

# EXACT SCIENCES CORP

## FORM 10-K (Annual Report)

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# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

## FORM 10-K

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

**FOR THE FISCAL YEAR ENDED: DECEMBER 31, 2000**

/ / 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  
(State or other jurisdiction of  
incorporation or organization)

02-0478229  
(IRS Employer Identification No.)

63 GREAT ROAD, MAYNARD, MASSACHUSETTS  
(Address of principal executive  
offices)

01754  
(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 /X/

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 29, 2001, was approximately \$70,852,913 (based on the closing price of the Registrant's Common Stock on March 29, 2001, of \$7.50 per share).

The number of shares outstanding of the Registrant's \$.01 par value Common Stock as of March 29, 2001 was 18,686,076.

### 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, 2000. Portions of such proxy statement are incorporated by reference into

Part III of this Form 10-K.

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**EXACT SCIENCES CORPORATION  
ANNUAL REPORT ON FORM 10-K  
YEAR ENDED DECEMBER 31, 2000**

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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 74 million Americans age 50 and above for whom the American Cancer Society and National Cancer Institute recommend regular colorectal cancer screening. Moreover, current detection methods for colorectal cancer have proven to be inadequate screening tools.

We have developed proprietary technologies that isolate the human DNA shed from the colon into stool. We then identify mutations in DNA shed from abnormal cells associated with colorectal cancer and pre-cancerous lesions. We have conducted blinded clinical studies at the Mayo Clinic 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 methods available for mass screening for colorectal cancer. Early detection results in less expensive and more effective treatment of patients. While our tests are more technically complex for a laboratory to perform and may be more expensive than some current colorectal screening methods, we believe that the benefits of early detection will convince medical practitioners and patients to use tests using our technologies. We are currently conducting an additional clinical study for colorectal cancer screening tests using our technologies and are seeking 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](http://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 graphic on this page consists of the words "Chromosome" and "Mutation" on the left side of the chart with the word "Chromosome" listed above "Mutation". Equally spaced and in line with the word "Chromosome" from left to right are the phrases "5q loss", "18q loss", "17p loss" and "8p loss". Equally spaced in line with the word "Mutation" from left to right are "Apc" directly underneath "5q loss", with the word "Beta-Catenin" directly underneath "Apc", "K-ras" directly underneath "18q loss", "Bat-26" directly underneath "17p loss", with "p53" directly underneath "Bat-26". Below these words are 5 equally spaced boxes connected by arrows from left to right. The following phrases are in the indicated box: "Normal Epithelium" in the first box, "Early Adenoma" in the second box, "Late Adenoma" in the third box, "Early Cancer" in the fourth box and "Late Cancer" in the fifth box. There is also an arrow connecting the corresponding chromosome and mutations to the space between the boxes.]

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 136,000 new cases and approximately 57,000 deaths in the year 2000 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:

[The chart is a rectangle with six vertical columns and three horizontal rows. The vertical columns, from left to right, are titled as follows: Column one is titled "Stage"; Column two is titled "Classification"; Column three is titled "Extent of Disease"; Column four is titled "% of Patients Diagnosed at This Stage"; Column five is titled "5-Year Survival Rates (approximate)"; and Column six is titled "Typical Treatment". The first row has the words: "Early" in the first column; the second column, which is subdivided into two rows, has the phrases "Dukes' A" in the top subdivison and "Dukes' B" in the bottom subdivision; the third column, which is subdivided into two rows, has the phrases "Confined to the surface lining of the colon" in the top subdivision and "Below the surface; no lymph node involvement" in the bottom subdivision; the fourth column has the percentage "37%" in the first row; the fifth column, which is subdivided into two rows, has the percentages "95%" in the top

subdivision and "85%" in the bottom subdivision; the sixth column has the word "Surgery". The second row has the word "Late" in the first column; the second column, which is subdivided into two rows, has the words "Dukes' C" in the top subdivision and "Dukes' D" in the bottom subdivision; the third column, which is also subdivided into two rows, has the phrases "Lymph node involvement" in the top subdivision and "Metastatic disease" in the bottom subdivision; the fourth column has the percentage "63%"; the fifth column, which is subdivided into two rows, has the percentages "50%-60%" in the top subdivision and "10%" in the bottom subdivision; and the sixth column has the phrase "Surgery and chemotherapy".]

Detection of pre-cancerous adenomas and cancer in its earliest stages increases the number of patients who survive and reduces the cost of treatment and care. As a result, the American Cancer Society and National Cancer Institute recommend that the 74 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 prostate cancer screening, mammography and fecal occult blood testing, or FOBT, 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 business opportunity is to use our technologies to lower mortality, morbidity and the costs associated with these cancers.

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, medical practitioners will refer them for colonoscopy for follow-up. 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 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 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, opinion leaders will educate primary care physicians, about the potential for improving detection of colorectal cancer with our technologies. We also believe that this will lead many primary care physicians to make regular testing based on our technologies a part of their physical examinations of patients aged 50 and above who, upon learning of the benefits, will be likely to submit 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 can treat early stage colorectal cancer and pre-cancerous lesions in a less expensive and more effective manner than late stage cancer.

- **SCALABILITY.** Screening 74 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 eleven issued U.S. patents and 25 pending U.S. patent applications relating to our testing process.

[This chart has three boxes and one oval connected by arrows from left to right with the following words in each box or oval: "Specimen Collection and Transportation", "Representative Sampling", "DNA Extraction, Purification and Amplification" and "Cancer Detection Methods".]

**SPECIMEN COLLECTION AND TRANSPORTATION.** We have based our tests on collecting a single whole stool in a self-contained device. Patients will bring the samples to their physicians who will forward them to the laboratory performing the colorectal cancer screening test.

**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. 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 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 longer human DNA fragments associated with abnormality	- Proprietary marker associated with cancer that does not require knowledge of which 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 missing gene and does not require knowledge of which genes cause cancer

**MULTIPLE MUTATION.** Multiple Mutation, or MuMu, identifies DNA mutations at specific sites. We have selected 15 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 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, pancreas, 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 from many body sites.

## **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 The 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 an agreement with Mayo Clinic, that expires on December 31, 2001, under which Dr. Ahlquist, a member of our scientific advisory board and a director of the Colorectal Neoplasia Clinic at Mayo, assists 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 also 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 and sell reagents 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 whose efforts will focus on securing adequate reimbursement for our products and services. This team will also educate senior staff of 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. In addition, we

believe that tests utilizing our technologies will be attractive to the 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 most existing tests.

## 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%

Based on these results, in August 2000 we initiated a multi-center clinical study for the primary purpose of establishing certain technological benchmarks for our DIA detection method on whole stools in anticipation of our multi-center clinical trial.

We intend to initiate a blinded multi-center clinical trial in the fourth quarter of 2001 that will include an estimated 5,300 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 compare the sensitivity and specificity of our tests for colorectal cancer to that of existing technologies on average-risk individuals. We intend to conduct this clinical trial in accordance with the applicable guidelines of the Food and Drug Administration, or FDA, so that the results may be used in any application that we may make to the FDA.

### 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 5,300-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 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 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 Health Care Financing Administration staff to cover all medical expenses of a patient participating in our clinical studies who tests positive for colorectal cancer, which we believe is a departure from the Health Care Financing Administration's policy of not reimbursing for these costs.

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 Cancer Act of 1999 requires private insurers to cover colorectal cancer screening tests deemed appropriate by the third-party payors and patients. 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. The person in each of these positions 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 save more lives more cost-effectively than any other colorectal cancer screening method available today. 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 \$180 to \$500, but flexible sigmoidoscopy at best can directly detect no more than half of all colorectal cancers and adenomas. Medicare will reimburse for colonoscopy for cancer screening once every 10 years in average risk individuals beginning July 1, 2001. 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 then enter into business relationships 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. We intend to collect additional data on these aero-digestive cancers in our planned 5,300-patient clinical trial. If the results are promising, we will 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. We have invented a new method for scanning regions of DNA at which mutations associated with adenoma development are often found.

NEW TECHNOLOGY PLATFORM. As part of this effort, we are also conducting research on a new technology 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 extensive regulation by the FDA under 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 these requirements can lead to stringent sanctions, including withdrawal of products from the market, recalls, refusal to

authorize government contracts, product seizures, civil money penalties, injunctions and criminal prosecution.

We intend to offer colorectal cancer screening services performed in our own laboratories. We then intend to license our intellectual property and sell our reagents that target specific areas in the genome 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 approval or clearance before they may be marketed. The FDA has not, however, actively regulated laboratory tests that have been developed and used by the laboratory conducting the tests. The FDA does regulate the sale of 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 to identify a specific DNA sequence or protein. They generally do not require FDA 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 boundaries are not well defined, and there has been some discussion within the government of changing the analyte specific reagent regulation, although it is not certain whether any such changes would affect our tests. We believe that our in-house testing and the analyte specific reagents that we intend to sell to leading clinical reference laboratories do not require FDA approval or clearance. We cannot be sure, however, that the FDA will not assert that our tests or one or more of our reagents require premarket approval or clearance. In addition, we cannot be sure that the FDA would not treat the licensing of our intellectual property as labeling that would subject the reagent to premarket approval or clearance and other FDA regulation. In addition, we cannot be sure that the FDA will not change its position in ways that could negatively affect our operations.

