—	—	—	52,271	—	—	—	(38,491)	—	13,780
Repurchase of common stock	—	—	—	—	—	—	—	—	—	—	—	9,625	(1,400)	—	—	—	(1,400)
Retirement of treasury stock	—	—	—	—	—	—	—	—	(17,875)	(179)	(2,421)	(17,875)	2,600	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(4,963,925)	(4,963,925)
Balance, December 31, 1999	902,414	9,024	996,196	9,962	1,007,186	10,072	—	—	1,582,848	15,828	15,674,878	—	—	(39,706)	(54,482)	(11,215,561)	4,410,015
Sale of Series D convertible preferred stock, net of issuance costs of $171,985	—	—	—	—	—	—	1,417,534	14,175	—	—	31,708,355	—	—	—	—	—	31,722,530
Sale of common stock	—	—	—	—	—	—	—	—	48,125	481	17,894	—	—	—	—	—	18,375
Repurchase of common stock	—	—	—	—	—	—	—	—	—	—	—	27,844	(5,215)	5,215	—	—	—
Retirement of treasury stock	—	—	—	—	—	—	—	—	(27,841)	(278)	(4,937)	(27,844)	5,215	—	—	—	—
Exercise of common stock options	—	—	—	—	—	—	—	—	1,186,449	11,865	1,176,707	—	—	(1,022,668)	—	—	165,904
Repayment of subscription receivable	—	—	—	—	—	—	—	—	—	—	—	—	—	81,716	—	—	81,716
Compensation expense related to issuance of stock options	—	—	—	—	—	—	—	—	—	—	11,358,768	—	—	—	(8,523,859)	—	2,834,909
Non-cash expense related to issuance of warrant	—	—	—	—	—	—	—	—	—	—	349,478	—	—	—	—	—	349,478
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(11,883,119)	(11,883,119)
Balance, December 31, 2000	902,414	9,024	996,196	9,962	1,007,186	10,072	1,417,534	14,175	2,789,581	27,896	60,281,143	—	—	(975,443)	(8,578,341)	(23,098,680)	27,699,808
Repurchase of common stock	—	—	—	—	—	—	—	—	—	—	—	50,646	(8,353)	—	—	—	(8,353)
Issuance shares under stock purchase plan	—	—	—	—	—	—	—	—	4,737	47	32,401	—	—	—	—	—	32,448
Exercise of common stock options	—	—	—	—	—	—	—	—	107,354	1,074	163,748	—	—	(49,931)	—	—	114,891
Sale of common stock at initial public offering, net of issuance costs of $5,442,264	—	—	—	—	—	—	—	—	4,000,000	40,000	50,517,736	—	—	—	—	—	50,557,736
Repayment of subscription receivable	—	—	—	—	—	—	—	—	—	—	—	—	—	78,941	—	—	78,941
Conversion of convertible preferred stock into common stock at initial public offering	(902,414)	(9,024)	(996,196)	(9,962)	(1,007,186)	(10,072)	(1,417,534)	(14,175)	11,889,135	118,891	(75,658)	—	—	—	—	—	—
Compensation expense related to issuance of stock options	—	—	—	—	—	—	—	—	—	—	(610,438)	—	—	—	4,398,936	—	3,788,498
Non-cash cost related to issuance of warrant	—	—	—	—	—	—	—	—	—	—	188,261	—	—	—	—	—	188,261
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(23,485,425)	(23,485,425)
Balance, December 31, 2001	—	$ —	—	$ —	—	$ —	—	$ —	18,790,807	$187,908	$110,497,193	50,646	$(8,353)	$ (946,433)	$(4,179,405)	$(46,584,105)	$ 58,966,805

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

EXACT SCIENCES CORPORATION

(A Development Stage Company)

