# SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 10-K

Mark one

[X] ANNUAL REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended July 31, 2001

or

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_

Commission File Number 1-9974

ENZO BIOCHEM, INC.

(P...-t ---- of P...i-t----t -- C.--ifi-d in The Chapter)

(Exact name of Registrant as Specified in Its Charter)

New York 13-2866202

(State or Other jurisdiction (I.R.S. Employer of Incorporation or Organization) Identification No.)

(631) 755-5500
-----(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Common Stock, \$.01 par value The New York Stock Exchange

(Title of Each Class) (Name of Each Exchange on Which Registered)

Securities registered pursuant to Section 12(g) of the Act:

NONE

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 reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes [X] No []

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

The aggregate market value of the Common Stock held by nonaffiliates as of October 11, 2001 was approximately \$430,323,400.

As of October 11, 2001, the Registrant had 27,082,200 shares of Common Stock outstanding.

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PART I

#### Item 1. Business

#### Overview

Enzo Biochem, Inc. (the "Company" or "Enzo") is a leading life sciences and biotechnology company focused on harnessing genetic processes to develop research tools, diagnostics and therapeutics and also provides diagnostic services to the medical community. Since our formation in 1976, we have concentrated on developing enabling technologies for detecting and identifying genes and modifying gene expression. These technologies are generally applicable for the diagnosis of infectious and other diseases and form the basis for a portfolio of over 300 products marketed to the biomedical and pharmaceutical research markets. We are further using these technologies as a platform for our planned entry into the clinical diagnostics market. In addition, our work in gene analysis has led to our development of significant therapeutic product candidates, three of which are currently in clinical trials, and a fourth is scheduled to begin clinical testing shortly. In the course of our research and development activities, we have built what we believe is a significant patent position (comprised of 37 issued U.S. patents, approximately 161 issued foreign patents and numerous pending applications worldwide) around our core technologies.

The business activities of the Company are performed by one of the Company's three wholly-owned subsidiaries--Enzo Diagnostics, Inc., Enzo Therapeutics, Inc., and Enzo Clinical Labs, Inc. ("Enzo Diagnostics", "Enzo Therapeutics" and "Enzo Clinical Labs", respectively). These activities are: (1) research and development, manufacturing and marketing of biomedical research products and tools through Enzo Diagnostics and research and development of therapeutic products through Enzo Therapeutics, and (2) the operation of a clinical reference laboratory through Enzo Clinical Labs. For information relating to the Company's business segments, see Note 12 of the Notes to Consolidated Financial Statements.

The Company's primary sources of revenue have historically been from sales of research products and from clinical laboratory services. Revenues from research products are comprised of sales of products utilized in life science research. Revenues from the clinical laboratory service are comprised of fees for the services provided by the laboratories. For the fiscal years ended July 31, 2001 and 2000, respectively, approximately 40% and 37% of the Company's operating revenues were derived from product sales and approximately 60% and 63% were derived from clinical reference laboratory services.

#### Markets

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# Background

DNA is the source of biological information that governs the molecular mechanisms underlying life. This information is stored in the linear sequences of nucleotides that comprise DNA. Recently, the first draft of the sequence of the human genome, comprising over 100,000 genes, was announced. The challenge for the next decade will be the determination of the function and relevance of each gene. This information will facilitate the understanding of biological mechanisms and how variations and mutations in such mechanisms result in disease, enabling more rapid and accurate detection of specific diseases and the development of new therapeutics to treat them.

# Tools for biomedical and pharmaceutical research

There is an increasing demand by biomedical and pharmaceutical researchers for tools that both facilitate and accelerate the generation of biological information. In response to this demand, a variety of formats, or tools, have been developed that allow researchers to study biological pathways and to identify mutations in gene sequences and variations in gene expression levels that can lead to disease. These tools include DNA sequencing instruments, micro-arrays, biochips, micro-spheres, and microfluidic chips. Common among these formats is the need for reagents that allow the identification, quantification and characterization of specific genes or nucleic acid sequences.

According to industry sources, an estimated \$2.1 billion was spent in 1997 on reagents for gene analysis. We believe this market will grow rapidly as a result of:

- o research spending by academic, government and private organizations to determine the function and clinical relevance of the gene sequences identified by the Human Genome Project;
  - development of commercial applications based on information derived

from this research; and

o ongoing advancements in tools that accelerate these research and development activities.

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#### Clinical diagnostics

Clinical diagnostics represented a \$20 billion market in 1999. It is comprised of a broad range of tests such as clinical chemistry, microbiology, immunoassay, blood screening and cancer screening. Many of these tests employ traditional technologies, such as immunoassays and cell culture technologies, for the detection of diseases. Immunoassays use antibodies directed against a specific target, or antigen, to detect that antigen in a patient sample. Cell culturing uses nutrients media to grow, isolate and visually detect the presence of microorganisms.

There are several drawbacks to these technologies. Immunoassays do not allow for early detection of diseases because they require minimum levels of antigens to be produced by the microorganism for detection. These levels vary by microorganism, and the delay involved could be several days or several years, as seen in HIV/AIDS. Cell cultures are slow, labor intensive, and not amenable to all microorganisms. For example, gonorrhea and chlamydia are difficult to culture.

Gene-based diagnostics have many advantages over traditional technologies. Since gene-based diagnostics focus on the identification of diseases at the gene level, they can identify the presence of the disease at its earliest stage of manifestation in the body. These tests provide results more rapidly, are applicable to a broad spectrum of microorganisms and can easily be automated in a multiplex platform.

Several advances in technology are accelerating the adoption of gene-based diagnostics in clinical laboratories. These advances include high through put automated formats that minimize labor costs, non-radioactive probes and reagents that are safe to handle, and amplification technologies that improve the sensitivity of such diagnostics.

According to industry sources, an estimated \$530 million was spent on gene-based diagnostics for clinical diagnosis in 1997. This market is projected to grow at 22% annually to \$1.75 billion in 2003 as a result of:

- o rising number of diagnostic tests being developed from discoveries in genome research;
- o advances in formats and other technologies that automate and accelerate gene-based diagnostic testing;
- o growing emphasis by the health-care industry on early diagnosis and treatment of disease; and
- o application of gene-based diagnostics as tools to match therapies to specific patient genetics, commonly referred to as pharmacogenomics.

# Therapeutics

Most diseases are the consequence of the expression of foreign genes, such as those residing in viruses and pathogenic organisms, or the abnormal or unregulated expression of the body's own genes. In other cases, it is the failure to express a gene that causes the disease. Recent advancements in gene analysis have provided the information and tools necessary to develop drugs that intervene in the disease process at the gene level. For a broad spectrum of diseases, this approach can be more precise and effective than intervening in the downstream molecular processes of the disease. Therapies targeting genetic processes are called gene medicines. There are two fundamental approaches to gene medicines, synthetic and genetic.

Synthetic gene medicine involves the administration of synthetic nucleic acid sequences called "oligos" that are designed to bind to, and thus deactivate, RNA produced by a gene. To date, this approach has demonstrated limited success. Since a single cell may contain thousands of strands of RNA, large amounts of oligos are necessary to shut down the production of unwanted proteins. Also, since oligos are synthetic, they are quickly metabolized or eliminated by the body. As a result, large quantities of oligos must be delivered in multiple treatments, which can be both toxic to the body as well as costly.

Genetic medicine, or gene therapies involve the insertion of a gene into a cell. The inserted gene biologically manufactures the therapy on an ongoing basis. This gene may be inserted to enable a beneficial effect or to disable a pathological mechanism within the cell. For example, the gene may be inserted to replace a missing or malfunctioning gene responsible for

synthesizing an essential protein. On the other hand, a gene coding for a molecule to deactivate either an overactive gene or a gene producing an unwanted protein may be inserted. As a permanent addition to the cellular DNA, the inserted gene produces RNA and/or proteins where needed.

A major challenge in designing gene therapy medicines has been the efficient and safe delivery of the gene to the appropriate target cell. Gene delivery is often accomplished using a delivery vehicle known as a vector. A critical quality of the  ${\bf R}$ 

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vector is its ability to bind to the target cell and effectively deliver, or transduce, the gene into the cell. It is also critical that the DNA of the vector not produce proteins or antigens that can trigger an adverse immune response

Our Strategy

Our objective is to be the leading developer and provider of medicines, as well as the tools and diagnostics used to study and detect disease at the molecular level. There can be no assurances that our objective will be met. Key elements of our strategy include:

Apply our innovative technology to the infectious disease market

Our core technologies have broad diagnostic and therapeutic applications. We have initially focused our efforts on the infectious disease market. Infectious diseases are among the largest contributors of healthcare costs worldwide. Generally, there are no long-term effective treatments for viral pathogens as there are for bacterial pathogens. We have developed novel technologies we believe can serve as enabling platforms for developing medicines that genetically target and inhibit viral functions, as well as regulate immune response. In addition to such therapeutic products, we have capitalized on our nucleic acid labeling, amplification and detection technologies to develop diagnostic and monitoring tests for infectious agents.