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 premarket notification, or 510(k) procedure, in which the manufacturer provides to the FDA a premarket 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, which means that the product has the same intended use as, is as safe and effective as, and does not raise different questions of safety and effectiveness than a legally marketed device. A 510(k) submission for an in vitro diagnostic device generally must include manufacturing and performance data, and in some cases, it must include data from human clinical studies. Marketing may commence when FDA issues a clearance letter.

If a medical device does not qualify for the 510(k) procedure, the FDA must approve a premarket 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 complex submission, usually including the results of preclinical and extensive clinical studies. Before 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 that most, if not all, of our products sold in diagnostic test kit form will 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 using 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 premarket 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 premarket 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 and product malfunctions 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 quality control and manufacturing procedures. 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 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 the Clinical Laboratory Improvement Amendments 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 the Clinical Laboratory Improvement Amendments 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. As of March 29, 2001, we had eleven issued patents in the United States, four issued foreign patents, twenty-five pending patent applications in the United States, three of which have been allowed, and forty-four pending foreign 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 any newly-developed products or technologies.

Each of our patents has a term of 20 years from their 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, from 2016 through 2017.

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 that 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 technology for performing a step in our testing methods 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 The 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 our reagents and 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 and 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., 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, 2000, we had 44 employees, seven of whom have Ph.Ds. Twenty-eight persons are engaged in research and development, four persons in sales and marketing and twelve persons in general and administration. None of our employees is represented by a labor union. We consider our relationships with our employees to be good.

## **ITEM 2. PROPERTIES**

We lease 17,877 square feet of space in our headquarters located in Maynard, Massachusetts. The lease expires on June 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 11,000 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**

In October 2000, we obtained the approval by written consent of holders of at least a majority of the then outstanding shares of our capital stock to:

(i) approve an amendment to our Fifth Amended and Restated Certificate of Incorporation to increase the authorized number of shares of our common stock to 100,000,000 shares; (ii) approve the filing of our Sixth Amended and Restated Certificate of Incorporation with the Delaware Secretary of State upon the closing of our initial public offering; (iii) approve the amendment and restatement of our By-Laws effective upon the closing of our initial public offering; (iv) approve an increase by 250,000 shares in the number of shares of our common stock reserved for issuance under our 1995 Stock Option Plan for an aggregate of 1,450,000 shares available for issuance thereunder; (v) adopt our 2000 Stock Option and Incentive Plan and approve the reservation of 1,000,000 shares of our common stock for issuance thereunder; (vi) adopt our 2000 Employee Stock Purchase Plan and approve the reservation of 300,000 shares of our common stock for

issuance thereunder; (vii) elect each of Noubar B. Afeyan, Don M. Hardison and William W. Helman, effective upon the closing of our initial public offering, to serve as Class I directors until the date of annual meeting of stockholders next following the year ending December 31, 2000 or until his earlier death, resignation or removal; (viii) elect each of Richard W. Barker, Wycliffe K. Grousbeck and Lance Willsey, effective upon the closing of our initial public offering, to serve as Class II directors until the date of annual meeting of stockholders next following the year ending December 31, 2001 or until his earlier death, resignation or removal; and (ix) elect each of Sally W. Crawford, Edwin M. Kania, Jr. and Stanley N. Lapidus, effective upon the closing of our initial public offering, to serve as Class III directors until the date of annual meeting of stockholders next following the year ending December 31, 2002 or until his or her earlier death, resignation or removal. Stockholders holding an aggregate of 8,922,511 shares of capital stock signed the action by written consent.

In December 2000, we obtained the approval by written consent of holders of at least a majority of the then outstanding shares of our capital stock to approve an amendment to our Fifth Amended and Restated Certificate of Incorporation to change the name of the corporation to EXACT Sciences Corporation. Stockholders holding an aggregate of 8,922,511 shares of capital stock signed the action by written consent.

## **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, including during the period covered by this report, there was no public market for our common stock. On March 29, 2001, the last reported price of our common stock on the Nasdaq National Market was \$7.50 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 29, 2001 was 173, 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.

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**

During the fiscal year ended December 31, 2000, we issued the following securities that were not registered under the Securities Act of 1933, as amended:

#### **(a) ISSUANCES OF CAPITAL STOCK**

In December 2000, we issued a warrant to purchase 48,125 shares of common stock at an exercise price of \$10.9091 per share to one investor.

In April 2000, we issued and sold an aggregate of 1,417,534 shares of Series D convertible preferred stock to 75 investors at a price of \$22.50 per share for aggregate consideration of \$31,894,515. Each share of Series D convertible preferred stock automatically converted into 2.75 shares of common stock upon the closing of our initial public offering on February 5, 2001.

In March 2000, we issued and sold an aggregate of 48,125 shares of common stock to one investor at a price of approximately \$0.38 per share for aggregate consideration of \$18,375.

#### **(b) EXERCISES OF STOCK OPTIONS**

From January 1, 2000 to December 31, 2000, we issued 1,186,449 shares of common stock at exercise prices ranging from \$0.04 to \$7.27 for an aggregate purchase price of \$1,188,572 pursuant to the exercise of options granted under our 1995 stock option plan. During the same period, we granted options to purchase an aggregate of 1,901,492 shares of common stock at exercise prices ranging from \$0.15 to \$10.91 under our 1995 stock option plan.

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, or, in the case of options to purchase common stock, Rule 701 of the Act. All of the foregoing securities are deemed restricted securities for the purposes of the Securities Act.

### **USE OF PROCEEDS FROM REGISTERED SECURITIES**

On January 30, 2001, we commenced our initial public offering of 4,000,000 shares of common stock, \$.01 par value per share, pursuant to our final U.S. prospectus and our final international prospectus, each 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. We offered the shares in the U.S. and Canada through

Merrill Lynch, Pierce, Fenner & Smith Incorporated, CIBC World Markets Corp. and Thomas Weisel Partners LLC, as U.S. representatives for the several U.S. underwriters, and outside the U.S. and Canada through Merrill Lynch International, CIBC World Markets plc and Thomas Weisel Partners LLC as lead managers for the several international managers. The initial public offering closed on February 5, 2001. We sold 4,000,000 shares of common stock covered by the Registration Statement. The several underwriters did not exercise their over-allotment option to purchase up to an additional 600,000 shares of common stock covered by the Registration Statement.

The aggregate offering price of the initial public offering to the public was \$56,000,000, with proceeds to us, after deduction of underwriting discounts and commissions, of \$52,080,000 (before deducting offering expenses payable by us). We estimate that the aggregate amount of expenses incurred by us in connection with the issuance and distribution of the shares of common stock offered and sold in the initial public offering was approximately \$4,920,000, including \$3,920,000 in underwriting discounts and \$1,000,000 in other expenses. These expenses were direct payments to persons other than directors, officers, persons owning ten percent or more of our equity securities, or our affiliates. None of the expenses paid by us in connection with the initial public offering was paid, directly or indirectly, to directors, officers, persons owning ten percent or more of our equity securities, or our affiliates.

The estimated net proceeds to us from the initial public offering, after deducting underwriting discounts and commissions and other expenses, were approximately \$51 million. We currently expect to use the net proceeds of the offering to fund clinical studies and trials, to fund other research and development and for working capital and other general corporate purposes. To date, none of the net proceeds from the initial public offering has been applied. As of March 29, 2001, we have invested all of the net proceeds of the offering in money-market mutual funds and direct and guaranteed obligations of the United States. None of the net proceeds were paid, directly or indirectly, to directors, officers, persons owning ten percent or more of our equity securities, or our affiliates.

## ITEM 6. SELECTED FINANCIAL DATA

The selected historical financial data set forth below as of December 31, 1999 and 2000 and for the years ended December 31, 1998, 1999 and 2000, 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, 1996, 1997 and 1998 and for the years ended December 31, 1996 and 1997 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.

	YEARS ENDED DECEMBER 31,				
	1996	1997	1998	1999	2000
	(DOLLARS IN THOUSANDS, EXCEPT PER SHARE DATA)				
STATEMENT OF OPERATIONS DATA:					
Research and development.....	\$ 366	\$ 1,222	\$ 2,849	\$ 3,689	\$ 5,332
General and administrative.....	312	814	1,170	1,560	4,814
Stock-based compensation(1).....	--	1	2	14	3,184
Loss from operations.....	(678)	(2,037)	(4,021)	(5,263)	(13,330)
Interest income.....	26	154	443	299	1,447
Net loss.....	\$ (652)	\$ (1,883)	\$ (3,578)	\$ (4,964)	\$ (11,883)
Net loss per common share:					
Basic and diluted(2).....	\$ (6.77)	\$ (10.70)	\$ (6.08)	\$ (5.32)	\$ (8.13)
Pro forma basic and diluted (unaudited)(3).....					\$ (0.97)
Weighted average common shares outstanding:					
Basic and diluted.....	96,250	175,953	588,143	932,593	1,461,726
Pro forma basic and diluted (unaudited)(3).....					12,311,358
	AS OF DECEMBER 31,				
	1996	1997	1998	1999	2000
					ACTUAL PRO FORMA(4)
BALANCE SHEET DATA:					
Cash and cash equivalents.....	\$ 3,896	\$ 1,792	\$ 8,826	\$ 3,553	\$ 26,470 \$ 77,550
Total assets.....	4,119	2,417	9,708	4,754	29,059 80,139
Stockholders' equity.....	4,010	2,305	9,298	4,410	27,700 78,700

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

Research and development.....	\$ --	\$ 1	\$ 2	\$ 9	\$ 810
General and administrative.....	--	--	--	5	2,374
Total.....	\$ 0	\$ 1	\$ 2	\$ 14	\$ 3,184

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

(3) Assumes conversion of all outstanding shares of preferred stock into common stock upon closing of our initial public offering.