Consolidated Statements of Cash Flows

	Year Ended December 31,			Period from Inception (February 10, 1995) to December 31, 2001
	1999	2000	2001	
Cash Flows from Operating Activities:				
Net loss	$(4,963,925)	$(11,883,119)	$(23,485,425)	$(46,584,105)
Adjustments to reconcile net loss to net cash used in operating activities —				
Depreciation and amortization	424,285	404,142	1,068,309	2,261,413
Non-cash stock-based compensation expense	13,780	2,834,909	3,788,498	6,639,934
Non-cash expense associated with the issuance of warrants	—	349,478		349,478
Changes in assets and liabilities:				
Prepaid expenses	(21,573)	(711,632)	17,296	(721,179)
Accounts payable	16,330	385,403	594,142	1,176,440
Accrued expenses	(76,494)	629,403	2,180,596	2,956,992
Net cash used in operating activities	(4,607,597)	(7,991,416)	(15,836,584)	(33,921,027)
Cash Flows from Investing Activities:				
Purchases of property and equipment	(292,183)	(762,647)	(2,615,399)	(4,450,947)
Increase in patent costs and other assets	(429,385)	(317,853)	(1,950,824)	(3,141,590)
Net cash used in investing activities	(721,568)	(1,080,500)	(4,566,223)	(7,592,537)
Cash Flows from Financing Activities:				
Payments on capital lease obligations	(6,405)	—	—	(16,951)
Net proceeds from sale of common stock	—	18,375	50,557,736	50,638,077
Net proceeds from sale of convertible preferred stock	—	31,722,530	—	47,157,703
Proceeds from exercise of common stock options and stock purchase plan	59,017	165,904	147,339	394,880
Repurchase of treasury shares	—	—	(8,353)	(8,353)
Repayment of stock subscription receivable	4,072	81,716	78,941	190,930
Net cash provided by financing activities	56,684	31,988,525	50,775,663	98,356,286
Net (Decrease) Increase in Cash and Cash Equivalents	(5,272,481)	22,916,609	30,372,856	56,842,722
Cash and Cash Equivalents, beginning of period	8,825,738	3,553,257	26,469,866	—
Cash and Cash Equivalents, end of period	$ 3,553,257	$ 26,469,866	$ 56,842,722	$ 56,842,722
Supplemental Disclosure of Non-Cash Investing and Financing Activities:				
Sale of restricted stock through issuance of notes receivable	$ —	$ 1,022,668	$ 49,931	$ 1,120,179
Purchase of treasury shares through the forgiveness of note receivable	$ 1,400	$ —	$ —	$ 2,600
Equipment purchased through capital lease obligations	$ —	$ —	$ —	$ 16,951
Issuance of warrant to purchase intellectual property	$ —	$ —	$ 188,261	$ 188,261

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

EXACT SCIENCES CORPORATION

(A Development Stage Company)

Notes to Financial Statements

December 31, 2001

(1) ORGANIZATION

EXACT Sciences Corporation (the "Company") was incorporated on February 10, 1995. The Company is in the development stage and applies proprietary genomics technologies to the early detection of several types of common cancers. The Company has selected colorectal cancer as the first application of its technology platform.

The Company is devoting substantially all of its efforts toward product research and development, raising capital and marketing products under development. The Company has not generated substantive revenue to date and is subject to a number of risks similar to those of other development-stage companies, including dependence on key individuals and the need for the continued development of commercially usable products. 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 $50.6 million after deducting the underwriters' commission and issuance costs. Upon consummation of the initial public offering, all 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. Cash equivalents primarily consist of money market funds at December 31, 2000 and 2001.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Depreciation and Amortization

Depreciation and amortization are 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

Net Loss Per Share

Basic and diluted net loss per share is presented in conformity with Statement of Financial Accounting Standards (SFAS) No. 128, *Earnings per Share,* for all periods presented. In accordance with SFAS No. 128, basic and diluted 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 conversion of outstanding preferred stock and options to purchase a total of 1,097,830, 1,771,621 and 2,228,077 common shares and 555,900, 996,806 and 649,963 unvested restricted shares have therefore been excluded from the computations of diluted weighted average shares outstanding for the years ended December 31, 1999, 2000 and 2001, 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 years ended December 31, 2000 and 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.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

The following table reconciles the Company's net loss, which excludes non-cash stock-based compensation, and the weighted average common shares outstanding to the net loss and shares used in the computation of pro forma basic and diluted net loss per share:

	Year Ended December 31,	
	2000	2001
Net loss	$(11,883,119)	$(23,485,425)
Stock-based compensation	3,184,053	3,788,498
Pro forma net loss	$ (8,699,066)	$(19,696,927)
Weighted average shares outstanding	1,461,726	16,487,499
Weighted conversion of preferred stock to common stock	10,849,632	1,023,786
Pro forma weighted average shares outstanding	12,311,358	17,511,285
Pro forma basic and diluted net loss per share	$ (0.71)	$ (1.12)

Patent Costs and Other Assets

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 4 issued patents and 40 pending patent applications. The purchase price for the assets included $1.3 million in cash and warrants to purchase 40,000 shares of common stock immediately, exercisable over a three-year period, at an exercise price of $7.33 per share which the Company valued at $188,261 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. Capitalized patent costs related to patents which are not issued or are no longer pursued by the Company 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. License fees are amortized over the five-year period of the license.