 ${\tt Maximize} \ \ {\tt our} \ \ {\tt resources} \ \ {\tt by} \ \ {\tt collaborating} \ \ {\tt with} \ \ {\tt others} \ \ {\tt in} \ \ {\tt research} \ \ {\tt and} \ \ {\tt commercialization} \ \ {\tt activities}$ 

We enter into research collaborations with leading academic and other research centers to augment our core expertise on specific programs. We have research collaborations with, among others, Hadassah University Hospital in Jerusalem, Israel regarding immune regulation and Cornell University regarding the application of our genetic antisense technology to HIV. Similarly, we seek to fully exploit the commercial value of our technology by partnering with for-profit enterprises in areas outside our primary commercial interests.

We intend to apply our gene-based tests to the clinical diagnostics market. We currently offer over 25 gene-based tests for the research market. We also have an extensive library of probes for the detection of various diseases. We have developed a standardized testing format that permits multiple diagnoses to be performed on the same specimen and are in discussions with third parties to develop instrumentation for this purpose.

Leverage marketing and distribution infrastructure of leading life sciences companies  $% \left( 1\right) =\left( 1\right) +\left( 1$ 

In addition to our direct sales, we distribute our research products through leading producers of gene analysis formats and other life sciences companies. By partnering with these industry leaders, we are able to leverage their established marketing and distribution infrastructure to expand the market for our products. We have distribution agreements with, among others, Roche Diagnostic Systems, Amersham Pharmacia Biotech, NEN Life Sciences and Affymetrix.

Expanding and protecting our intellectual property estate

Since our inception, we have followed a strategy to create a broad encompassing patent position in the life sciences and therapeutics areas. We have made obtaining patent protection a central strategic policy, both with respect to our proprietary platform technologies and products, as well as broadly in the areas of our research activities.

Our Core Technologies

We have developed a portfolio of proprietary technologies with a variety of research, diagnostic and therapeutic applications.

#### Gene analysis technology

All gene-based testing is premised on the knowledge that DNA forms a double helix comprised of two complementary strands that match and bind to each other. If a complementary piece of DNA (a probe) is introduced into a sample containing its matching DNA, it will bind to, or hybridize, to form a double helix with that DNA. Gene-based testing is carried out by:

- o amplification of the target DNA sequence (a process that is essential for the detection of very small amounts of nucleic acid);
- o labeling the probe with a marker that generates a detectable signal upon hybridization;
- o addition of the probe to the sample containing the DNA; and
- o binding or hybridization of the probe to the target DNA sequence, if present, to generate a detectable signal.

We have developed a broad technology base for the labeling, detection, amplification and formatting of nucleic acids for gene analysis. We believe we have a significant proprietary position in these fields.

Non-radioactive labeling and detection. Traditionally, nucleic acid probes were labeled with radioactive isotopes. However, radioactively labeled probes have a number of shortcomings. They are unstable and consequently have a limited shelf life. They are potentially hazardous, resulting in restrictive licensing requirements and safety precautions for preparation, use and disposal. Finally, radioactive components are expensive. Our technologies permit gene analysis without the problems associated with radioactively labeled probes and are adaptable to a wide variety of formats.

Formats. There are various processes, or formats, for performing probe-based tests. In certain formats, the probe is introduced to a target sample affixed to a solid matrix; in others the probe is combined with the sample in solution (homogeneous assay). Solid matrix assays include: in situ assays in which the probe reaction takes place directly on a microscope slide; dot blot assays in which the target DNA is fixed to a membrane; and microplate and microarray assays in which the DNA is fixed on a solid surface, and the reaction can be quantified by instrumentation.

Amplification. In the early stages of infection, a pathogen may be present in very small amounts and consequently may be difficult to detect. Using DNA amplification, samples can be treated to cause a pathogen's DNA to be replicated, or amplified, to detectable levels. We have developed a proprietary amplification process for multicopy production of nucleic acid, as well as proprietary techniques for amplifying the signals of our probes to further improve sensitivity. Our amplification technologies are particularly useful for the early detection of very small amounts of target DNA and, unlike PCR, (currently the most commonly used method of amplification,) we have developed isothermal amplification procedures that can be performed at constant temperatures and thus do not require expensive heating and cooling systems or specialized heat-resistant enzymes.

# Therapeutic Technology Platforms

We have developed proprietary technologies in the areas of genetic antisense (antisense RNA) and immune regulation that we are using as a platform for a portfolio of novel therapeutics.

Our Genetic Antisense Technology. We are pursuing a novel approach to gene regulation known as genetic antisense or antisense RNA. Our technology involves the introduction into cellular DNA of a gene that codes for an RNA molecule that binds to, and thus deactivates, RNA produced by a specific gene. To deliver our antisense gene to the target cell, we have developed proprietary vector technology. Our vector technology has the following three strengths:

- o Efficient transduction. A principal problem to date of most gene therapy programs has been inefficient transduction, or an unacceptably low rate of delivery of operating genes to the target cells. We have achieved transduction rates significantly higher than those reported by other researchers.
- o Immunologically "Quiet." Transduced cells often produce non-essential proteins that trigger an immune response, causing such cells to be cleared from the body before they can produce a therapeutic effect. Cells transduced with our vectors have not expressed extraneous proteins.
- o "Smart" Vectors. We incorporate into the surface of our vectors proteins that have an affinity for the surface of the cell types intended to be transduced. By including this targeting mechanism, we create in essence "smart" vectors that preferentially transduce the intended cell type. This may

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We believe that our vector technology has broad applicability in the field of gene medicine. We believe that our vector technology has broad applicability in the field of gene medicine. This can be attributed to the following properties of our construct.

- o the viral promoters are inactivated;
- o insertional gene activation is prevented a major safety factor;
- o chromosomal integration;
- o nuclear localization

Our Immune Regulation Technology. We have developed a novel therapeutic approach based on immune regulation. Our immune regulation technology seeks to control an individual's immune response to a specific antigen in the body. An antigen is a substance that the body perceives is foreign and, consequently, against which the body mounts an immune response. We are developing our technology to treat immune-mediated diseases, infectious diseases and complications arising from transplantation. Our technology utilizes oral administration of known proteins to regulate the patient's immune response against the antigen. Specific formulations of the protein are administered orally to the patient according to precise dosing protocols.

We have filed patent applications relating to this technology, as well as to our therapeutics and protocols under development, relating to areas of infectious diseases and immunological adjustments and enhancements characteristic of this reaction. We are applying our expertise in immune regulation to develop proprietary therapeutics for the treatment of a variety of diseases, including HIV-1 infection, chronic hepatitis caused by HBV and HCV infection, graft versus host disease and ulcerative colitis.

Our Products and Services

We are applying our core technologies to develop novel therapeutics as well as research tools for the life sciences and clinical diagnostics markets. In addition, we provide clinical laboratory services to physicians and other health care providers in the greater New York area.

Research and Diagnostic Products

We are a leading developer and marketer of novel research tools for gene analysis. We manufacture over 300 products that may be sold individually or combined in a kit to meet the specific needs of the researcher. We market these products to biomedical and pharmaceutical firms worldwide. We have summarized our products into the following major categories:

Pre-Formatted In Situ Kits. Our pre-formatted in situ kits include all of the components necessary to identify or detect a gene in a cell or tissue on a glass slide. These components include specific labeled non-radioactive nucleic acid probes on a glass slide, signaling reagents and buffers. We offer probes that will detect a variety of infectious agents, such as human papillomavirus (HPV), hepatitis B (HBV), cytomegalovirus (CMV) and chlamydia. We market these kits under the PathoGene(R) brand name. These kits target the pathology market.

Pre-Formatted Microplate Kits. Our pre-formatted microplate kits include all of the components necessary to identify or detect a gene in a microplate assay. These components include specific labeled non-radioactive nucleic acid probes on a microplate, signaling reagents and buffers. We offer probes that will detect a variety of infectious agents, such as HIV, hepatitis B (HBV) and tuberculosis. This microplate format enables the development of probe-based tests that can be readily automated and quantified.

Membrane Kits. Our membrane kits include all of the reagents and buffers necessary to perform a gene analysis on a membrane. The researcher will supply the probe required for their individual needs. Membrane technology is broadly used in life sciences research. We market these kits under the MaxSense(R) brand name.

Labeled Probes. We have developed a line of non-radioactive nucleic acid probes that have been chemically-labeled to allow detection of infectious agents. We offer labeled probes that can detect such infectious agents as adenovirus, hepatitis B (HBV), cytomegalovirus (CMV), herpes simplex virus (HSV) and chlamydia, as well as certain oncogenes. These probes can be used in hybridization and detection assays in the format chosen by the researcher. These probes are broadly sold into the life sciences research market under the BioProbe(R) brand name.

Labeling and Signaling Reagents. We have developed an extensive line of labeling and signaling systems and reagents for the life sciences research market. These reagents can be used by researchers to identify and detect genes on any particular format. We recently introduced an expanded line of gene labeling products, called BioArray(TM) Labeling Systems, for micro-array and biochip formats.

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#### Therapeutic Development Programs

We have a number of therapeutics in various stages of development that are based on our proprietary genetic antisense and immune regulation technologies. Our therapeutic programs are described below.

Human Immunodeficiency Virus (HIV-1). We are developing complementary HIV-1 therapeutics utilizing both our genetic antisense and immune regulation technologies.