(4) Reflects the sale of 4,000,000 shares of common stock at the initial public offering price of \$14.00 per share net of underwriting discounts and commissions and offering expenses.

## 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 and sell reagents 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 operating revenues since our inception and do not expect operating revenues for the foreseeable future. As of December 31, 2000, we had an accumulated deficit of approximately \$23.1 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 study which includes a population of both high-risk and average-risk patients and thereafter intend to conduct a clinical trial that will include an estimated 5,300 average-risk patients from at least 40 academic and community-based practices, the costs of which will be borne by us.

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

Stock-based compensation 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. As of March 29, 2001, we expect to recognize amortization expense of deferred compensation recorded related to employee and director

options of approximately \$4.0 million, \$2.3 million, \$1.4 million, \$674,000 and \$230,000 during the years ended December 31, 2001, 2002, 2003, 2004 and 2005, respectively.

## **RESULTS OF OPERATIONS**

### **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 lab expenses, an increase of \$579,000 in trials and studies expenses and an additional \$63,000 related to the leasing of additional laboratory space.

**GENERAL AND ADMINISTRATIVE EXPENSES.** 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.

### **COMPARISON OF THE YEARS ENDED DECEMBER 31, 1999 AND 1998**

**RESEARCH AND DEVELOPMENT EXPENSES.** Research and development expenses, excluding departmental allocations of stock-based compensation, increased to \$3.7 million for the year ended December 31, 1999 from \$2.8 million for the year ended December 31, 1998. This increase was attributable primarily to an increase of \$303,000 in research and development personnel and an additional \$53,000 related to the leasing of additional laboratory space. In addition, we incurred \$429,000 in connection with our ongoing clinical studies during 1999.

**GENERAL AND ADMINISTRATIVE EXPENSES.** General and administrative expenses, excluding departmental allocations of stock-based compensation, increased to \$1.6 million for the year ended December 31, 1999 from \$1.2 million for the year ended December 31, 1998. This increase was attributable primarily to an increase of \$200,000 in general and administrative personnel, an increase of \$76,000 in legal and consulting fees and an increase of \$55,000 in amortization and depreciation expense.

**STOCK-BASED COMPENSATION.** Stock-based compensation expense increased to \$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. Stock-based compensation expense was \$2,000 for the year ended December 31, 1998, of which \$1,500 was related to research and development personnel and \$500 related to general and administrative personnel.

**INTEREST INCOME.** Interest income decreased to \$299,000 for the year ended December 31, 1999 from \$443,000 for the year ended December 31, 1998. The decrease in 1999 was primarily due to a decrease in our cash and cash equivalents balances as a result of losses from operations.

## QUARTERLY RESULTS OF OPERATIONS

The following table sets forth unaudited quarterly statement of operations data for each the eight quarters ended December 31, 2000. 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.

	THREE MONTHS ENDED							
	MAR. 31, 1999	JUNE 30, 1999	SEPT. 30, 1999	DEC. 31, 1999	MAR. 31, 2000	JUNE 30, 2000	SEPT. 30, 2000	DEC. 31, 2000
Statement of Operations								
Data								
Research and development.....	\$ 865	\$ 950	\$ 924	\$ 951	\$ 1,154	\$ 1,145	\$ 1,516	\$ 1,517
General and administrative.....	360	392	372	435	483	824	1,135	2,372
Stock-based compensation.....	0	0	14	0	242	505	772	1,665
Loss from operations.....	(1,225)	(1,342)	(1,310)	(1,386)	(1,879)	(2,474)	(3,423)	(5,554)
Interest income.....	98	80	70	51	41	451	500	455
Net loss.....	\$ (1,127)	\$ (1,262)	\$ (1,240)	\$ (1,335)	\$ (1,838)	\$ (2,023)	\$ (2,923)	\$ (5,099)
Net loss per common share:								
Basic and diluted(1).....	\$ 1.40	\$ 1.37	\$ 1.27	\$ 1.28	\$ 1.54	\$ 1.41	\$ 1.91	\$ 3.03
Weighted average common shares outstanding:								
Basic and diluted.....	805,111	920,832	980,072	1,039,313	1,194,025	1,434,267	1,534,010	1,684,602

(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 of December 31, 2000, we had received net proceeds of \$47.2 million from the issuance of preferred stock. As of December 31, 2000, we had approximately \$26.5 million in cash and cash equivalents.

Net cash used in operating activities was \$8.0 million for the year ended December 31, 2000, \$4.6 million in 1999 and \$3.0 million in 1998. These increases are primarily due to the increase in our research and development activities and associated general and administrative expenses.

Net cash used in investing activities was \$1.1 million for the year ended December 31, 2000, \$722,000 in 1999 and \$496,000 in 1998. 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.



Net cash provided by financing activities was \$32.0 million for the year ended December 31, 2000, \$57,000 in 1999 and \$10.6 million in 1998. Cash provided during these periods resulted from the sale of our preferred stock during the year ended December 31, 2000 and the year ended 1998.

We expect that the net proceeds of approximately \$51 million from our initial public offering in February 2001, together with our current working capital, will fund our operations through 2003. Our future capital requirements include, but are not limited to, continuing our research and development programs, supporting our clinical trial 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, 2000, we had net operating loss carryforwards of approximately \$22 million and research and development tax credit carryforwards of approximately \$609,000. The net operating loss and tax credit carryforwards will expire at various dates through 2020, if not utilized. The Internal Revenue Code and applicable state law 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, or the FASB, issued Statement of Financial Accounting Standards (SFAS) No. 133, ACCOUNTING FOR DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES. This statement established accounting and reporting standards for derivative instruments and hedging activities. SFAS 133, as amended by SFAS 137, will be effective for our financial reporting beginning in the first quarter of 2001. SFAS 133 will require that we recognize all derivatives as either assets or liabilities on the balance sheet and measure those instruments at fair value. The accounting for gains and losses from changes in the fair value of a particular derivative will depend on the intended use of that derivative. We believe the adoption of this statement will not have a significant impact on our financial position, results of operations or cash flows.

In December 1999, the SEC issued Staff Accounting Bulletin No. 101, REVENUE RECOGNITION. This bulletin establishes guidelines for revenue recognition and is in effect beginning October 1, 2000. The adoption of this guidance did not have a material impact on our financial condition or results of operations.

In March 2000, the FASB issued Interpretation No. 44, ACCOUNTING FOR CERTAIN TRANSACTIONS INVOLVING STOCK COMPENSATION--AND INTERPRETATION OF APB OPINION NO. 25. The interpretation clarifies the application of APB Opinion No. 25 to accounting for stock issued to employees. The interpretation is effective July 1, 2000, but covers events occurring during the period between December 15, 1998 and July 1, 2000. If events covered by the interpretation occur during this period, the effects of applying the interpretation to the events would be recognized on a prospective basis from July 1, 2000. As a result, the interpretation will not require that any adjustments be made to our consolidated financial statements for periods before July 1, 2000, and no expense would be recognized for any additional compensation cost measured that is attributable to periods before July 1, 2000. The adoption of this interpretation did not have an impact on our financial position, results of operations or cash flows.

## **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 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, 2000, we have accumulated a total deficit of approximately \$23.1 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 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 we will ever commercialize any of our products or services, or 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 fourth quarter of 2001, we intend to initiate a blinded multi-center clinical trial that will include approximately 5,300 patients with average risk profiles. The results of this clinical trial 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 represent the results we obtain from any future studies, including our planned clinical trial, which will include substantially more samples and average-risk patients. See "Business--Clinical Studies."

### **WE MAY BE UNABLE TO RECRUIT A SUFFICIENT NUMBER OF PATIENTS FOR OUR PLANNED AVERAGE-RISK CLINICAL TRIAL.**

We intend to conduct a blinded multi-center clinical trial of approximately 5,300 average-risk patients. 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 trial 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 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 price our products and services competitively, 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 sell reagents and license our proprietary technologies to leading clinical reference laboratories that will perform colorectal cancer screening tests. We currently have no business relationships with these laboratories and have limited experience in establishing these business relationships. If we are unable to establish these business relationships, we will have limited ability to obtain revenues beyond revenue we can generate from our limited in-house capacity to process tests.