The Company applies SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of,* 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. The Company does not believe that its long-lived assets have been impaired through December 31, 2001.

Revenue Recognition

The Company's revenue for the year ended December 31, 2001 is primarily composed of amortization of up-front technology license fees which are being amortized on a straight-line basis over the license period.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Research and Development Expenses

The Company charges research and development expenses to operations as incurred.

Advertising Costs

The Company expenses the costs of media advertising at the time the advertising take place.

Comprehensive Income

SFAS No. 130, *Reporting Comprehensive Income*, requires disclosure of all components of comprehensive income on an annual and interim basis. Comprehensive income is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive net loss is the same as reported net loss for all periods presented.

Stock Split

The Company effected a 2.75-for-1 common stock split on December 1, 2000. All common share and per-share amounts in the accompanying consolidated financial statements prior to December 1, 2000 have been retroactively adjusted to reflect this stock split.

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 equivalents, accounts payable and capital lease obligations. The estimated fair value of these financial instruments approximates their carrying values.

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 and cash equivalents. The Company maintains its cash and cash equivalents with financial institutions with high credit ratings.

Segment Information

The Company has adopted SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information,* which 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's chief decision-maker, as defined under SFAS No. 131, is a combination of the chairman, vice president and chief financial officer and president. 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

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

herein represents all of the material financial information related to the Company's principal operating segment.

Recent Accounting Pronouncements

In June 1998, the Financial Accounting Standards Board (FASB) issued SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities.* As amended in June 1999, the statement is effective for all fiscal quarters of all fiscal years beginning after June 15, 2000. In June 2000, the FASB issued SFAS No. 138, which is a significant amendment to SFAS No. 133. SFAS No. 133 and its amendments establish accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts (collectively, the derivatives) and for hedging activities. The EITF has also issued a number of derivative-related tentative and final consensuses. These statements do not have an impact on its consolidated position or results of operations.

In July 2001, the FASB issued SFAS No. 141, *Business Combinations*, and SFAS No. 142, *Goodwill and Other Intangible Assets*. SFAS 141 requires the purchase method of accounting for all business combinations initiated after June 30, 2001 and eliminates the pooling-of-interests method. SFAS 142 is effective January 1, 2002 and requires, among other things, the discontinuance of goodwill amortization. In addition, the standard includes provisions for the reclassification of certain existing recognized intangibles as goodwill, the reassessment of the useful lives of existing recognized intangibles, the reclassification of certain intangibles out of previously reported goodwill and the identification of reporting units for purposes of assessing potential future impairments of goodwill. The Company does not expect the adoption of these statements to have a material impact on its financial statements.

In October 2001, the FASB issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long-lived Assets,* which is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal years. This SFAS develops one accounting model for long-lived assets that are to be disposed of by sale as well as addressing the principal implementation issues. The Company does not expect the adoption of this statement to have a material impact on its financial statements.

(3) INCOME TAXES

The Company accounts for income taxes under 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, 2001, the Company had net operating loss and research tax credit carryforwards of approximately $37 million and $943,000, respectively, for financial reporting purposes, which may be used to offset future taxable income. The carryforwards expire through 2021 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.

(3) INCOME TAXES (Continued)

The components of the net deferred tax asset with the approximate income tax effect of each type of carryforward, credit and temporary difference are as follows:

	December 31,	
	2000	2001
Operating loss carryforwards	$ 9,206,000	$ 14,811,000
Tax credit carryforwards	609,000	943,000
Temporary differences	(318,000)	3,815,000
	9,497,000	19,569,000
Less — Valuation allowance	(9,497,000)	(19,569,000)
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.

(4) SUBSCRIPTIONS RECEIVABLE

In February 1998, the Company issued full recourse notes receivable to several employees totaling $47,580 for the exercise of stock options. The notes bear interest at 8.5% with principal and interest payments due monthly over a five-year period.

In March 2000, the Company issued full recourse notes receivable to several employees totaling $262,080 for the exercise of stock options. The notes bear interest at 9.0% with interest payments due monthly over a five-year period. Notes representing an aggregate principal amount of $69,680 are payable monthly. Notes representing aggregate principal amounts of $192,400 are payable in March 2005.

In June 2000, the Company issued full recourse notes receivable to an executive totaling $299,999 to purchase restricted stock. The note bears interest at 9.5% with interest and principal due on June 23, 2010.