HIV-1 is a human pathogenic virus. After infection it runs a slow course in which certain of the cells in the immune system (CD4+ cells) are progressively destroyed. This results in a state in which the infected person can no longer mount an immune response. This loss of immune responsiveness is the cause of the complex of diseases known as AIDS and ultimately of death.

According to estimates by the World Health Organization, over 34 million people are infected with the human immunodeficiency virus worldwide. At present, two classes of products have received FDA marketing approval for HIV-1 infection: reverse transcriptase inhibitors and protease inhibitors. These drugs are typically used in combination and require more than a dozen tablets to be taken at specific times each day. The cost for treatment of HIV infected individuals, once the disease has progressed to AIDS, is estimated to exceed \$38,000 per person annually.

While combination therapy slows the progression of disease, it is not a cure. HIV's rapid rate of mutation results in the development of viral strains that no longer respond to these medications. This problem is often exacerbated by interruptions in dosing as non-compliance is common in patients on combination therapies. Moreover, currently approved drugs produce toxic side-effects in many patients, affecting a variety of organs and tissues, including the peripheral nervous system and gastrointestinal tract, which side-effects also often result in patients interrupting or discontinuing therapy.

Our HGTV43 genetic antisense product. HGTV43 consists of our proprietary vector carrying antisense genes directed against the genes responsible for viral replication. HGTV43 is designed to deliver the antisense genes to targeted blood cells of patients infected with HIV-1. These genes are incorporated into the DNA of the blood cells, and subsequent production of the antisense RNA prevents replication of the virus, providing resistance to the virus.

Preclinical in vitro studies, performed in conjunction with our collaborators at Cornell University's Weill Medical College demonstrated resistance to HIV-1 in human immune cells into which the antisense genes had been inserted. We are currently concluding a Phase 1 clinical trial of the HIV-1 product, with five evaluable patients. In this study, white blood cell precursors, known as stem cells, were collected from the patient. These stem cells were then treated with HGTV43 ex vivo and infused into the subject. Results of the trial have shown that all patients tolerated the procedure and that anti-HIV-1 antisense RNA continued to be expressed in the patient's circulating

- o all patients tolerated the procedure;
- o anti HIV-1 antisense RNA was detected in the circulation of all patents, the first two patients for as long as 20 months thus far;
- o purified CD4+ cells from all five evaluable patients were tested for the presence of anti HIV-1 antisense RNA and these cells contained the antisense RNA;
- o CD34+ cells from the bone marrow of all patients were tested for the presence of anti HIV-1 antisense RNA at least six months after infusion and these cells all contained the antisense RNA (one patient was tested after six months, two patients after nine months, one after 13 months and one after 20 months.

Based on the Phase 1 trial results demonstrating long-term survival and functioning of antisense RNA in white blood cells and in CD4+ cells we are preparing for the next phase of the study in which we will test strategies to

increase the percentage of CD4+ cells that contain the anti-HIV-1 antisense genes.

One arm of the next phase of clinical trials is expected to be conducted at New York Presbyterian Hospital-Cornell Medical Center. In a significant step, the Company's protocol for this phase of the study was successfully presented to and approved by the National Institutes of Health Recombinant DNA Advisory Committee (RAC). The Cornell site will focus on a strategy to increase the percentage of engineered CD4+ cells by using a combination of radiation and immune conditioning. We anticipate beginning expanded studies of the trial at additional sites. Enzo is now focusing on completing all the necessary protocols for submission to move this program forward.

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Our immune regulation product. We are developing a complementary approach to treat HIV infection and the related autoimmune aspect of the disease. It is suggested that this autoimmune aspect may lead to depletion of CD4+ cells. This therapeutic approach utilizes our immune regulation technology to adjust and enhance the body's immune response to the virus. This treatment, consisting of oral administration of an HIV protein, is designed to reduce or eliminate the autoimmune aspect of HIV infection. In addition, it enhances the antiviral immune response, which may increase the population of CD4+ cells in the patient. This program is currently in pre-clinical development.

Hepatitis B (HBV). We are developing complementary HBV therapeutics utilizing both our genetic antisense and immune regulation technologies.

HBV is a viral pathogen that can lead to a condition in which the body destroys its own liver cells through an immune response. This condition is commonly referred to as chronic active hepatitis. According to the latest figures published by the World Health Organization, approximately 2 billion people are infected by HBV, in whom an estimated 350 million are chronically infected and therefore at risk of death from liver disease.

Chronic active hepatitis is generally treated with interferon or lamivudine. Both of these drugs, however, are toxic, and many patients cannot tolerate their side effects. These treatments have a limited success rate (5-15%).

Our EHT899 immune regulation product. EHT899 is a proprietary formulation of an HBV viral protein designed to eliminate the undesirable immune response elicited by the HBV infection. It also apparently enhances a secondary immune response to clear the viral infection, resulting in reduction in liver damage and decrease in viral load.

In our clinical trial, conducted at the Liver Unit of Hadassah-Hebrew University Medical Center, in Jerusalem, Israel, a formulation of EHT899 was administered orally to a total of 42 patients with chronic active hepatitis. Patients received the medication three times a week for 20 - 30 weeks and followed for an additional 20 weeks. Results of the trial have shown that:

- o The drug was well tolerated in all patients;
- o 46% of patients showed a decrease in HBV viral load and improvement in liver function tests;
- o 33% of patients showed a decrease in inflammation seen on liver biopsy;
- o 95% of patients showed a favorable augmentation in anti-HBV specific T-cell response, a marker of immunological regulation that is significant in that it demonstrates an induction or an enhancement of the immune response to HBV.

Preclinical animal studies with EHT899 showed that this medication was able to achieve complete suppression of HBV-associated human liver cancer and significantly reduced mortality in laboratory mice. These studies may have significant potential application for treatment of liver and other cancers in humans.

Our genetic antisense product. We are applying our genetic antisense to treat chronic active hepatitis. We have developed antisense genes that interfere with the replication of HBV. We are currently developing a vector that will specifically deliver the genes to liver cells. This product is in pre-clinical development.

Hepatitis C (HCV). We are using our immune regulation technology in the development of a treatment for HCV. This disease affects approximately 170 million people worldwide, including 3.9 million in the U.S., of which approximately 69%, or 2.7 million, are chronically infected, according to the National Center for Infectious Diseases. Approximately 30,000 new infections are

recorded each year in the U.S. About 85% of people infected with HCV are reported to develop chronic hepatitis, and about 20% develop cirrhosis, an incurable disease, with approximately half of these cases progressing to end-stage liver disease, including liver cancer. It has been predicted that HCV-related deaths in the U.S. may soon overtake the number of AIDS-related deaths in the U.S.

The ongoing clinical trial is being conducted by physicians at the Liver Unit of Hadassah University Medical Center in Jerusalem, Israel and will test our next generation of immune regulation medicine, EHC18, a broad spectrum of specific HCV proteins.

Inflammatory bowel diseases. We are applying our immune regulation technology to treat inflammatory bowel disease (IBD), including ulcerative colitis and Crohn's Disease. According to the Inflammatory Bowel Disease Foundation, approximately one million persons in the United States suffer from IBD. Although the cause of these disorders remains unknown, various features suggest immune system involvement in their pathogenesis.

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There is currently no effective treatment for these diseases. Patients are managed during short-term episodes through the use of anti-inflammatory medications, or immunosuppressants, that provide symptomatic relief over short periods of time but do nor provide a cure. These drugs are all based on a generalized suppression of the immune response and are non-specific. As such, they have considerable side effects and cannot be used for long periods of time because of their inherent toxicity.

Enzo recently received approval from the Ministry of Health in Isreal to begin a Phase 1 clinical trial to test an innovative immune regulation medicine for treatment of Crohn's Disease. The clinical study is based on successful preclinical results achieved in an animal model sysytem. The study results showed that when laboratory animals with experimentally induced colitis were given specific proteins by oral administration, a remission of the condition was seen. The experimental animals exhibited a marked amelioration of the symptoms, including significant reduction in tissue inflammation, as well as a decrease in the levels of gamma interferon in the serum, both indicative of remission.

Graft versus Host Disease. We are applying our immune regulation technology to treat graft versus host disease. Graft versus Host Disease (GvHD) is a major complication of bone marrow and stem cell transplantation accounting for many of the failures of these transplant procedures. GvHD is characterized by an immune response mounted by the immune cells within the engrafted tissue against the recipient that leads to a wasting syndrome and occasionally death. It is estimated that there are only 15,000 bone marrow transplants performed annually worldwide due, in part, to GvHD. It is assumed that the elimination of GvHD would lead to a dramatic rise in the number of these procedures. GvHD is currently treated by immunosuppressant drugs, which are toxic and only reduce the extent of the wasting reaction.

We are conducting pre-clinical and animal studies at Hadassah University Hospital. The results of these studies have demonstrated that our immune regulation technology could be effective in treating GvHD. We have developed clinical protocols and, subject to regulatory approval, expect to commence human trials during 2002.

In the fiscal years ended July 31, 2001, 2000 and 1999, the Company incurred costs of 6,081,000, 5,431,000 and 4,427,000, respectively, for research and development activities.