**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 expires 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 recommendation 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. See "Business--Research and Development."

**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 conducting the test. Although the FDA does regulate reagents, such as ours, that react with a biological substance 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 premarket review requirements. If the FDA were to decide to regulate in-house developed laboratory tests, decide to require premarket approval or clearance of our analyte specific reagents, conclude that our reagents do not meet the requirements for analyte specific reagents, or conclude that licensing our intellectual property constitutes non-compliant labeling, the commercialization of our products and services could be delayed, halted or prevented. In addition, the FDA may impose penalties on us or seek other enforcement actions. Similarly, if the FDA were to determine that our stool collector requires premarket 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 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 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 74 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 marketed by Beckman Coulter, Inc. 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, a screening test 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, including Stanley N. Lapidus, our Chairman, Don M. Hardison, our President, John A. McCarthy, Jr., our Vice President and Chief Financial Officer, and Anthony P. Shuber, our Vice President of Molecular Biology. Messrs. Lapidus and Shuber 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 March 29, 2001, we had eleven issued patents in the United States, four issued foreign patents, twenty-five pending patent applications in the United States, three of which have been allowed, and forty-four pending foreign 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 not hold our patents to be invalid or unenforceable.

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 you 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 eleven issued U.S. patents and twenty-five 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, 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, 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 29, 2001, our executive officers, directors and principal stockholders and their affiliates together control approximately 49.4% 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 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, have 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 in our cash and cash equivalents. 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  
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## **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, 1999 and 2000, and the related consolidated statements of operations, stockholders' equity and cash flows for the period from inception (February 10, 1995) to December 31, 2000. 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, 1999 and 2000, and the results of their operations and their cash flows for the period from inception (February 10, 1995) to December 31, 2000, in conformity with accounting principles generally accepted in the United States.

Boston, Massachusetts  
January 30, 2001

# EXACT SCIENCES CORPORATION

(A DEVELOPMENT STAGE COMPANY)

## CONSOLIDATED BALANCE SHEETS

	DECEMBER 31,		
	1999	2000	
		ACTUAL	PRO FORMA
			(UNAUDITED)
ASSETS			
Current Assets:			
Cash and cash equivalents.....	\$ 3,553,257	\$ 26,469,866	\$ 77,549,866
Prepaid expenses.....	26,843	738,475	738,475
Total current assets.....	3,580,100	27,208,341	78,288,341
Property and Equipment, at cost:			
Laboratory equipment.....	594,385	1,011,052	1,011,052
Office and computer equipment.....	255,161	429,014	429,014
Leasehold improvements.....	125,688	236,437	236,437
Furniture and fixtures.....	114,618	175,996	175,996
	1,089,852	1,852,499	1,852,499
Less--Accumulated depreciation and amortization.....	(663,397)	(988,967)	(988,967)
	426,455	863,532	863,532
Patent Costs and Other Assets, net of accumulated amortization of approximately \$149,000 and \$223,000 at December 31, 1999 and 2000, respectively (Note 2).....			
	747,348	986,629	986,629
	\$ 4,753,903	\$ 29,058,502	\$ 80,138,502
	=====	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current Liabilities:			
Accounts payable.....	\$ 196,895	\$ 582,298	\$ 582,298
Accrued expenses.....	146,993	776,396	776,396
Total current liabilities.....	343,888	1,358,694	1,358,694
Commitments (Note 7)			
Stockholders' Equity:			
Series A convertible preferred stock, \$0.01 par value--			
Authorized--1,000,000 shares			
Issued and outstanding--902,414 shares actual; none pro			
forma (liquidation preference of \$1,046,800).....			
	9,024	9,024	--
Series B convertible preferred stock, \$0.01 par value--			
Authorized--1,250,000 shares			
Issued and outstanding--996,196 shares actual; none pro			
forma (liquidation preference of \$3,934,974).....			
	9,962	9,962	--
Series C convertible preferred stock, \$0.01 par value--			
Authorized--1,015,000 shares			
Issued and outstanding--1,007,186 shares actual; none			
pro forma (liquidation preference of \$10,575,453).....			
	10,072	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; none pro forma (liquidation preference of			
\$31,894,515).....			
	--	14,175	--
Common stock, \$0.01 par value--			
Authorized--100,000,000 shares			
Issued--1,582,848, 2,789,581 and 18,678,715 shares at			
December 31, 1999, 2000 and 2000 pro forma,			
respectively.....			
	15,828	27,896	186,788
Subscriptions receivable.....	(39,706)	(975,443)	(975,443)
Deferred compensation.....	(54,482)	(8,578,341)	(8,578,341)
Additional paid-in capital.....	15,674,878	60,281,143	111,245,484
Deficit accumulated during the development stage.....	(11,215,561)	(23,098,680)	(23,098,680)
Total stockholders' equity.....	4,410,015	27,699,808	78,779,808
	\$ 4,753,903	\$ 29,058,502	\$ 80,138,502
	=====	=====	=====

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, 2000
	1998	1999	2000	
Operating Expenses:				
Research and development.....	\$ 2,848,763	\$ 3,688,796	\$ 5,332,055	\$ 13,456,922
General and administrative.....	1,170,366	1,560,368	4,813,715	8,814,692
Stock-based compensation(1).....	1,902	13,780	3,184,053	3,200,580
	-----	-----	-----	-----
Loss from operations.....	(4,021,031)	(5,262,944)	(13,329,823)	(25,472,194)
Interest Income.....	442,651	299,019	1,446,704	2,373,514
	-----	-----	-----	-----
Net loss.....	\$(3,578,380)	\$(4,963,925)	\$(11,883,119)	\$(23,098,680)
	=====	=====	=====	=====
Net Loss per Share:				
Basic and diluted.....	\$ (6.08)	\$ (5.32)	\$ (8.13)	
	=====	=====	=====	
Pro forma basic and diluted (unaudited).....			\$ (0.97)	
			=====	
Weighted Average Common Shares Outstanding:				
Basic and diluted.....	588,143	932,593	1,461,726	
	=====	=====	=====	
Pro forma basic and diluted (unaudited).....			12,311,358	
			=====	

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

Research and development.....	\$ 1,427	\$ 8,819	\$ 809,880	\$ 820,709
General and administrative.....	475	4,961	2,374,173	2,379,871
	-----	-----	-----	-----
Total.....	\$ 1,902	\$ 13,780	\$ 3,184,053	\$ 3,200,580
	=====	=====	=====	=====

**THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE CONSOLIDATED FINANCIAL STATEMENTS.**

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

[illegible]

Balance, December 31, 1998.....	902,214	\$9,024	996,196	\$9,962	1,007,186	\$10,072	--	\$ --	1,445,232	\$14,452
---------------------------------	---------	---------	---------	---------	-----------	----------	----	-------	-----------	----------