In November 2000, the Company issued full recourse notes receivable to executives and employees totaling $460,589 to purchase restricted stock. The notes bear interest at 9.5% with interest and principal due on November 27, 2010.

In January 2001, the Company issued full recourse notes receivable to an executive for $49,931 to purchase restricted stock. The note bears interest at 9.0% with interest and principal due on January 29, 2010.

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 remain in effect.

(5) RELATED PARTY TRANSACTIONS

In February 1998, the Company entered into a letter agreement with one of its shareholders, the Mayo Foundation, for a clinical study. The Company paid approximately $114,000 and $229,000 in connection with the clinical study during the years ended December 31, 1999 and 2000, respectively, which represents the total amount to be paid under the agreement. Such amounts have been charged to research and development expenses as incurred. In December 2000, the Company issued a warrant to the same shareholder to purchase 48,125 shares of common stock at an exercise price of $10.91 per share (see Note 6).

In October 2001, the Company signed a Clinical Trial Agreement with the Mayo Foundation, a shareholder of the Company, and Mayo Clinic pursuant to which the Company's genomics-based colorectal cancer technology will be the subject of an independent study by Mayo Clinic. This three-year study will involve approximately 4,000 patients at average risk for developing colorectal cancer and compare the results of Company's non-invasive, genomics-based screening technology with those of the fecal occult blood test, a common first-line colorectal cancer screening option. Using its proprietary technologies, the Company agreed to process all the stool samples at its CLIA-approved laboratory and to pay total fees of $654,000 over approximately three years which is being charged to research and development expense as incurred. The Company paid approximately $109,000 to the Mayo Clinic during the year ended December 31, 2001 related to this study.

In March 2001, the Company entered into a consulting agreement with a member of its Board of Directors. The Company paid approximately $37,000 for services provided under the agreement for the year ended December 31, 2001.

(6) STOCKHOLDERS' EQUITY

Convertible Preferred Stock

The Company has authorized 4,700,373 shares of $0.01 par value convertible preferred stock, of which 1,000,000 are designated as Series A convertible preferred stock (Series A preferred), 1,250,000 are designated as Series B convertible preferred stock (Series B preferred), 1,015,000 are designated as Series C convertible preferred stock (Series C preferred) and 1,435,373 are designated as Series D convertible preferred stock (Series D preferred).

In February 1995 and May through November 1996 the Company issued 159,308 and 743,106 shares, respectively, of Series A preferred for $1.16 per share. In December 1996 and February 1997, the Company issued 964,551 and 31,645 shares, respectively, of Series B preferred for $3.95 per share. In March 1998, the Company issued 1,007,186 shares of Series C preferred for $10.50 per share. In April 2000, the Company issued 1,417,534 shares of Series D preferred for $22.50 per share.

Dividends

The holders of Series A, B, C and D preferred are entitled to receive dividends, as defined, if and when declared by the Company's Board of Directors. To date, no dividends have been declared.

(6) STOCKHOLDERS' EQUITY (Continued)

Voting Rights

Each holder of outstanding shares of Series A, B, C and D preferred is entitled to a number of votes equal to the number of whole shares of common stock into which such preferred shares are then convertible. All outstanding holders of convertible preferred stock shall vote together with the holders of common stock as a single class.

Liquidation

In the event of any voluntary or involuntary dissolution of the Company and before any distribution or other payment is made to any holders of any class or series of capital stock of the Company, the holders of each share of Series A, B, C and D preferred shall be entitled to receive $1.16, $3.95, $10.50 and $22.50, respectively, plus any dividends declared but unpaid.

Conversion

Each share of Series A, B, C and D preferred was convertible, at the option of the holder, into such number of shares of common stock as is determined by dividing $1.16, $3.95, $10.50 and $22.50 per share, respectively, by the conversion price, as defined. Series A, B, C and D preferred automatically converted into 11,889,135 shares of common stock upon the closing of the Company's initial public offering on February 5, 2001.

Restricted Common Stock

On May 10, 1996, the Company sold 550,000 shares of restricted common stock to a key employee. In 1997, the Company sold 68,750 shares of restricted common stock to a key employee and 134,857 shares of restricted common stock to another employee. In February 1998, the Company sold 492,250 shares of restricted common stock to employees of the Company pursuant to the exercise of options, 368,500 shares of which were purchased through issuance of notes receivable (see Note 4). During 2000, the Company sold 1,080,952 shares of restricted common stock to employees of the Company pursuant to the exercise of options, 968,202 shares of which were purchased through issuance of notes receivable (see Note 4). During 2001, the Company sold 6,875 shares of restricted common stock to an employee of the Company pursuant to the exercise of options which were purchased through issuance of a note receivable (see Note 4). The shares were sold at the then fair market value and vest over a three to five-year period. At December 31, 2001, 649,963 shares were unvested.