Clinical Laboratory Services

We operate a regional clinical reference laboratory that offers full diagnostic services to the greater New York medical community. The services we provide include chemistry, blood tests, cytology studies, tissue pathology, hormone studies and screening for cancer and infectious diseases. We provide these services primarily to physicians, as well as to clinics and other clinical laboratories.

The Company offers over 2,000 different routine and esoteric clinical laboratory tests or procedures. These tests are frequently used in general patient care by physicians to establish or support a diagnosis, to monitor treatment or medication, or search for an otherwise undiagnosed condition. These routine and esoteric procedures are most often used by practicing physicians in their outpatient office practices.

We operate a clinical reference laboratory on Long Island and seventeen satellite patient service centers in the greater New York area. Patient service centers collect the specimens as requested by physicians. The specimens are sent through our in-house courier system to our Long Island laboratory facility for testing. We also operate a STAT laboratory in Manhattan. A "STAT" lab is a

laboratory that has the ability to perform certain routine tests quickly and report results to the physician immediately.

Patient specimens are delivered to our facilities accompanied by a test request form. These forms, which are completed by the physician, indicate the tests to be performed and provide the necessary billing information. Once this information is entered into the computer system, the tests are performed and the results are entered primarily through a computer interface or manually. Most routine testing is completed by early the next morning, and test results are printed and prepared for distribution. Some physicians have local printer capability and have reports printed out directly in their offices. Physicians who request that they be called with a result are so notified in the morning.

We utilize our clinical reference laboratory to evaluate and demonstrate the benefits of our internally developed gene-based diagnostic products. In addition, our laboratory is currently performing gene-based tests in support of our HIV-1 clinical studies.

Approximately 82% at July 31, 2001 and 2000, of the Company's net accounts receivable relates to its clinical reference laboratory business which operates in the New York Metropolitan area. The Company believes that the concentration of credit risk with respect to accounts receivable is limited due to the diversity of the Company's client base. However, the Company provides services to certain patients covered by various third-party payors, including the Federal Medicare program. Revenue, net of contractual allowances, from direct billings under the Federal Medicare program during July 31, 2001 was approximately 15% of the Company's total revenue.

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#### Research & Development

Our principal research and development efforts are directed toward expanding our research and diagnostic product lines, as well as developing innovative new therapeutic products to meet unmet market needs. We have developed our core research expertise in genomics through 20 years of dedicated focus in this area. We conduct our research and other product development efforts through internal research and collaborative relationships.

Our Internal Research Programs

Our internal research and development activities, centered in Farmingdale, New York, are performed by a staff of approximately 30 professionals and scientists. Our product development programs incorporate various scientific areas of expertise, including recombinant DNA, monoclonal antibody development, enzymology, microbiology, biochemistry, molecular biology, organic chemistry, and fermentation. In addition, we continuously review in-licensing opportunities in connection with new technology.

Our External Research Collaborations

We have and continue to explore collaborative relationships with prominent companies and leading-edge research institutions in order to maximize the application of our technology in areas where we believe such relationship will benefit the development of our technology.

The following table describes our existing collaborations:

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 Collaborator	Project
 <s> Cornell University Medical College</s>	<c> Application of our genetic antisense technology for the treatment of HIV-1.</c>
University of California, San Francisco	Human clinical trials of HGTV43, our genetic antisense product for the treatment of HIV-1.
Hadassah University Hospital, Jerusalem, Israel	<ul> <li>(i) Human clinical trials of EHT899, our immune regulation product to treat HBV.</li> <li>(ii) Human clinical trials of EHC18, our immune regulation product to treat HCV.</li> <li>(iii) Human clinical trials of our immune regulation treatment for Crohn's Disease</li> <li>(iv) Pre-clinical analysis of various therapeutic products using our proprietary immune regulation</li> </ul>

</TABLE>

Sales and Marketing

Our sales and marketing strategy is to sell our products through two distinct channels: (i) direct sales to end-users; and (ii) supply agreements with manufacturers and distributors.

Our Direct Sales and Marketing Effort

We internally market our products through our catalogue, direct field sales and telemarketing, as well as through our e-commerce web site. We maintain a team of professionals to perform direct field sales and telemarketing activities. Our field sales force was increased substantially during the past year. Our worldwide marketing efforts also consist of advertisements in major scientific journals; direct mailings to researchers; presentations at scientific seminars; and exhibitions at scientific meetings.

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Our Supply and Distribution Arrangements

We also distribute our products through leading life sciences companies. These companies include manufacturers of instruments for gene analysis, where our reagents are critical for the identification and detection of genes and nucleic acid sequences. Through these arrangements, we are able to leverage the established marketing and distribution infrastructure of these companies. We have distribution agreements with, among other companies:

- o Affymetrix;
- o Amersham Pharmacia Biotech;
- o Dako;
- o NEN Life Sciences;
- o Ortho Diagnostics;
- o Roche Diagnostics;
- o VWR Scientific Products.

# Competition

We compete with other life science and biotechnology companies, as well as pharmaceutical, chemical and other companies. Competition in our industry is intense and is expected to increase. Many of these companies are performing research in the same areas as we are. These competitors have more significant financial resources than we do. The primary competitive factors in our industry are the ability to create scientifically advanced technology, successfully develop and commercialize products on a timely basis, establish and maintain intellectual property rights and attract and retain a breadth and depth of human resources.

Our clinical laboratory services business competes with numerous national and local entities, some of which are larger and have greater financial resources than we do. Our laboratory competes primarily on the basis of the quality and specialized nature of its testing, reporting and information services, its reputation in the medical community, the pricing of its services, its reliability and speed in performing diagnostic tests, and its ability to employ qualified laboratory personnel.

Intellectual Property

We consider our intellectual property program to be a key asset and a major strategic component to the execution of our business strategy. Our core technology platforms are supported by a broad portfolio of issued patents and pending patent applications. Our policy is to seek patent protection for our core technology platforms, as well as for ancillary technologies that support these platforms and provide a competitive advantage.

At the end of fiscal 2001 we owned or licensed 37 U.S. and approximately 161 foreign patents relating to products, methods and procedures resulting from our internal or sponsored research projects. Patents relating to the BioProbe(R) nucleic acid probe system have issued in the U.S. and Europe. We cannot assure, however, that patents will be issued on pending applications or that any issued patents will have commercial benefit. We do not intend to rely on patent protection as the sole basis for protecting our proprietary technology. We also rely on our trade secrets and continuing technological innovation. We require each of our employees to sign a confidentiality agreement that prohibits the employee from disclosing any confidential information about us, including our technology or trade secrets.

In some instances, we may enter into royalty agreements with collaborating research parties in consideration for the commercial use by us of the developments of their joint research. In other instances a patent might be

obtained by the collaborating party, but we receive the license to use the patented subject matter. In such cases, we will seek to secure exclusive licenses. In other instances, we might have an obligation to pay royalties to, or reach a royalty arrangement with, a third party in consideration of our use of developments of such third party. We have an exclusive licensing agreement with Yale for the technology used in nucleic acid probe products. That agreement covers licensed patents owned by Yale and licensed to us for the life of the patents, which expire not earlier than 2004. The Research Foundation of the State University of New York has granted us the exclusive rights to a genetic engineering technology using antisense nucleic acid control methodologies.

# Regulation of Pharmaceutical Products

New drugs and biological drug products are subject to regulation under the Federal Food, Drug and Cosmetic Act, and biological products are also regulated under the Public Health Service Act. We believe that products developed by us or our collaborators will be regulated either as biological products or as new drugs. Both statutes and the regulations promulgated thereunder govern, among other things, the testing, licensing, manufacturing, marketing, distributing, safety, and efficacy requirements, labeling, storage, exporting, record keeping, advertising and other promotional practices involving biologics or new drugs, as the case may be. FDA review or approval or other clearances must be obtained before clinical testing, and before

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manufacturing and marketing, of biologics and drugs. At the FDA, the Center for Biological Evaluation and Research ("CBER") is responsible for the regulation of biological drugs and the Center for Drug Evaluation and Research ("CDER") is responsible for the regulation of non-biological drugs. Biological drugs are licensed and other drugs are approved before commercialization.

Any gene medicine products that we develop will require regulatory review before clinical trials, and additional regulatory clearances before commercialization. New human gene medicine products, as therapeutics, are subject to regulation by the FDA and comparable agencies in other countries. The precise regulatory requirements with which we will have to comply are uncertain at this time because of the novelty of the human gene therapies currently under development. Each protocol is currently reviewed by the FDA on a case-by-case basis. The FDA has published "Points to Consider" guidance documents with respect to the development of gene medicine protocols. The National Institute of Health ("NIH") is also involved in the oversight of gene therapies and the FDA has required compliance with certain NIH requirements.

Obtaining FDA approval has historically been a costly and time-consuming process. Generally, to gain FDA approval, a developer first must conduct pre-clinical studies in the laboratory evaluating product chemistry, formulation and stability and, if appropriate, in animal model systems, to gain preliminary information on safety and efficacy. Pre-clinical safety tests must be conducted by laboratories that comply with FDA regulations governing Good Laboratory Practices. The results of those studies are submitted with information characterizing the product and its manufacturing process and controls as a part of an investigational new drug ("IND") application, which the FDA must review and declare effective before human clinical trials of an investigational drug can start. The IND application includes a detailed description of the clinical investigations to be undertaken in addition to other pertinent information about the product, including descriptions of any previous human experience and the company's future plans for studying the drug.