	TREASURY STOCK					DEFICIT		
	NUMBER OF	\$0.01	SUBSCRIPTIONS	DEFERRED	ADDITIONAL	ACCUMULATED	TOTAL	
	SHARES	PAR VALUE	RECEIVABLE	COMPENSATION	PAID-IN	DURING THE	STOCKHOLDERS'	
					CAPITAL	DEVELOPMENT	EQUITY	
						STAGE		
Inception, February 10, 1995.....	--	\$ --	\$ --	\$ --	\$ --	--	\$ --	--
Sales of Series A convertible preferred stock, net of issuance costs of \$6,665.....	--	--	--	--	176,574	--		178,167
Sale of common stock.....	--	--	--	--	(613)	--		350
Net loss.....	--	--	--	--	--	(138,163)		(138,163)
Balance, December 31, 1995.....	--	--	--	--	175,961	(138,163)		40,354
Sale of Series A convertible preferred stock, net of issuance costs of \$12,321.....	--	--	(25,000)	--	842,617	--		825,048
Sale of Series B convertible preferred stock, net of issuance costs of \$36,892.....	--	--	--	--	3,763,444	--		3,773,090
Sale of common stock.....	--	--	--	--	18,500	--		24,000
Net loss.....	--	--	--	--	--	(652,020)		(652,020)
Balance, December 31, 1996.....	--	--	(25,000)	--	4,800,522	(790,183)		4,010,472
Sale of Series B convertible preferred stock, net of issuance costs of \$4,138.....	--	--	--	--	120,500	--		120,816
Sale of common stock.....	--	--	--	--	27,580	--		29,616
Exercise of common stock options...	--	--	--	--	787	--		1,020
Compensation expense related to issuance of stock options...	--	--	--	(9,310)	10,155	--		845
Repayment of subscription receivable.....	--	--	25,000	--	--	--		25,000
Net loss.....	--	--	--	--	--	(1,883,073)		(1,883,073)
Balance, December 31, 1997.....	--	--	--	(9,310)	4,959,544	(2,673,256)		2,304,696
Sale of Series C convertible preferred stock, net of issuance costs of \$37,414.....	--	--	--	--	10,527,979	--		10,538,051
Sale of common stock.....	--	--	--	--	7,450	--		8,000
Exercise of common stock options...	--	--	(47,580)	--	64,010	--		21,600
Repayment of subscription receivable.....	--	--	3,802	--	--	--		3,802
Compensation expense related to issuance of stock options...	--	--	--	(6,681)	8,583	--		1,902
Repurchase of common stock....	8,250	(1,200)	--	--	--	--		(1,200)
Net loss.....	--	--	--	--	--	(3,578,380)		(3,578,380)
Balance, December 31, 1998.....	8,250	\$(1,200)	\$(43,778)	\$(15,991)	\$15,567,566	\$(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	
	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	--	\$ --
Exercise of common stock options.....	--	--	--	--	--	--	--	--
Repayment of subscription receivable.....	--	--	--	--	--	--	--	--
Compensation expense related to issuance of stock options.....	--	--	--	--	--	--	--	--
Repurchase of common stock....	--	--	--	--	--	--	--	--
Retirement of treasury stock.....	--	--	--	--	--	--	--	--
Net loss.....	--	--	--	--	--	--	--	--
Balance, December 31, 1999.....	902,414	9,024	996,196	9,962	1,007,186	10,072	--	--
Sale of Series D convertible preferred stock, net of issuance costs of \$171,985.....	--	--	--	--	--	--	1,417,534	14,175
Sale of common stock.....	--	--	--	--	--	--	--	--
Repurchase of common stock....	--	--	--	--	--	--	--	--
Retirement of treasury stock.....	--	--	--	--	--	--	--	--
Exercise of common stock options.....	--	--	--	--	--	--	--	--
Repayment of subscription receivable.....	--	--	--	--	--	--	--	--
Compensation expense related to issuance of stock options.....	--	--	--	--	--	--	--	--
Non-cash expense related to issuance of warrant.....	--	--	--	--	--	--	--	--
Net loss.....	--	--	--	--	--	--	--	--
Balance, December 31, 2000.....	902,414	\$ 9,024	996,196	\$ 9,962	1,007,186	\$ 10,072	1,417,534	\$ 14,175
Sale of common stock at initial public offering.....	--	--	--	--	--	--	--	--
Conversion of convertible preferred stock into common stock.....	(902,414)	(9,024)	(996,196)	(9,962)	(1,007,186)	(10,072)	(1,417,534)	(14,175)
Pro Forma Balance, December 31, 2000 (unaudited).....	--	\$ --	--	\$ --	--	\$ --	--	\$ --
	=====	=====	=====	=====	=====	=====	=====	=====
	COMMON STOCK		TREASURY STOCK		SUBSCRIPTIONS RECEIVABLE	DEFERRED COMPENSATION	ADDITIONAL PAID-IN CAPITAL	
	NUMBER OF SHARES	\$0.01 PAR VALUE	NUMBER OF SHARES	\$0.01 PAR VALUE				
Balance, December 31, 1998.....	1,445,232	\$ 14,452	8,250	\$ (1,200)	\$ (43,778)	\$ (15,991)	\$ 15,567,566	
Exercise of common stock options.....	155,491	1,555	--	--	--	--	57,462	
Repayment of subscription receivable.....	--	--	--	--	4,072	--	--	
Compensation expense related to issuance of stock options.....	--	--	--	--	--	(38,491)	52,271	
Repurchase of common stock....	--	--	9,625	(1,400)	--	--	--	
Retirement of treasury stock.....	(17,875)	(179)	(17,875)	2,600	--	--	(2,421)	
Net loss.....	--	--	--	--	--	--	--	
Balance, December 31, 1999.....	1,582,848	15,828	--	--	(39,706)	(54,482)	15,674,878	
Sale of Series D convertible preferred stock, net of issuance costs of \$171,985.....	--	--	--	--	--	--	31,708,355	
Sale of common stock.....	48,125	481	--	--	--	--	17,894	
Repurchase of common stock....	--	--	27,844	(5,215)	5,215	--	--	
Retirement of treasury stock.....	(27,841)	(278)	(27,844)	5,215	--	--	(4,937)	
Exercise of common stock options.....	1,186,449	11,865	--	--	(1,022,668)	--	1,176,707	
Repayment of subscription receivable.....	--	--	--	--	81,716	--	--	
Compensation expense related to issuance of stock options.....	--	--	--	--	--	(8,523,859)	11,358,768	
Non-cash expense related to								

issuance of warrant.....	--	--	--	--	--	--	349,478
Net loss.....	--	--	--	--	--	--	--
Balance, December 31, 2000.....	2,789,581	\$ 27,896	--	\$ --	\$ (975,443)	\$ (8,578,341)	\$ 60,281,143
Sale of common stock at initial public offering.....	4,000,000	40,000	--	--	--	--	51,040,000
Conversion of convertible preferred stock into common stock.....	11,889,134	118,892	--	--	--	--	(75,659)
Pro Forma Balance, December 31, 2000 (unaudited).....	18,678,715	\$186,788	--	\$ --	\$ (975,443)	\$ (8,578,341)	\$111,245,484
	=====	=====	=====	=====	=====	=====	=====

	DEFICIT ACCUMULATED DURING THE DEVELOPMENT STAGE	TOTAL STOCKHOLDERS' EQUITY
Balance, December 31, 1998.....	\$ (6,251,636)	\$ 9,298,471
Exercise of common stock options.....	--	59,017
Repayment of subscription receivable.....	--	4,072
Compensation expense related to issuance of stock options.....	--	13,780
Repurchase of common stock....	--	(1,400)
Retirement of treasury stock.....	--	--
Net loss.....	(4,963,925)	(4,963,925)
Balance, December 31, 1999.....	(11,215,561)	4,410,015
Sale of Series D convertible preferred stock, net of issuance costs of \$171,985.....	--	31,722,530
Sale of common stock.....	--	18,375
Repurchase of common stock....	--	--
Retirement of treasury stock.....	--	--
Exercise of common stock options.....	--	165,904
Repayment of subscription receivable.....	--	81,716
Compensation expense related to issuance of stock options.....	--	2,834,909
Non-cash expense related to issuance of warrant.....	--	349,478
Net loss.....	(11,883,119)	(11,883,119)
Balance, December 31, 2000.....	\$(23,098,680)	\$ 27,699,808
Sale of common stock at initial public offering.....	--	51,080,000
Conversion of convertible preferred stock into common stock.....	--	--
Pro Forma Balance, December 31, 2000 (unaudited).....	\$(23,098,680)	\$ 78,779,808
	=====	=====

**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, 2000
	1998	1999	2000	
Cash Flows from Operating Activities:				
Net loss.....	\$(3,578,380)	\$(4,963,925)	\$(11,883,119)	\$(23,098,680)
Adjustments to reconcile net loss to net cash used in operating activities--				
Depreciation and amortization.....	243,832	424,285	404,142	1,193,104
Non-cash stock-based compensation expense.....	1,902	13,780	2,834,909	2,851,436
Non-cash expense associated with issuance of warrants.....	--	--	349,478	349,478
Changes in assets and liabilities--				
Prepaid expenses.....	(5,270)	(21,573)	(711,632)	(738,475)
Accounts payable.....	137,106	16,330	385,403	582,298
Accrued expenses.....	166,515	(76,494)	629,403	776,396
Net cash used in operating activities.....	(3,034,295)	(4,607,597)	(7,991,416)	(18,084,443)
Cash Flows from Investing Activities:				
Purchases of property and equipment.....	(355,201)	(292,183)	(762,647)	(1,835,548)
Increase in patent costs and other assets.....	(140,312)	(429,385)	(317,853)	(1,190,766)
Net cash used in investing activities.....	(495,513)	(721,568)	(1,080,500)	(3,026,314)
Cash Flows from Financing Activities:				
Payments on capital lease obligations.....	(7,709)	(6,405)	--	(16,951)
Net proceeds from sale of convertible preferred stock.....	10,538,051	--	31,722,530	47,157,703
Net proceeds from sale of common stock.....	8,000	--	18,375	80,341
Proceeds from exercise of common stock options.....	21,600	59,017	165,904	247,541
Repayment of stock subscription receivable.....	3,802	4,072	81,716	111,989
Net cash provided by financing activities.....	10,563,744	56,684	31,988,525	47,580,623
Net Increase (Decrease) in Cash and Cash Equivalents.....	7,033,936	(5,272,481)	22,916,609	26,469,866
Cash and Cash Equivalents, beginning of period....	1,791,802	8,825,738	3,553,257	--
Cash and Cash Equivalents, end of period.....	\$ 8,825,738	\$ 3,553,257	\$ 26,469,866	\$ 26,469,866
	=====	=====	=====	=====
Supplemental Disclosure of Non-cash Investing and Financing Activities:				
Sale of restricted stock through issuance of notes receivable.....	\$ 47,580	\$ --	\$ 1,022,668	\$ 1,070,248
	=====	=====	=====	=====
Purchase of treasury shares through forgiveness of note receivable.....	\$ 1,200	\$ 1,400	\$ 0	\$ 2,600
	=====	=====	=====	=====
Equipment purchased through capital lease obligations.....	\$ --	\$ --	\$ --	\$ 16,951
	=====	=====	=====	=====

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, 2000

### **(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 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 proceeds of \$52,080,000 after deducting the underwriters commission and issuance costs. Upon consummation of the initial public offering, all shares of preferred stock outstanding automatically converted into 11,889,137 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 generally accepted accounting principles 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.