Warrant

In December 2000, the Company issued a warrant to the Mayo Foundation to purchase 48,125 shares of common stock at an exercise price of $10.91 per share. The warrant was exercisable immediately. The Company has valued the warrant using the Black-Scholes model in accordance with EITF 96-18 and recorded as research and development stock-based compensation of $349,478 in 2000.

In November 2001, the Company issued two warrants to MT Technologies (formerly known as Mosaic Technologies, Inc.) to purchase an aggregate of 40,000 shares of common stock at an exercise price of $7.33 per share in connection with the purchase of intellectual property surrounding its

(6) STOCKHOLDERS' EQUITY (Continued)

Hybrigel technology (see Note 2). The warrants are exercisable immediately and have a term of three years. The Company has valued these warrants using the Black-Scholes option pricing model in accordance with EITF 96-18 and recorded additional capitalized patent cost of $188,261.

(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, 2001.

(8) 2000 EMPLOYEE STOCK PURCHASE PLAN

The 2000 Employee Stock Purchase Plan (the 2000 Purchase Plan) was adopted on October 17, 2000. The 2000 Purchase Plan provides for the issuance of up to an aggregate of 300,000 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 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 4,737 shares of common stock at a price of $6.85 per share for the first offering period ended July 31, 2001.

(9) STOCK OPTION PLANS

1995 Stock Option Plan

The Company has a 1995 stock option plan (the 1995 Option Plan) under which the Board of Directors may grant incentive and non-qualified stock options to purchase an aggregate of 3,987,500 shares of common stock to employees and consultants of the Company. Non-qualified stock options may be granted to any employee or consultant of the Company. The exercise price of each option is determined by the Board of Directors. Incentive stock options may not be less than the fair market value of the stock on the date of grant, as defined by the Board of Directors. Options granted under the 1995 Option Plan vest over a three-to-five-year period and expire 10 years from the grant date.

The 1995 Option Plan was terminated on January 31, 2001, the effective date of the Company's registration statement in connection with its initial public offering. Options granted prior to the date of termination will remain outstanding and may be exercised in accordance with their terms, unless sooner terminated by vote of the board of directors. At December 31, 2001, 1,646,827 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. A total of 1,000,000 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, 2001, options to purchase 581,250 were outstanding under the 2000 Option Plan and 418,750 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, 1998	1,150,080	$0.30
Granted	132,000	0.38
Exercised	(155,491)	0.38
Canceled	(28,759)	0.15
Outstanding, December 31,1999	1,097,830	0.30
Granted	1,901,492	3.41
Exercised	(1,186,449)	1.00
Canceled	(41,252)	0.38
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
Exercisable, December 31, 1999	623,587	$0.19
Exercisable, December 31, 2000	360,722	$0.14
Exercisable, December 31, 2001	819,174	$3.90

The following table summarizes information relating to currently outstanding and exercisable stock options as of December 31, 2001:

	Outstanding			Exercisable	
Exercise Price	Number of Shares	Weighted Average Remaining Contractual Life (Years)	Exercisable Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
$0.04-$0.18	262,250	4.94	$ 0.08	262,250	$ 0.08
$0.38	377,076	7.93	0.38	185,319	0.38
$2.05	467,126	8.47	2.05	109,769	2.05
$5.50-$7.50	309,125	8.82	7.27	84,076	7.27
$8.00-$9.75	217,500	9.56	9.19	219	8.94
$10.10-$10.91	250,750	9.05	10.78	56,031	10.74
$11.15-$14.00	344,250	9.33	12.69	121,510	13.68
	2,228,077	8.32	$ 5.58	819,174	$ 3.90

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 paragraphs 8-12 of SFAS No. 123 and EITF 96-18, *Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. Compensation expense, computed using the Black-Scholes option pricing model, of $13,780, $528,593 and $167,030 was recorded in the accompanying consolidated statements of operations for the years ended December 31, 1999, 2000 and 2001, respectively. The following assumptions were used for 1999, 2000 and 2001: (i) expected lives of the options of seven years; (ii) no dividend yield; (iii) expected volatility of 70% to 100%; and (iv) risk-free interest rates of 2.86% to 6.51%.