In order to commercialize any products, we (as the sponsor) file an IND and will be responsible for initiating and overseeing the clinical studies to demonstrate the safety and efficacy necessary to obtain FDA marketing approval of any such products. For INDs that we sponsor, we will be required to select qualified clinical sites (usually physicians affiliated with medical institutions) to supervise the administration of the products, and ensure that the investigations are conducted and monitored in accordance with FDA regulations and the general investigational plan and protocols contained in the IND. Each clinical study is reviewed and approved by an Institutional Review Board (IRB). The IRB will consider, among other things, ethical factors and the safety of human subjects. Clinical trials are normally conducted in three phases, although the phases might overlap. Phase I trials, concerned primarily with the safety and tolerance of the drug, and its pharmacokinetics (or how it behaves in the body including its absorption and distribution) involve fewer than 100 subjects. Phase II trials normally involve a few hundred patients and are designed primarily to demonstrate preliminary effectiveness and the most suitable dose or exposure level for treating or diagnosing the disease or condition for which the drug is intended, although short-term side effects and risks in people whose health is impaired may also be examined. Phase III trials are expanded, adequate and well-controlled clinical trials with larger numbers of patients and are intended to gather the additional information for proper dosage and labeling of the drug. Clinical trials generally take two to five years, but the period may vary. Certain regulations promulgated by the FDA may shorten the time periods and reduce the number of patients required to be tested

in the case of certain life-threatening diseases, which lack available alternative treatments.

The FDA receives reports on the progress of each phase of clinical testing, and it may require the modification, suspension or termination of clinical trials if an unwarranted risk is presented to patients. Human gene medicine products are a new category of therapeutics. We cannot assure the length of the clinical trial period, the number of patients that the FDA will require to be enrolled in the clinical trials in order to establish the safety, purity and potency of human gene medicine products, or that the clinical and other data generated will be acceptable to the FDA to support marketing approval.

After completion of clinical trials of a new product, FDA marketing approval must be obtained before the product can be sold in the United States. If the product is regulated as a new biologic, CBER requires the submission and approval of a Biologics License Application (BLA) before commercial marketing of the Biologic. If the product is classified as a new drug, we must file a New Drug Application ("NDA") with CDER and receive approval before commercial marketing of the drug. The NDA or BLA must include results of product development, pre-clinical studies and clinical trials. The testing and approval processes require substantial time and effort and we cannot assure that any approval will be granted on a timely basis, if at all. The median time to obtain new product approvals after submission to the FDA is approximately 12 months. If questions arise during the FDA review process, approval can take longer. Before completing its review, the FDA may seek guidance from an Advisory Committee of outside experts at a public or closed meeting. While the advice of these committees is not binding on the FDA, it is often followed. Notwithstanding the submission of relevant data, the FDA might ultimately decide that the NDA or BLA does not satisfy its regulatory criteria for approval and, thus, reject the application, refuse to approve it, or require additional clinical, preclinical or chemistry studies. Even after FDA regulatory approval or licensure, a marketed drug product is subject to continual review by the FDA. In addition, if previously unknown problems are discovered or we fail to comply with the applicable regulatory requirements, we might be restricted from marketing a product, we might be required to withdraw the product from the market, and we miaht

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possibly become subject to seizures, injunctions, voluntary recalls, or civil, monetary or criminal sanctions. In addition, the FDA may condition marketing approval on the conduct of specific post-marketing studies to further evaluate safety and effectiveness.

For commercialization of our biological or other drug products, the manufacturing processes described in our NDA or BLA must receive FDA approval and the manufacturing facility must successfully pass an inspection prior to approval or licensure of the product for sale within the United States. The pre-approval inspection assesses whether, for example, the facility complies with the FDA's current good manufacturing practices (cGMP) regulations. These regulations elaborate testing, control, documentation, personnel, record-keeping and other quality assurance procedure requirements that must be met. Once FDA approves our biological or other drug products for marketing, we must continue to comply with the cGMP regulations. FDA periodically inspects biological and other drug manufacturing facilities to ensure compliance with applicable cGMP requirements. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product or voluntary recall of a product.

If a developer obtains designations by the FDA of a biologic or other drug as an "orphan" for a particular use, the developer may request grants from the federal government to defray the costs of qualified testing expenses in connection with the development of such drug. Orphan drug designation is possible for drugs for rare diseases, including many genetic diseases, which means the drug is for a disease that has a prevalence of less than 200,000 patients in the United States. The first applicant who receives an orphan drug designation and who obtains approval of a marketing application for such drug acquires the exclusive marketing rights to that drug for that use for a period of seven years unless the subsequent drug can be shown to be clinically superior. Accordingly, no other company would be allowed to market an identical orphan drug with the same active ingredient for the use approved by the FDA for seven years after the approval.

### Regulation of Diagnostics

The diagnostic products that are developed by us or our collaborators are likely to be regulated by the FDA as medical devices. Unless an exemption applies, medical devices must receive either "510(k) clearance" or "PMA approval" from the FDA before marketing them in the United States. The FDA's 510(k) clearance process usually takes from four to 12 months, but it can last longer. The process of obtaining PMA approval is much more costly, lengthy and

uncertain. It generally takes from one to three years or even longer. We cannot be sure that  $510\,(k)$  clearance or PMA approval will ever be obtained for any product we propose to market.

The FDA decides whether a device must undergo either the 510(k) clearance or PMA approval process based upon statutory criteria. These criteria include the level of risk that the agency perceives is associated with the device and a determination whether the product is a type of device that is similar to devices that are already legally marketed. Devices deemed to pose relatively less risk are placed in either class I or II, which requires the manufacturer to submit a premarket notification requesting 510(k) clearance, unless an exemption applies. The premarket notification must demonstrate that the proposed device is "substantially equivalent" in intended use and in safety and effectiveness to a legally marketed "predicate device" that is either in class I, class II, or is a "preamendment" class III device (i.e., one that was in commercial distribution before May 28, 1976) for which the FDA has not yet called for submission of a PMA application.

After a device receives  $510\,(k)$  clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new  $510\,(k)$  clearance or could require a PMA approval. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new  $510\,(k)$  clearance, the agency may retroactively require the manufacturer to seek  $510\,(k)$  clearance or PMA approval. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until  $510\,(k)$  clearance or PMA approval is obtained.

Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or deemed not substantially equivalent to a legally marketed class I or class II predicate device, or to a preamendment class III device for which PMAs have not been called, are placed in class III. Such devices are required to undergo the PMA approval process in which the manufacturer must prove the safety and effectiveness of the device to the FDA's satisfaction. A PMA application must provide extensive preclinical and clinical trial data and also information about the device and its components regarding, among other things, device design, manufacturing and labeling. After approval of a PMA, a new PMA or PMA supplement is required in the event of a modification to the device, its labeling or its manufacturing process.

Although clinical investigations of most devices are subject to the investigational device exemption ("IDE") requirements, clinical investigations of in vitro diagnostic ("IVDS") tests are exempt from the IDE requirements, including the need to obtain the FDA's prior approval, provided the testing is noninvasive, does not require an invasive sampling procedure that presents a significant risk, does not introduce energy into the subject, and is not used as a diagnostic procedure without confirmation by another medically established test or procedure. In addition, the IVD must be labeled for Research Use Only (RUO) or

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Investigational Use Only (IUO), and distribution controls must be established to assure that IVDs distributed for research or investigation are used only for those purposes. The FDA expressed its intent to exercise heightened enforcement with respect to IUO and RUO devices improperly commercialized prior to receipt of FDA clearance or approval.

We have developed products that we currently distribute in the United States on a RUO basis. There can be no assurance that the FDA would agree that our distribution of these products meets the requirements for RUO distribution. Futhermore, failure of us or recipients of our RUO products to comply with the regulatory limitations on the distribution and use of such devices could result in enforcement action by the FDA, including the impostion of restrictions on our distribution of these products.

Any devices that we manufacture or distribute will be subject to a host of regulatory requirements, including the Quality System Regulation (which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures), the Medical Device Reporting regulation (which requires that manufacturers report to the FDA certain types of adverse events involving their products), labeling regulations, and the FDA's general prohibition against promoting products for unapproved or "off label" uses. Class II devices also can have special controls such as performance standards, postmarket surveillance, patient registries, and FDA guidelines that do not apply to class I devices. Unanticipated changes in existing regulatory requirements or adoption of new requirements could hurt our business, financial condition and results of operations.

We are subject to inspection and market surveillance by the FDA to determine compliance with regulatory requirements. If the FDA finds that we have

failed to comply, the agency can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as fines, injunction, civil penalties, recall or seizure of our products, the issuance of public notices or warnings, operating restrictions, partial suspension or total shutdown of production, refusal of our requests for 510(k) clearance or PMA approval of new products, withdrawal of 510(k) clearance or PMA approvals already granted, and criminal prosecution.

The FDA also has the authority to request repair, replacement or refund of the cost of any medical device manufactured or distributed by us. Our failure to comply with applicable requirements could lead to an enforcement action that may have an adverse effect on our financial condition and results of operations.

Unanticipated changes in existing regulatory requirements, our failure to comply with such requirements or adoption of new requirements could have a material adverse effect on us.