#### **UNAUDITED PRO FORMA PRESENTATION**

The unaudited pro forma balance sheet and statement of stockholders' equity reflect the sale of 4,000,000 shares of common stock at the initial public offering price of \$14.00 per share net of underwriting discount and commissions and offering expenses as well as the automatic conversion of each outstanding share of convertible preferred stock which occurred upon consummation of the Company's initial public offering on February 5, 2001.

#### **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, 1999 and 2000.

# EXACT SCIENCES CORPORATION

(A DEVELOPMENT STAGE COMPANY)

## NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 2000

### (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.....	Life of lease
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 antidilutive. All shares issuable upon conversion of outstanding preferred stock and options to purchase a total of 1,150,080, 1,097,830 and 1,771,621 common shares and 800,568, 555,900 and 996,806 unvested restricted shares have therefore been excluded from the computations of diluted weighted average shares outstanding for the years ended December 31, 1998, 1999 and 2000, 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.

The Company's historical capital structure is not indicative of its capital structure after its initial public offering due to the automatic conversion of all shares of preferred stock into 11,889,137 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 for the year ended December 31, 2000, 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.

# EXACT SCIENCES CORPORATION

(A DEVELOPMENT STAGE COMPANY)

## NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 2000

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED) The following table reconciles the weighted average common shares outstanding to the shares used in the computation of pro forma basic and diluted net loss per share:

	YEAR ENDED DECEMBER 31, 2000
Net loss.....	\$(11,883,119)
Weighted average shares outstanding.....	1,461,726
Weighted conversion of preferred stock to common stock.....	10,849,632
	-----
Pro forma weighted average shares outstanding.....	12,311,358
	=====
Pro forma basic and diluted net loss per share.....	\$ (0.97)
	=====

### PATENT COSTS AND OTHER ASSETS

Patent costs, which primarily consist of related legal fees, are capitalized as incurred and are amortized beginning when patents are approved over an estimated useful life of five years. Capitalized patent costs 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. SFAS No. 121 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. To compute whether assets have been impaired, the estimated gross cash flows for the estimated remaining useful life of the assets are compared to the carrying value. To the extent that the gross cash flows are less than the carrying value, the assets are written down to the estimated fair value of the asset. The Company does not believe that its long-lived assets have been impaired.

### RESEARCH AND DEVELOPMENT EXPENSES

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

### 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 nonowner sources. Comprehensive net loss is the same as reported net loss for all periods presented.

# **EXACT SCIENCES CORPORATION**

(A DEVELOPMENT STAGE COMPANY)

## **NOTES TO FINANCIAL STATEMENTS (CONTINUED)**

DECEMBER 31, 2000

### **(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED) 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 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 value.

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

### **RECENT ACCOUNTING PRONOUNCEMENTS**

In June 1999, the Financial Accounting Standards Board (FASB) issued SFAS No. 137, ACCOUNTING FOR DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES--DEFERRAL OF THE EFFECTIVE DATE OF FASB STATEMENT NO. 133, which defers the effective date of SFAS No. 133 to all fiscal quarters of all fiscal years beginning after June 15, 2000. SFAS No. 133, ACCOUNTING FOR DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES, issued in June 1998, establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts, and hedging activities. It requires an entity to recognize all derivatives as either assets or liabilities in the statement of financial position



# EXACT SCIENCES CORPORATION

(A DEVELOPMENT STAGE COMPANY)

## NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 2000

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED) and measure those instruments at fair value. The adoption of this statement did not have any impact on the Company's financial position or results of operations.

In December 1999, the SEC issued SAB No. 101, REVENUE RECOGNITION. This bulletin establishes guidelines for revenue recognition and is in effect beginning October 1, 2000. The adoption of this guidance did not have an impact on the Company's financial condition or results of operations.

In March 2000, the FASB issued Interpretation No. 44, ACCOUNTING FOR CERTAIN TRANSACTIONS INVOLVING STOCK COMPENSATION--AND INTERPRETATION OF APB OPINION NO. 25. The interpretation clarifies the application of APB Opinion No. 25 to accounting for stock issued to employees. The interpretation is effective July 1, 2000, but covers events occurring during the period between December 15, 1998 and July 1, 2000. If events covered by the interpretation occur during the period between December 19, 1998 and July 11, 2000, the effects of applying the interpretation to the events would be recognized on a prospective basis from July 1, 2000. As a result, the interpretation will not require that any adjustments be made to the consolidated financial statements for periods before July 1, 2000, and no expense would be recognized for any additional compensation cost measured that is attributable to periods before July 1, 2000. Management believes the adoption of this interpretation does not have an impact on the Company's financial position, results of operations or cash flows.

### (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 credits are based on changes in the asset or liability from period to period. At December 31, 2000, the Company had net operating loss and research tax credit carryforwards of approximately \$22,220,000 and \$609,000, respectively, for financial reporting purposes, which may be used to offset future taxable income. The carryforwards expire through 2020 and are subject to review and possible adjustment by the Internal Revenue Service. The Internal Revenue Code contains provisions that may limit the net operating loss and research tax credit carryforwards in the event of certain changes in the ownership interests of significant stockholders.

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

	DECEMBER 31,	
	1999	2000
Operating loss carryforwards.....	\$4,262,000	\$9,206,000
Tax credit carryforwards.....	389,000	609,000
Temporary differences.....	(127,000)	(318,000)
	4,524,000	9,497,000
Less--Valuation allowance.....	(4,524,000)	(9,497,000)
Net deferred tax asset.....	\$ 0	\$ 0
	=====	=====

# **EXACT SCIENCES CORPORATION**

(A DEVELOPMENT STAGE COMPANY)

## **NOTES TO FINANCIAL STATEMENTS (CONTINUED)**

DECEMBER 31, 2000

(3) **INCOME TAXES (CONTINUED)** The Company has recorded a full valuation allowance against its deferred tax assets 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 near 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 and are collateralized by the underlying stock. Notes representing an aggregate principal amount of \$69,680 are payable monthly. Notes representing an aggregate principal amount 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.

### **(5) RELATED PARTY TRANSACTION**

In February 1998, the Company entered into a letter agreement with one of its shareholders. The Company paid approximately \$114,000 and \$229,000 in connection with a 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 \$10.9091 per share (see Note 6).

### **(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.

# **EXACT SCIENCES CORPORATION**

(A DEVELOPMENT STAGE COMPANY)

## **NOTES TO FINANCIAL STATEMENTS (CONTINUED)**

DECEMBER 31, 2000

(6) STOCKHOLDERS' EQUITY (CONTINUED) 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.

### **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 is 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 11,889,137 shares of common stock upon the closing of the Company's initial public offering on February 5, 2001.

**EXACT SCIENCES CORPORATION**  
(A DEVELOPMENT STAGE COMPANY)

**NOTES TO FINANCIAL STATEMENTS**  
DECEMBER 31, 2000

(6) STOCKHOLDERS' EQUITY (CONTINUED)

**STOCK OPTION PLAN**

The Company has a stock option plan (the Plan) under which the Board of Directors may grant incentive and nonqualified stock options to purchase an aggregate of 3,987,500 shares of common stock to employees and consultants of the Company. Nonqualified 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 Plan vest over a three-to-five-year period and expire 10 years from the grant date. At December 31, 2000, 386,175 shares were available for future grant under the Plan.

Information with respect to activity under the Plan is as follows:

	NUMBER OF SHARES	WEIGHTED EXERCISE PRICE
Outstanding, December 31, 1997.....	558,250	\$0.09
Granted.....	1,122,580	0.32
Exercised.....	(517,000)	0.13
Canceled.....	(13,750)	0.15
	-----	
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
	=====	=====
Exercisable, December 31, 1998.....	130,144	\$0.08
	=====	=====
Exercisable, December 31, 1999.....	623,587	\$0.19
	=====	=====
Exercisable, December 31, 2000.....	360,722	\$0.14
	=====	=====

**EXACT SCIENCES CORPORATION**  
(A DEVELOPMENT STAGE COMPANY)

**NOTES TO FINANCIAL STATEMENTS**  
**DECEMBER 31, 2000 (CONTINUED)**

(6) STOCKHOLDERS' EQUITY (CONTINUED) The following table summarizes information relating to currently outstanding and exercisable stock options as of December 31, 2000:

OUTSTANDING			EXERCISABLE		
EXERCISE PRICE	NUMBER OF SHARES	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE (YEARS)	EXERCISE PRICE	NUMBER OF SHARES	WEIGHTED AVERAGE EXERCISE PRICE
\$ 0.04	189,750	5.75	\$ 0.04	189,750	\$ 0.04
0.15	90,750	6.07	0.15	90,674	0.15
0.38	411,359	8.66	0.38	80,298	0.38
2.05	587,512	9.49	2.05	--	2.05
7.27	316,250	9.80	7.27	--	7.27
10.91	176,000	9.93	10.91	--	10.91
	1,771,621	8.82	\$ 3.16	360,722	\$ 0.14
	=====	=====		=====	=====

**ACCOUNTING FOR STOCK-BASED COMPENSATION**

The Company accounts for its stock-based compensation plan under APB Opinion 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 nonemployees are recorded at fair value based on the fair value measurement criteria of paragraphs 8-12 of SFAS No. 123 and Emerging Issues Task Force (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 and \$528,593 was recorded in the accompanying consolidated statements of operations for the years ended December 31, 1999 and 2000, respectively. The following assumptions were used for 1999 and 2000: (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 5.53% 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.