In connection with certain 1999 and 2000 stock option grants to employees and directors, the Company recorded deferred compensation of $52,271 and $11,358,768 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.* All stock options granted and stock sold prior to 1999 were at fair market value, and therefore did not result in a compensation charge.

As of December 31, 2001, the Company expects to recognize amortization expense of deferred compensation recorded related to employee and director options of approximately $2.1 million, $1.3 million, $600,000 and $200,000 during the years ended December 31, 2002, 2003, 2004 and 2005, respectively.

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, 1999, 2000 and 2001, using the Black-Scholes option pricing model prescribed by SFAS No. 123.

The assumptions used for the years ended December 31, 1999, 2000 and 2001 are as follows:

	December 31,		
	1999	2000	2001
Risk-free interest rates	5.44%-5.97%	4.98%-6.16%	2.86%-4.98%
Expected lives	7 years	7 years	7 years
Expected volatility	0%	100%	100%
Dividend yield	0%	0%	0%
Weighted average fair value of grants	$ 0.13	$ 2.91	$ 3.07

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

	Years Ended December 31,		
	1999	2000	2001
Net loss as reported	$(4,963,925)	$(11,883,119)	$(23,485,425)
Pro forma net loss	$(4,993,586)	$(11,955,270)	$(26,615,376)
Basic and Diluted Net Loss Per Share:			
As reported	$ (5.32)	$ (8.13)	$ (1.42)
Pro forma	$ (5.35)	$ (8.18)	$ (1.61)

(10) COMMITMENTS

The Company leases certain equipment and conducts its operations in a leased facility under noncancelable operating leases expiring through June 2003. Future minimum rental payments under the operating leases as of December 31, 2001 are approximately as follows:

Year Ending December 31,	
2002	$304,000
2003	162,000
Total lease payments	$466,000

Rent expense included in the accompanying consolidated statements of operations was approximately $146,000, $216,000 and $301,000 for the years ended December 31, 1999, 2000 and 2001, respectively.

(11) ROYALTY AGREEMENTS

Roche License

The Company licenses, on a non-exclusive basis, the 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 the Company utilizes expires in mid-2004. In exchange for the license, the Company agreed to pay Roche a royalty based on net revenues received from tests using the Company's technologies. Roche may terminate this license upon notice if the Company fails to pay royalties, fails to submit reports or breaches a material term of the license. Royalty payments will be expensed as they become due.

Genzyme License

The Company licenses, on a non-exclusive basis, technology for performing a step in its testing methods from Genzyme Corporation (Genzyme), the exclusive 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 and methodologies related thereto in connection with its products and services and lasts for the life of the patent term of the last licensed Genzyme patent. In exchange for the license,

(11) ROYALTY AGREEMENTS (Continued)

the Company has agreed to pay Genzyme an upfront license fee that is being amortized over the life of the contract, a royalty based on net revenues received from performing the Company's tests and the sale of diagnostic test kits, as well as certain milestone payments and maintenance fees. In addition, the Company 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 the Company fails to pay milestone payments and royalties, achieve a stated level of sales and submit reports. In addition, if the Company fails to request FDA clearance for a diagnostic test as required by the agreement, Genzyme may terminate the license. The Company has recorded research and development expense associated with this agreement of $42,500, $50,000 and $50,000 for the years ended December 31, 1999, 2000 and 2001, respectively.

(12) ACCRUED EXPENSES

Accrued expenses at December 31, 2000 and 2001 consisted of the following:

	December 31,	
	2000	2001
Research and trial-related expenses	$ 48,926	$1,094,861
Payroll and payroll-related	93,667	620,244
Professional fees	194,440	206,043
Consulting	246,899	163,625
Shareholder services	100,000	65,000
Other	92,464	257,594
	$776,396	$2,407,367

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

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

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 13, 2002, 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, 2001, 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 have been advised that our Chairman of the Board of Directors, Stanley N. Lapidus, has entered into a trading plan in accordance with Rule 10b5-1 and our policy governing transactions in our securities. 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 13, 2002, 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, 2001, is hereby incorporated by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The information under 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 13, 2002, 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, 2001, is hereby incorporated by reference.

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 13, 2002, 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, 2001, is hereby incorporated by reference.