We have employees to expedite the preparation and filing of documentation necessary for FDA clearances and approvals, patent issuances and licensing agreements. We have received clearance from the FDA to market five of our in vitro diagnostic products.

We cannot assure you that future clinical diagnostic products developed by us or our collaborators will not be required to be reviewed by FDA under the more expensive and time consuming pre-market approval process.

Clinical Laboratory Regulation and Reimbursement

The clinical laboratory industry is also subject to significant governmental regulation at the federal, state, and local levels. Under the Clinical Laboratory Improvement Act of 1967 and the Clinical Laboratory Improvement Amendments of 1988 (collectively, as amended, "CLIA"), our clinical laboratories must be certified by the Federal government, or exempt from federal certification, as discussed below. Many clinical laboratories also must meet other governmental standards, undergo proficiency testing, and are subject to inspection. Clinical laboratory certificates or licenses are also required by various state and local laws.

The health care industry has been undergoing significant change because third-party payors, such as Medicare (serving primarily patients 65 and older), Medicaid (serving primarily indigent patients) and commercial insurers, have increased their efforts to control the cost, utilization and delivery of health care services. To address the problem of increasing health care costs, legislation has been proposed or enacted at both the Federal and state levels to regulate health care delivery in general and clinical laboratories in particular. Additional health care reform efforts are likely to be proposed in the future. In particular, we believe that reductions in reimbursement for Medicare services will continue to be implemented from time to time. Reductions in the reimbursement rates of other third-party payors are likely to occur as well. We cannot predict the effect that health care reform, if enacted, would have on our business, and there can be no assurance that such reforms, if enacted, would not have a material adverse effect on our business and operations.

In 1992, the U.S. Department of Health and Human Services ("HHS") published regulations implementing CLIA. Most of the CLIA regulations became effective in 1992, although certain personnel, quality control and proficiency testing requirements are being phased in by HHS. The regulations place all tests into one of three categories of complexity (waived, moderate complexity and high complexity) and establish varying requirements depending upon the complexity category of the test performed. A

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laboratory that performs high complexity tests must meet more stringent requirements than a laboratory that performs only moderate complexity tests, while those that perform only waived tests may apply for a certificate of waiver from most of the requirements of CLIA. Our facility is certified to perform highly complex tests. In general, the HHS regulations require laboratories that perform high or moderate complexity tests to implement systems that ensure the accurate performance and reporting of test results, establish quality control and quality assurance systems, ensure hiring of personnel that meet specified standards, engage in proficiency testing by approved agencies and undergo biennial inspections.

The sanction for failure to comply with these regulations may be suspension, revocation, or limitation of a laboratory's CLIA certificate necessary to conduct business, significant fines and criminal penalties. The loss of, or adverse action against, a license, the imposition of a fine, or future changes in Federal, state and local laboratory laws and regulations (or in the interpretation of current laws and regulations) could have a material adverse effect on our business.

Clinical laboratories also are subject to state regulation. CLIA provides that a state may adopt different or more stringent regulations than Federal law, and permits states to apply for exemption from CLIA if HHS determines that the state's laboratory laws are equivalent to, or more stringent than, CLIA. The State of New York's clinical laboratory regulations contain provisions that are more stringent than Federal law, and New York has received exemption from CLIA. Therefore, as long as New York maintains its CLIA-exempt status, laboratories in New York, including our laboratory, are regulated under New York law rather than CLIA. Our laboratory is licensed in New York and has continuing programs to ensure that its operations meet all applicable regulatory requirements.

Containment of health care costs, including reimbursement for clinical laboratory services, has been a focus of ongoing governmental activity. In 1984, Congress established a Medicare fee schedule for clinical laboratory services performed for patients covered under Part B of the Medicare program. Subsequently, Congress imposed a national ceiling on the amount that can be paid under the fee schedule. Laboratories must accept the scheduled amount as payment in full for most tests performed on behalf of Medicare beneficiaries and must bill the program directly. Medicaid payments for clinical lab tests also may not exceed the Medicare fee schedule amount. In addition, our other business depends significantly on continued participation in these programs because clients often want a single laboratory to perform all of their testing services. Since 1984, Congress has periodically reduced the ceilings on Medicare reimbursement to clinical laboratories from previously authorized levels. Because a significant portion of our costs are fixed, these Medicare reimbursement reductions have a direct adverse effect on our net earnings and cash flows. We cannot predict whether additional Medicare reductions will be implemented.

On January 1, 1993, numerous changes in the Physicians' Current Procedural Terminology ("CPT") were published. The CPT is a coding system that is published by the American Medical Association. The CPT lists descriptive terms and identifying codes for reporting medical and medically related services. The Medicare and Medicaid programs require suppliers, including laboratories, to use CPT codes when they bill the programs for services performed. HCFA adopted these CPT changes for Medicare and Medicaid on August 1, 1993. The CPT changes have altered the way we bill Medicare and Medicaid for some of our services, thereby reducing the reimbursement that we receive from those programs for some of our services. In March 1996, HCFA implemented changes in the policies used to administer Medicare payments to clinical laboratories for the most frequently performed automated blood chemistry profiles. Among other things, the changes established a consistent standard nationwide for the content of the automated chemistry profiles. Another change requires laboratories performing certain automated blood chemistry profiles to obtain and provide documentation of the medical necessity of tests included in the profiles for each Medicare beneficiary. Reimbursements have been reduced as a result of this change.

Future changes in federal, state and local regulations (or in the interpretation of current regulations) affecting governmental reimbursement for clinical laboratory testing could have a material adverse effect on our business. We cannot predict, however, whether and what type of legislation will be enacted into law.

# Infectious Wastes and Radioactive Materials

We are subject to licensing and regulation under federal, state and local laws relating to the handling and disposal of medical specimens, infectious and hazardous waste and radioactive materials, as well as to the safety and health of laboratory employees. All our laboratories are required to operate in accordance with applicable federal and state laws and regulations relating to biohazard disposal of all facilities specimens and we use outside vendors to dispose such specimens. Although we believe that we comply in all material respects with such federal, state and local laws, our failure to comply with those laws could subject us to denial of the right to conduct business, fines, criminal penalties and/or other enforcement actions.

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#### Occupational Safety

In addition to its comprehensive regulation of safety in the workplace, the Federal Occupational Safety and Health Administration ("OSHA") has established extensive requirements relating to workplace safety for health care employers, including clinical laboratories, whose workers may be exposed to blood-borne pathogens such as HIV and the hepatitis B virus. These regulations, among other things, require work practice controls, protective clothing and equipment, training, medical follow-up, vaccinations and other measures designed to minimize exposure to, and transmission of, blood-borne pathogens. The use of controlled substances in testing for drugs of abuse is regulated by the Federal Drug Enforcement Administration. We are also subject to OSHA's requirement that employers using hazardous chemicals communicate the properties and hazards presented by those chemicals to their employees. We believe that we are in

material compliance with these OSHA requirements. Our failure to comply with those regulations and requirements could subject us to tort liability, civil fines, criminal penalties and/or other enforcement actions.

# Other Regulation

Our business is and will continue to be subject to regulation under various state and federal environmental, safety and health laws, including Occupational Safety and Health Act, the Recourse Conservation and Recovery Act, and the Atomic Energy Act or their state law analogs. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in our operations and wastes generated by our operations. We are required to possess licenses under, or are otherwise subject to federal and state regulations pertaining to, the handling and disposal of medical specimens, infectious and hazardous waste and radioactive materials.

We believe that we are in material compliance with applicable environmental, safety and health laws and that our continual compliance therewith will not have a material adverse effect on our business. All of our laboratories are operated in accordance with applicable federal and state laws and regulations relating to hazardous substances and wastes, and we use qualified third-party vendors to dispose biological specimens and other hazardous wastes. Although we believe that we comply in all material respects with such federal, state and local laws, our failure to comply with those laws could subject us to denial of the right to conduct business, civil fines, criminal penalties and/or other enforcement actions. Environmental contamination resulting from spills or disposal of hazardous substances generated by our operations, even if caused by a third-party contractor or occurring at a remote location, could result in material liability.

#### Manufacturing and Facilities

We manufacture the majority of our products internally. Most of our production and clinical laboratory operations take place at our 43,000 square feet facilities in Farmingdale, New York. We have a completely integrated manufacturing facility, with special handling facilities and clean rooms.

We also contract with qualified third-party contractors to manufacture our products in cases where we deem it appropriate, for example, when it is not cost-effective to produce a product ourselves or where we seek to leverage the expertise of another manufacturer in a certain area.

## Employees

As of July 31, 2001, we employed 219 full-time and 36 part-time employees. Of the full-time employees, 36 were engaged in research, development, manufacturing and marketing of research products and 183 at the clinical reference laboratories. Our scientific staff possesses a wide range of experience and expertise in the areas of recombinant DNA, nucleic acid chemistry, molecular biology and immunology. We believe that the relationships we have established with our employees are good.

# Information Systems

We believe that with respect to our clinical reference laboratory business, the health care provider's need for data will continue to place high demands on its information systems staff. We believe that the efficient handling of information involving clients, patients, payors and other parties will be a critical factor in our future success.