**EXACT SCIENCES CORPORATION**  
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**NOTES TO FINANCIAL STATEMENTS**  
**DECEMBER 31, 2000 (CONTINUED)**

(6) STOCKHOLDERS' EQUITY (CONTINUED) As of December 31, 2000, the Company expects to recognize amortization expense of deferred compensation recorded related to employee and director options of approximately \$3,979,000, \$2,314,000, \$1,382,000, \$674,000 and \$230,000 during the years ending December 31, 2001, 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, 1998, 1999 and 2000, using the Black-Scholes option pricing model prescribed by SFAS No. 123.

The assumptions used for the years ended December 31, 1998, 1999 and 2000 are as follows:

	DECEMBER 31,		
	1998	1999	2000
Risk-free interest rates.....	4.65%-5.62%	5.44%-5.97%	4.98%-6.16%
Expected lives.....	7 years	7 years	7 years
Expected volatility.....	0%	0%	100%
Dividend yield.....	0%	0%	0%
Weighted average remaining contractual life of options outstanding.....	9.30	8.33	8.82
Weighted average fair value of grants.....	\$0.11	\$0.13	\$2.91

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

	YEARS ENDED DECEMBER 31,		
	1998	1999	2000
Net loss as reported.....	\$(3,578,380)	\$(4,963,925)	\$(11,883,119)
Pro forma.....	(3,581,433)	(4,993,586)	(11,955,270)
Basic and Diluted Net Loss Per Share--			
As reported.....	\$ (6.08)	\$ (5.32)	\$ (8.13)
Pro forma.....	\$ (6.08)	\$ (5.35)	\$ (8.18)

## 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 restricted common shares 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). The shares were sold at the then fair market value and vest over a five-to-seven-year period. At December 31, 2000, 511,874 shares were vested.

**EXACT SCIENCES CORPORATION**  
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**NOTES TO FINANCIAL STATEMENTS**  
**DECEMBER 31, 2000 (CONTINUED)**

**(6) STOCKHOLDERS' EQUITY (CONTINUED) 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 \$10.9091 per share. The warrant is exercisable immediately. The Company has valued the warrant using the Black-Scholes model in accordance with EIFT 96-18 and recorded research and development stock-based compensation of \$349,478 in 2000.

**(7) 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, 2000 are approximately as follows:

Year Ending December 31,	
2001.....	\$236,000
2002.....	236,000
2003.....	118,000
	-----
Total lease payments.....	\$590,000
	=====

Rent expense included in the accompanying consolidated statements of operations was approximately \$84,000, \$146,000 and \$216,000 for the years ended December 31, 1998, 1999 and 2000, respectively.

**(8) ROYALTY AGREEMENTS**

**ROCHE LICENSE**

The Company licenses, on a non-exclusive basis, technology for performing a step in its testing methods from Roche Molecular Systems, Inc. (Roche). 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 The 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, the Company has agreed to pay Genzyme a royalty based on net revenues received from performing the Company's tests and the sale of its reagents and diagnostic test kits, as well as certain milestone payments and maintenance fees. In addition, the Company must use reasonable efforts to make

**EXACT SCIENCES CORPORATION**  
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**NOTES TO FINANCIAL STATEMENTS**  
**DECEMBER 31, 2000 (CONTINUED)**

(8) **ROYALTY AGREEMENTS (CONTINUED)** 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. To date, the Company has paid an initial license fee, which was charged to research and development expense in the accompanying consolidated statement of operations for the year ended December 31, 1999. Milestone payments will be expensed as milestones are achieved. Royalties will be expensed as they become due.

(9) **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, 2000.

(10) **2000 STOCK OPTION AND INCENTIVE 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. Through December 31, 2000, no options have been granted under the 2000 Option Plan.

(11) **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



**EXACT SCIENCES CORPORATION**  
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**NOTES TO FINANCIAL STATEMENTS**  
**DECEMBER 31, 2000 (CONTINUED)**

(11) 2000 EMPLOYEE STOCK PURCHASE PLAN (CONTINUED) 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 2000 Purchase Plan is administered by the compensation committee of the Board of Directors. 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 the shares issued in connection with the Company's initial public offering of its common stock on January 30, 2001 and continues 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.

(12) ACCRUED EXPENSES

Accrued expenses at December 31, 1999 and 2000 consisted of the following:

	DECEMBER 31,	
	1999	2000
Consulting.....	\$ 20,000	\$246,899
Professional fees.....	48,265	194,440
Shareholder services.....	--	100,000
Payroll and payroll-related.....	47,000	93,667
Research.....	--	48,926
Occupancy.....	19,500	45,770
Other.....	5,428	32,293
Travel and entertainment.....	6,800	14,401
	\$146,993	\$776,396
	=====	=====

## **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 May 16, 2001, 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, 2000, 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 Vice President of Molecular Biology, Anthony P. Shuber, 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 any 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 May 16, 2001, 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, 2000, 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 May 16, 2001, 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, 2000, 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 May 16, 2001, 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, 2000, 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)
10.1*	1995 Stock Option Plan (previously filed as Exhibit 10.1 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.2*	2000 Stock Option and Incentive Plan (previously filed as Exhibit 10.2 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.3*	2000 Employee Stock Purchase Plan (previously filed as Exhibit 10.3 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.4*	Sixth Amended and Restated Registration Rights Agreement between the Registrant and the parties named therein dated as of April 7, 2000 (previously filed as Exhibit 10.4 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.5*	Restricted Stock Purchase Agreement between the Registrant and Stanley N. Lapidus dated February 11, 1998 (previously filed as Exhibit 10.5 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.6*	Restricted Stock Purchase Agreement between the Registrant and Stanley N. Lapidus dated as of March 31, 2000 (previously filed as Exhibit 10.6 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
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)

EXHIBIT NUMBER	DESCRIPTION
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)
10.21*	Severance Agreement between the Registrant and Stanley N. Lapidus dated January 4, 2001 (previously filed as



EXHIBIT NUMBER	DESCRIPTION
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)
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)

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

(b) Reports on Form 8-K.

No reports on form 8-K were filed on behalf of EXACT Sciences Corporation during the quarter ended December 31, 2000.

## 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  
(Registrant)

Date: March 29, 2001

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

VICE-PRESIDENT AND CHIEF FINANCIAL OFFICER

## POWER OF ATTORNEY AND SIGNATURES

We, the undersigned officers and directors of EXACT Sciences Corporation, hereby severally constitute and appoint Stanley N. Lapidus, 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 ----
<u>/s/ STANLEY N. LAPIDUS</u> ----- Stanley N. Lapidus	Chairman of the Board and Director (Principal Executive Officer)	March 29, 2001
<u>/s/ DON M. HARDISON</u> ----- Don M. Hardison	President and Director	March 29, 2001
<u>/s/ JOHN A. MCCARTHY, JR.</u> ----- John A. McCarthy, Jr.	Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 29, 2001
<u>/s/ NOUBAR B. AFEYAN</u> ----- Noubar B. Afeyan	Director	March 29, 2001
<u>/s/ RICHARD W. BARKER</u> ----- Richard W. Barker	Director	March 29, 2001
<u>/s/ SALLY W. CRAWFORD</u> ----- Sally W. Crawford	Director	March 29, 2001
<u>/s/ WYCLIFFE K. GROUSBECK</u> ----- Wycliffe K. Grousbeck	Director	March 29, 2001
<u>/s/ WILLIAM W. HELMAN</u> ----- William W. Helman	Director	March 29, 2001
<u>/s/ EDWIN M. KANIA, JR.</u> ----- Edwin M. Kania, Jr.	Director	March 29, 2001
<u>/s/ LANCE WILLSEY</u> ----- Lance Willsey	Director	March 29, 2001

**EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-K  
FOR FISCAL YEAR ENDED DECEMBER 31, 2000**

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)
10.1*	1995 Stock Option Plan (previously filed as Exhibit 10.1 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.2*	2000 Stock Option and Incentive Plan (previously filed as Exhibit 10.2 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.3*	2000 Employee Stock Purchase Plan (previously filed as Exhibit 10.3 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.4*	Sixth Amended and Restated Registration Rights Agreement between the Registrant and the parties named therein dated as of April 7, 2000 (previously filed as Exhibit 10.4 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.5*	Restricted Stock Purchase Agreement between the Registrant and Stanley N. Lapidus dated February 11, 1998 (previously filed as Exhibit 10.5 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
10.6*	Restricted Stock Purchase Agreement between the Registrant and Stanley N. Lapidus dated as of March 31, 2000 (previously filed as Exhibit 10.6 to our Registration Statement on Form S-1 (File No. 333-48812), which is incorporated herein by reference)
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



EXHIBIT NUMBER	DESCRIPTION
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)
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)
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)

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\* Indicates a management contract or any compensatory plan, contract or

arrangement.