PART IV

Item 14. 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)
4.2	Warrant issued to The Mayo Foundation for Medical Research dated December 28, 2000 (previously filed as Exhibit 4.2 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
4.3	Warrant between the Registrant and GATX Ventures, Inc. dated November 7, 2001
4.4	Warrant between the Registrant and TBCC Funding Trust dated November 7, 2001
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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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Exhibit Number	Description
10.7*	Restricted Stock Purchase Agreement between the Registrant and Don M. Hardison dated as of June 23, 2000, as amended (previously filed as Exhibit 10.7 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.8*	Secured Promissory Note between the Registrant and Stanley N. Lapidus dated as of March 31, 2000 (previously filed as Exhibit 10.8 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.9*	Pledge Agreement between the Registrant and Stanley N. Lapidus dated as of March 31, 2000 (previously filed as Exhibit 10.9 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.10*	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)
10.11	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)
10.12	Fourth Amendment to Lease Agreement, dated February 7, 2001, between C.B. Realty Limited Partnership and the Registrant
10.13	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)
10.14	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)
10.15	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)
10.16	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)
10.17	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)
10.18*	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)
10.19*	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)
10.20*	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)

Exhibit Number	Description
10.21*	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)
10.22*	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)
10.23*	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)
10.24*	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)
10.25	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)
10.26*	Amendment No 1. to Full Recourse Promissory Note between the Registrant and Stanley N. Lapidus dated as of November 30, 2001
10.27*	Amendment No 1. to Full Recourse Promissory Note between the Registrant Don M. Hardison dated as of November 30, 2001
10.28*	Amendment No 1. to Full Recourse Promissory Note between the Registrant and John A. McCarthy, Jr. dated as of November 30, 2001
10.29*	Executive Cash Incentive Plan dated October 15, 2001
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 Arthur Andersen LLP
24.1	Power of Attorney (included on signature page)
99.1	Letter to Commission pursuant to Temporary Note 3T

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

(b) Reports on Form 8-K.

During the quarter ended December 31, 2001, we filed one report on Form 8-K, dated October 16, 2001, which announced a conference call to discuss our third quarter of 2001 financial results. We filed no other reports on Form 8-K during the quarter ended December 31, 2001.

SIGNATURES

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

EXACT SCIENCES CORPORATION

Date: March 26, 2002

By: /s/ JOHN A. MCCARTHY, JR.

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

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	March 26, 2002
/s/ DON M. HARDISON Don M. Hardison	President, Chief Executive Officer and Director (Principal Executive Officer)	March 26, 2002
/s/ JOHN A. MCCARTHY, JR. John A. McCarthy, Jr.	Executive Vice President, Chief Operating Officer, Chief Financial Officer and Treasurer (Duly Authorized Officer and Principal Financial Officer)	March 26, 2002
/s/ RICHARD W. BARKER Richard W. Barker	Director	March 26, 2002
/s/ SALLY W. CRAWFORD Sally W. Crawford	Director	March 26, 2002
/s/ WYCLIFFE K. GROUSBECK Wycliffe K. Grousbeck	Director	March 26, 2002
/s/ WILLIAM W. HELMAN William W. Helman	Director	March 26, 2002
/s/ EDWIN M. KANIA, JR. Edwin M. Kania, Jr.	Director	March 26, 2002
/s/ CONNIE MACK, III Connie Mack, III	Director	March 26, 2002
/s/ LANCE WILLSEY Lance Willsey	Director	March 26, 2002

Exhibit Index to Annual Report on Form 10-K
for Fiscal Year Ended December 31, 2001

Exhibit Number	Description
3.1	Sixth Amended and Restated Certificate of Incorporation of the Registrant (previously filed as Exhibit 3.3 to our Registration Statement on Form S-1 File No. 333-48812), which is incorporated herein by reference)
3.2	Amended and Restated By-Laws of the Registrant (previously filed as Exhibit 3.4 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
4.1	Specimen certificate representing the Registrant's Common Stock (previously filed as Exhibit 4.1 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
4.2	Warrant issued to The Mayo Foundation for Medical Research dated December 28, 2000 (previously filed as Exhibit 4.2 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
4.3	Warrant between the Registrant and GATX Ventures, Inc. dated November 7, 2001
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* Indicates a management contract or any compensatory plan, contract or arrangement.

Exhibit 23.1

CONSENT OF INDEPENDENT PUBLIC ACCOUNTANTS

As independent public accountants, we hereby consent to the incorporation of our reports included in this Form 10-K, into the Company's previously filed Registration Statements (File Numbers: 333-48812 and 333-54618).