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# Quality Assurance

We consider the quality of our clinical reference laboratory tests to be of critical importance, and, therefore, we established a comprehensive quality assurance program designed to help assure accurate and timely test results. In addition to the compulsory external inspections and proficiency programs demanded by the Medicare program and other regulatory agencies, our clinical laboratory has in place systems to emphasize and monitor quality assurance.

In addition to our own internal quality control programs, our laboratory participates in numerous externally administered, blind quality surveillance programs, including on-site evaluation by the College of American Pathologies ("CAP") proficiency testing program and the New York State survey program. The blind programs supplement all other quality assurance procedures and give our management the opportunity to review our technical and service performance from the client's perspective.

The CAP accreditation program involves both on-site inspections of our laboratory and participation in the CAP's proficiency testing program for all categories in which our laboratory is accredited by the CAP. The CAP is an

independent nongovernmental organization of board certified pathologists which offers an accreditation program to which laboratories can voluntarily subscribe. A laboratory's receipt of accreditation by the CAP satisfies the Medicare requirement for participation in proficiency testing programs administered by an external source. Our clinical laboratory facilities are accredited by the CAP.

CAUTIONARY STATEMENT FOR PURPOSES OF THE "SAFE HARBOR" PROVISIONS OF THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for forward-looking statements to encourage companies to provide prospective information about their companies without fear of litigation so long as those statements are identified as forward-looking and are accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those projected in the statement. The Company desires to take advantage of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and is including this section herein in order to do so. Accordingly, the Company hereby identifies the following important factors that could cause the Company's actual financial results to differ materially from those projected, forecast, estimated, or budgeted by the Company in forward-looking statements.

- (a) Heightened competition, including the intensification of price competition.
- (b) Impact of changes in payor mix, including the shift from traditional, fee-for-service medicine to managed-cost health care.
- (c) Adverse actions by governmental or other third-party payors, including unilateral reduction of fee schedules payable to the Company.
- (d) The impact upon the Company's collection rates or general or administrative expenses resulting from compliance with Medicare administrative policies including specifically the HCFA's recent requirement that laboratories performing certain automated blood chemistry profiles obtain and provide documentation of the medical necessity of tests included in the profiles for each Medicare beneficiary.
- (e) Failure to obtain new customers, retain existing customers or reduction in tests ordered or specimens submitted by existing customers.
- (f) Adverse results in significant litigation matters.
- (g) Denial of certification or licensure of any of the Company's clinical laboratories under CLIA, by Medicare programs or other Federal, state or local agencies.
- (h) Adverse publicity and news coverage about the Company or the clinical laboratory industry.
- (i) Inability to carry out marketing and sales plans.
- (j) Loss or retirement of key executives.
- (k) Impact of potential patent infringement by others or the Company.

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- (1) Inability to obtain patent protection or secure and maintain proprietary positions on its technology.
- (m) Our product development efforts depend on new technologies, and our product candidates are in early stage of development.
- (n) Clinical trials for our products will be expensive and their outcome is uncertain. We incur substantial expenses that might not result in viable products.
- (o) May need additional capabilities in the future, if additional capital is not available, we may need to curtail or cease operations.

Principal Operations

# Item 2. Properties

The following are the principal facilities of the Company:

<TABLE>

<\$>	<c></c>	<c></c>	<c></c>	<c></c>
60 Executive Blvd.	Corporate			
Farmingdale, N.Y.	headquarters, clinical reference and development facilities (See note 5 of Notes to Consolidated Financial Statements)	43,000	\$1,140,000	November 30, 2004
527 Madison Ave. New York, NY				

 Executive office | 6,400 | \$ 288,000 | December, 2003 |Management believes that the current facilities will be adequate for current operating needs and in the foreseeable future.

#### Item 3. Legal Proceedings

In 1993, the Company filed suit in U.S. district court against Calgene, Inc., alleging that Calgene's "Flavr Savr" tomato infringed several of the Company's patents concerning antisense technology. After a trial, the district court ruled against the Company, ruling that claims of these patents were invalid and not infringed. In September 1999, the U.S. Court of Appeals for the Federal Circuit affirmed the decision of the district court. On August 10, 2001, the case was dismissed pursuant to stipulation of the parties, with each party to bear its own costs and attorneys' fees. No significant adverse monetary impact to the Company occurred.

In June 1999, the Company filed suit in the United States District Court for the Southern District of New York against Gen-Probe Incorporated, Chugai Pharma U.S.A., Inc., Chugai Pharmaceutical Co., Ltd., bioMerieux, Inc., bioMerieux SA, and Becton Dickinson and Company, charging them with infringing the Company's U.S. Patent 4,900,659, which concerns probes for the detection of the bacteria that causes gonorrhea. On January 26, 2001, the court granted the defendants' motion for summary judgment that the Company's patent is invalid. The grant of summary judgment is being appealed to the Court of Appeals for the Federal Circuit. The appeal proceedings are at an early stage. There can be no assurance that the Company will be successful in these proceedings. However, even if the Company is not successful, management does not believe that there will be a significant adverse monetary impact.

Item 4. Submission of Matters to a Vote of Security Holders

No matters were brought to a vote of the Company's stockholders in the fourth fiscal quarter ended July 31, 2001.

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## PART II

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

The common stock of the Company is traded on the New York Stock Exchange (Symbol:ENZ). The following table sets forth the high and low price of the Company's Common Stock for the periods indicated as reported on the New York Stock Exchange.

	High	Low
2000 Fiscal Year (August 1, 1999		
to July 31, 2000):		
1st Quarter	\$ 36.69	\$16.13
2nd Quarter	\$ 139.00	\$20.75
3rd Quarter	\$ 104.19	\$31.81
4th Quarter	\$ 75.75	\$31.63
2001 Fiscal Year (August 1, 2000		
to July 31, 2001):		
1st Quarter	\$ 58.81	\$34.29
2nd Quarter	\$ 42.06	\$17.96
3rd Quarter	\$ 23.18	\$13.95
4th Quarter	\$ 34.98	\$22.87

On October 11, 2001, the last sale price of the Common Stock of the Company as reported on the New York Stock Exchange was \$19.85.

As of October 11, 2001, the Company had approximately 1,180 record holders of its Common Stock.

The Company has not paid a cash dividend on its Common Stock and

intends to continue to follow a policy of retaining future earnings to finance its operations. Accordingly, the Company does not anticipate the payment of cash dividends to holders of Common Stock in the foreseeable future.

The Company declared a 5% stock dividend on January 16, 2001 payable March 20, 2001 to shareholders of record as of February 27, 2001. The shares and per share data have been adjusted to retroactively reflect this stock dividend. The Company recorded a charge to accumulated deficit and a credit to common stock and additional paid-in capital in the amount of approximately \$32,274,000, which reflects the fair value of the dividend on the date of declaration.

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Item 6. Selected Financial Data

<TABLE> <CAPTION>

For the Years Ended July 31, -----(In thousands, except per share data) 2001 1999 2000 1998 1997 ---------------<S> <C> <C> <C> <C> <C> Operating Results: 58,406 \$ 50,029 \$ 44,319 \$ 40,417 Operating revenues \$ 34,939 3,003 2,585 Interest income 1,984 1,885 1.799 Income before (provision) benefit for taxes on income 12,231 7,668 5,387 2,570 1,564 (Provision) benefit for taxes on (5,418) (1,044) 1,128 822 income (1111)Net income 6,813 \$ 6,625 \$ 6,515 \$ 3,392 Ś \$ 1,453 \$ 0.25 \$ 0.25 \$ 0.13 Basic net income per common share: \$ 0.06 ========= ========= \$ 0.24 \$ 0.23 \$ 0.24 \$ 0.13 Diluted net income per common share: \$ 0.05 Denominator for per share calculation: 26,999 26,180 26,597 25,886 Basic 25.370 28,126 Diluted 28,335 26,751 27,033 26.773 Financial Position: 59**,**323 \$ \$ 85,094 \$ 74,094 \$ 52,973 Working capital \$ 43,232 \$ 102,931 \$ 92,886 \$ 78,901 \$ 72,153 Total assets \$ 67,419 Long-term debt and obligation under capital lease --------46 Stockholders' equity 97,517 \$ 87,176 \$ 75,648 \$ Ś 68,783 64,009 </TABLE>

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

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and related notes. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements. See "Cautionary Statement for Purposes of the "Safe Harbor" Provisions of the Private Securities Litigation Reform Act of 1995". Because of the foregoing factors, you should not rely on past financial results as an indication of future performance. We believe that period-to-period comparisons of our financial results to date are not necessarily meaningful and expect that our results of operations might fluctuate from period to period in the future.

Liquidity and Capital Resources

At July 31, 2001, our cash and cash equivalents totaled \$58.7 million, an increase of \$7.6 million from July 31, 2000. We had working capital of \$85.1 million at July 31, 2001 compared to \$74.1 million at July 31, 2000.

Net cash provided by operating activities for the year ended July 31, 2001 was approximately \$8.0 million and as compared to net cash provided by operating activities of \$4.9 million for the year ended July 31, 2000. The increase in net cash provided by operating activities from fiscal 2000 to fiscal 2001 was primarily due to an increase in the tax benefit for stock options exercised of approximately \$1.4 million.