## EXHIBIT 10.12

### FOURTH AMENDMENT TO LEASE

REFERENCE is made to Lease dated December 10, 1996 by and between C.B. Realty Limited Partnership, a Massachusetts limited partnership, with an address at 27 Windsong Landing, Chatham, Massachusetts ("Landlord") and EXACT Laboratories, Inc., a corporation with an address at 63 Great Road, Maynard, Massachusetts ("Tenant"), as amended by Lease Amendment executed by Tenant on July 22, 1997, Lease Amendment executed by Tenant on January 21, 1999, and Lease Amendment and Extension executed by Tenant on April 25, 2000 (the "Lease") for premises consisting of approximately seventeen thousand one hundred eighty five (17,185) square feet in the building (the "Building") located at 63 Great Road, Maynard, Massachusetts (the "Premises").

In consideration of One Dollar (\$1.00) and other good and valuable consideration, the receipt of which is hereby acknowledged, Landlord and Tenant hereby amend the Lease as follows:

1. Effective September 1, 2000, there is added to the Premises approximately six hundred ninety two (692) square feet formerly occupied by IntexLX located on the first floor of the Building shown as outlined on Exhibit A attached hereto and made a part hereof (the "Additional Premises"). Effective September 1, 2000, the Additional Premises shall be deemed part of the Premises and the Term of the Lease (as defined in the Lease) shall expire with respect to the Additional Premises on June 30, 2003, being the date of expiration of the Term with respect to the remainder of the Premises. The Additional Premises are delivered to Tenant in "AS IS" condition, with no warranties, expressed or implied.

Base Rent for the Additional Premises shall be Eleven Dollars (\$11.00) per square foot per annum (payable in equal installments on the first day of each month), and Tenant shall be responsible for the payment of Real Estate Taxes and Operating Expenses with respect to the Additional Premises (together with the remainder of the Premises) in accordance with paragraph numbered 2 below.

2. Paragraph 4(a) of the Lease is hereby deleted and the following is substituted in its place:

"4(a) (i) Tenant shall pay the Base Rent (sometimes called "Annual Fixed Rent"), in equal monthly payments, in advance, without setoff, deduction or demand, in lawful money of the United States, on the first day of each and every month during the Term, at Landlord's Office or to such other payee and/or at such other place as the Landlord may from time to time designate in writing.

(ii) Tenant shall pay to Landlord, as Additional Rent, the percentage of any Real Estate Taxes levied against the Building, the land serving the Building (the "Land"), and other improvements, located at 63 Great Road, Maynard, Massachusetts during the Term hereof determined by dividing the number of square feet within the Premises by the Rentable Floor Area in the Building. For the purposes hereof, (x) "Rentable Floor Area" shall be deemed to include all space within the Building designed for Tenant occupancy and

(y) "Real Estate Taxes" shall include all taxes and extraordinary and/or special assessments (and all costs and reasonable fees incurred by Landlord in contesting the same and/or negotiating with the public authorities as to the same) which may be levied or assessed by the lawful taxing authorities against the Land, Building and all other improvements forming a part of the project of which the Premises are a part. TENANT shall pay in advance of the first day of each month an estimate of one twelfth ( 1/12) of Tenant's annual obligation on account of Real Estate Taxes, which shall be an amount estimated and billed by LANDLORD prior to the beginning of each "Tax Year" (which shall mean the twelve (12) month period established as the real estate tax year by the taxing authorities as having lawful jurisdiction over the Premises). Such estimate and billing may be revised by LANDLORD at LANDLORD'S sole option, during the Tax Year based on tax bills or assessments actually received by LANDLORD relating to the current Tax Year. Within ninety (90) days of the end of each Tax Year, LANDLORD shall furnish to TENANT, in reasonable detail, the final computation and allocation of Real Estate Taxes for the preceding Tax Year. If the amount allocated to TENANT

exceeds the sum of the estimated Real Estate Taxes already paid by TENANT, TENANT shall pay such excess to Landlord within thirty (30) days of demand therefor.

If the amount allocated to TENANT is less than that already paid by TENANT, LANDLORD shall credit the difference to future payments of Real Estate Taxes hereunder or, if at the end of the Term, refund such amount to Tenant.

For the Tax Year in which the Lease commences or terminates, the provisions of this Section shall apply, but TENANT'S liability for its proportionate share of any taxes for such year shall be subject to a pro rata adjustment, based upon the amount of time within said Tax Year during which TENANT is obligated under the Lease to occupy the Premises and pay Base Rent.

In the event LANDLORD shall contest the amount of real estate taxes due and payable under this provision and shall be successful and receive a refund, TENANT shall receive credit for its pro rata share of such refund less the reasonable cost of obtaining such refund.

(iii) TENANT shall pay to LANDLORD, as Additional Rent, the percentage of "Operating Expenses" during the Term hereof determined by dividing the number of square feet within the Premises by the Rentable Floor Area in the Building. "Operating Expenses" shall mean any and all expenses, costs and disbursements (but not specific costs billed to and paid by specific Tenants) of every kind and nature incurred by Landlord in connection with the management, operation, maintenance, servicing and repair of the Building and appurtenances thereto, including without limitation the parking lots and the common areas thereof, and the Land, including but not limited to employees' wages, salaries, welfare and pension benefits and other fringe benefits; payroll taxes; the costs, including reasonable attorneys' fees, of appealing assessments of Real Estate Taxes; painting of common areas of the Building; extermination service; detection and security services; sewer rents and charges; premiums for fire and casualty, liability, rent, workmen's compensation, sprinkler, water damage and other insurance; repairs and maintenance; building supplies; uniforms and dry cleaning; snow removal; the cost of obtaining and providing electricity, water, and other public utilities to all areas of the Building; janitorial and cleaning services; window cleaning; service contracts for the maintenance of elevators, boilers, EVAC and other mechanical, plumbing and electrical equipment; fees for all licenses and permits required for the ownership and operation of the Land and the Building; business license fees and taxes; sales and use taxes payable in connection with tangible personal property and services purchased for the management, operation, maintenance, repair, cleaning, safety and administration of the Land and the Building; legal fees; accounting fees relating to the determination of Operating Expenses and Tenants' share thereof and the preparation of statements required by Tenants' leases; management fees (which shall not exceed market rates), whether or not paid to any person having an interest in or under common ownership with Landlord; purchase and installation of indoor plants in the Common Areas; and landscaping maintenance and the purchase and replacement of landscaping services, plants and shrubbery. If Landlord makes an expenditure for a capital improvement to the Land or the Building, and if, under generally accepted accounting principles ("GAAP"), such expenditure is not a current expense, then the cost thereof shall be amortized over a period equal to the useful life of such improvement, determined in accordance with generally accepted accounting principles, and the amortized costs allocated to each calendar year during the Term.

With respect to each calendar month falling wholly within the Term of this Lease, TENANT shall pay in advance on the first of the month a tentative charge equal to one twelfth ( 1/12) of Landlord's estimate of Tenant's share of Operating Costs for the current "Operating Year". For the purposes hereof, an "Operating Year" shall be deemed to be twelve (12) consecutive calendar months commencing January 1st and ending December 31st. With respect to any fractional calendar month at the end of the Term, TENANT shall pay in advance on the first day of such month an amount equal to one-thirtieth ( 1/30) of the tentative monthly charge for the next preceding calendar month multiplied by the remaining number of days in the Term of the Lease.

Within ninety (90) days after the end of each operating Year, LANDLORD shall compute the actual annual Operating Expenses for the Operating Year. TENANT shall be furnished a copy in

reasonable detail of such final computation and allocation and reasonable breakdown of charges. If the amount allocated to TENANT exceeds the sum of the tentative charges for the same Operating Year already paid by the TENANT, TENANT shall pay such excess to LANDLORD within thirty (30) days of demand. If the amount thus allocated to TENANT is less than the sum of the tentative charges for the same Operating Year already paid by the TENANT, LANDLORD shall credit the difference to future payment(s) of Operating Charges. Within ninety (90) days after then end of the Term, the sum of the tentative charges for the year in which termination occurs shall be adjusted and any deficiency or excess shall be paid by or refunded to TENANT."

3. In all other respects the Lease shall remain the same.

IN WITNESS WHEREOF, the parties hereto have set their hands and seals this 7th day of February, 2001.

LANDLORD:	TENANT:
C.B. REALTY LIMITED PARTNERSHIP	EXACT LABORATORIES, INC.
By: /s/ Thomas R. Patton III	By: /s/ Don Hardison
-----	-----
Name: Thomas R. Patton III	Name: Don Hardison
-----	-----
Title: General Partner	Title: President
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## 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 30, 2001*

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**End of Filing**

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