/s/ ARTHUR ANDERSEN LLP

Boston, Massachusetts
March 26, 2002

Management

Stanley N. Lapidus
Chairman and Director

Don M. Hardison
President, CEO and Director

John A. McCarthy, Jr.
Executive Vice President, Chief Operating Officer and Chief Financial Officer

Anthony P. Shuber
Senior Vice President and Chief Technology Officer

Barry M. Berger, MD
Vice President of Laboratory Medicine

David M. Deems
Vice President of Product Development

David W. Nikka
Vice President of Resources and Development

William J. Pignato
Vice President of Regulatory Affairs

Stephen A. Read
Vice President and Corporate Controller

Robert B. Rochelle
Vice President of Marketing

Michael E. Ross, MD
Vice President of Clinical Affairs

Jeffrey T. Walsh
Vice President of Business Development

Board of Directors

Stanley N. Lapidus
Chairman, EXACT Sciences

Don M. Hardison
President and CEO, EXACT Sciences

Richard W. Barker, PhD
President, New Medicine Partners, LLC

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

Wycliffe K. Grousbeck
General Partner, Highland Capital Partners; Director, LivePerson, Inc.

William W. Helman
General Partner, Greylock (Venture Capital Partnership); Director, Jupiter Media Metrix, Inc.

Edwin M. Kania, Jr.
Managing General Partner, OneLiberty Ventures, Special Partner, AGTC Funds; Director, Aspect Medical Systems

Connie Mack
Former U.S. Senator; Of Counsel to Pittman Shaw; Director, Genzyme Corporation

Lance Willsey, MD
Director, Exelixis, Inc.

Scientific Advisory Board

David F. Ransohoff, MD
Chairman, Scientific Advisory Board, EXACT Sciences; Professor of Medicine and Clinical Professor of Epidemiology, University of North Carolina, Chapel Hill

David A. Ahlquist, MD
Professor of Medicine at Mayo Medical School; Director of Colorectal Neoplasia Clinic in the Gastroenterology and Hepatology Division at Mayo Clinic

C. Richard Boland, MD
Professor of Medicine and Chief, Division of Gastroenterology, University of California, San Diego

Robert Fletcher, MD
Professor of Ambulatory Care and Prevention at Harvard Medical School and Harvard Pilgrim Health Care

Kenneth Kinzler, PhD
Professor of Oncology, The Johns Hopkins University School of Medicine

David A. Lieberman, MD
Professor of Medicine and Chief, Division of Gastroenterology, Oregon Health Sciences University; Section Chief, Gastroenterology, Portland VA Medical Center

Bert Vogelstein, MD
Professor of Oncology and Pathology, The Johns Hopkins University School of Medicine; Investigator, Howard Hughes Medical Institute

James W. Winkelman, MD
Director, Clinical Laboratories, Vice President, Brigham and Women's Hospital; Professor of Pathology, Harvard Medical School

Corporate Information

Corporate Headquarters
63 Great Road
Maynard, MA 01754
Telephone 978.897.2800
Fax 978.897.3481
Web site www.exactsciences.com

Corporate Counsel
Testa, Hurwitz & Thibeault, LLP
Boston, Massachusetts

Independent Auditors
Arthur Anderson LLP
Boston, Massachusetts

Registrar and Transfer Agent
American Stock Transfer & Trust Company
59 Maiden Lane
New York, New York 10038
Telephone 800.937.5449
Fax 718.236.2641
Web site www.amstock.com

Stockholder Inquiries
Inquiries related to stock transfers or lost certificates should be directed to American Stock Transfer & Trust Company, 59 Maiden Lane, New York, New York 10038. General information regarding the Company can be obtained by contacting EXACT Sciences' Investor Relations Department at 978.897.2800, ext. 252. Recent news releases and other information can also be obtained by accessing the Company's web site at www.exactsciences.com.

Annual Report on Form 10-K
A copy of the EXACT Sciences Annual Report on Form 10-K for the year ended December 31, 2001, filed with the Securities and Exchange Commission, is available without charge on request to:

Investor Relations Department
EXACT Sciences Corporation
63 Great Road
Maynard, MA 01754
Telephone 978.897.2800, ext. 234
Fax 978.897.3481
Web site www.exactsciences.com

Stock Information
The Company's common stock trades on NASDAQ under the symbol EXAS. As of April 22, 2002, there were 188 holders of record of the Company's common stock. No cash dividends have been paid on the common stock to date, and the Company does not anticipate paying any cash dividends in the foreseeable future.

Annual Meeting
The annual meeting will be held on June 13, 2002, at 10:00 AM at the offices of Testa, Hurwitz & Thibeault, LLP, 125 High Street Tower, 20th Floor, Boston, Massachusetts 02110.