Net cash used in investing activities increased by approximately \$.3 million from fiscal 2000, primarily as a result of an increase in capital expenditures and patent costs deferred.

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Net cash provided by financing activities decreased by \$2.9 million from fiscal 2000 primarily as a result of the decrease in proceeds from the exercise of stock options.

Net accounts receivable of \$24.6 million and \$20.2 million represented 147 days and 134 days of operating revenues at July 31, 2001 and 2000, respectively. The change in net accounts receivable is due to an increase in accounts receivable at the clinical reference laboratory of approximately \$3.5 million and an increase of research products accounts receivable of approximately \$.9 million. The increase is primarily due to the increase in revenue from the clinical laboratory.

We believe that our current cash position is sufficient for our foreseeable liquidity and capital resource needs, although there can be no assurance that future events will not alter such view.

Management is not aware of any material claims, disputes or settled matters concerning third-party reimbursements that would have a material effect on our financial statements.

Results of Operations

Fiscal 2001 Compared to Fiscal 2000  $\,$ 

Revenues from operations for the fiscal year ended July 31, 2001 were \$58.4 million an increase of \$8.4 million over revenues from operations for the fiscal year ended July 31, 2000. This increase was due to an increase of \$3.7 million in revenues from our clinical reference laboratory operations and an increase of \$4.7 million in revenues from research product sales over revenues for such activities in fiscal 2000. The increase in revenues from the clinical laboratory operations resulted primarily from an increase in volume of esoteric testing and from an increase in doctor accounts being serviced. The increase in research product sales resulted primarily from and an increase in direct sales of research products of labeling and detection reagents for the genomics and sequencing markets.

The cost of clinical laboratory services increased by \$2.0 million primarily due to an increase in direct operating expenses based on the increased sales volume of testing in fiscal 2001. In addition, the cost of sales for research products decreased by \$.6 million as a result of a change in the revenue mix from two of the Company's non-exclusive distribution agreements.

Research and development expenses increased by approximately \$.6 million as a result of an increase in the clinical trial studies and the expansion of certain research activities.

Selling expenses increased by approximately \$.6 million primarily due to an increase in costs associated with the increase in revenue. General and Administrative expenses increased by approximately \$.9 million as a result of an increase in facility overhead costs associated with the increase in testing volume at the clinical laboratory facilities.

Our provision for uncollectible accounts receivable increased by \$.7 million, primarily due to increased revenues from our clinical reference laboratory.

Interest income, increased by \$.4 million as a result of an increase in cash and cash equivalents investments in fiscal 2001 as compared to fiscal 2000.

In fiscal 2001, we recorded a provision for income taxes of \$5.4 million which was based on the combined effective federal, state and local income tax rates. In fiscal 2000 we recorded a provision for income taxes of \$1.0 million which included a deferred benefit from the change in the deferred tax asset valuation reserve and benefits recognized from net operating losses.

Net accounts receivable from our clinical laboratory operations of \$20.1 million and \$16.6 million represented an average of 190 and 193 days of operating revenues at July 31, 2001 and 2000, respectively.

Income before (provision) benefit for taxes on income from research and development activities and related costs was \$8.3 million in fiscal 2001, as compared to income before (provision) benefit for taxes on income of \$3.8 million in fiscal 2000. The increase in the profit is principally related to the increase in sales of research products. Income before (provision) benefit for taxes on income from the clinical reference laboratories activities amounted to \$3.8 million for fiscal 2001, as compared to \$3.7 million for fiscal 2000.

2.2

#### Fiscal 2000 Compared to Fiscal 1999

Revenues from operations for the fiscal year ended July 31, 2000 were \$50.0 million, an increase of \$5.7 million over revenues from operations for the fiscal year ended July 31, 1999. This increase was due to an increase of \$3.4 million in revenues from our clinical reference laboratory operations and an increase of \$2.3 in revenues from research product sales over revenues for such activities in fiscal 1999. The increase in revenues from the clinical laboratory operations resulted primarily from an increase in volume of diagnostic screening tests and an increase in esoteric testing revenues. The increase in research product sales resulted primarily from an increase in sales from the non-exclusive distribution agreements and an increase in direct sales of research products.

The cost of clinical laboratory services increased by \$.2 million primarily as a result of an increase in operating expenses based on the increased sales in fiscal 2000 and the cost of sales for research products decreased by .4 million as a result in a change in the revenue mix from two of the company's non-exclusive distribution agreements.

Research and development expenses increased by approximately \$1.0 million as a result of an increase in research programs and the increased amortization of patent costs.

Our provision for uncollectible accounts receivable increased by \$1.3 million, primarily due to increased revenues from our clinical reference laboratory and reduced reimbursements received from Medicare and other third party insurers who generally follow the reimbursement policies of Medicare.

Net accounts receivable from our clinical laboratory operations of \$16.6 million and \$13.2 million represented an average of 193 and 172 days of operating revenues at July 31, 2000 and 1999, respectively. We expect that in the future, as a result of the revised Medicare reimbursement policies, we will receive reimbursements and cash flows at the clinical reference laboratory at lower rates then those realized in fiscal 2000. We will continue to attempt to control costs associated with the performance of the tests; however, we cannot assure that such efforts will be successful.

Income before (provision) benefit for taxes on income from research and development activities and related costs was \$3.8 million in fiscal 2000, as compared to income before (provision) benefit for taxes on income of \$2.7 million in fiscal 1999. The increase in the profit is principally related to the increase in sales of product from the non-exclusive distribution agreements. Income before (provision) benefit for taxes on income from the clinical reference laboratories activities amounted to \$3.7 million (12% of clinical laboratory services) as compared to \$2.4 million (8% of clinical laboratory services) in fiscal 1999. This increase resulted principally from the increase in the operating revenues of esoteric testing.

In fiscal 2000, we recorded a benefit for income taxes of \$1.0 million versus a benefit of \$1.1 million in fiscal 1999. In the fourth quarter of fiscal 2000, we recorded a tax provision of \$.9 million which included a reduction in our deferred tax asset of .3 million.

Not Applicable

Item 8. Financial Statements and Supplementary Data

The response to this item is submitted in a separate section of this report. See Item  $14\,(a)\,(1)$  and  $(2)\,$ 

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

Not applicable.

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PART III

Item 10. Directors and Executive Officers of the Registrant

(a) Directors - The following sets forth certain information regarding directors of the Company who are not executive officers of the Company. Information with respect to directors of the Company who are also executive officers of the Company appears below under the subcaption "Executive Officers." The Company has a classified Board of Directors consisting of three classes.

JOHN B. SIAS (age 74) has been a Director of the Company since January 1982. Mr. Sias has been President and Chief Executive Officer of Chronicle Publishing Company since April 1993. From January 1986 until April 1993, Mr. Sias was President of ABC Network Division, Capital Cities/ABC, Inc. From 1977 until January 1986 he was the Executive Vice President, President of the Publishing Division (which includes Fairchild Publications) of Capital Cities Communications, Inc.

JOHN J. DELUCCA (age 58) has been a Director of the Company since January 1982. Since January 1999, Mr. Delucca has been Chief Financial Officer & Executive Vice President, Finance & Administration of Coty, Inc. From October 1993 until January 1999, he was Senior Vice President and Treasurer of RJR Nabisco, Inc. From January 1992 until October 1993, he was managing director and Chief Financial Officer of Hascoe Associates, Inc. From October 1, 1990 to January 1992 he was President of The Lexington Group. From September 1989 until September 1990, he was Senior Vice President-Finance of the Trump Group. From May 1986 until August 1989, he was senior Vice President-Finance at International Controls Corp. From February 1985 until May 1986, he was a Vice President and Treasurer of Textron, Inc. Prior to that he was a Vice President and Treasurer of the Avco Corporation, which was acquired by Textron.

IRWIN C. GERSON (age 71) has been a Director of the Company since May, 2001. From 1995 until December 1998, Mr. Gerson served as Chairman of Lowe McAdams Healthcare and prior thereto had been, since 1986, Chairman and Chief Executive Officer of William Douglas McAdams, Inc., one of the largest advertising agencies in the U.S. specializing in pharmaceutical marketing and communications to healthcare professionals. In February 2000, he was inducted into the Medical Advertising Hall of Fame. Mr. Gerson has a B.S. in Pharmacy from Fordham University and an MBA from the NYU Graduate School of Business Administration. He is a director of Andrx Corporation, which specializes in proprietary drug delivery technologies, and eXegenics, Inc., a biopharmaceutical drug development company both Nasdaq listed public companies, and Bio Sample Inc., a privately held corporation. Mr. Gerson holds an honorary Doctor of Humane Letters from the Albany College of Pharmacy and Long Island University. Mr. Gerson served as a Trustee of Long Island University, Chairman of The Council of Overseers - Arnold and Marie Schwartz College of Pharmacy, member of the Board of Trustees of the Albany College of Pharmacy and, from 1967 through 1974, was a lecturer on sales management and pharmaceutical marketing at the Columbia College of Pharmacy. He is currently Vice President of the Lifetime Learning Society of Florida Atlantic University. Mr. Gerson also has served as a Member of the Board of Governors, American Association of Advertising Agencies, a Director and Chairman of Business Publications Audit, a Director of the Connecticut Grand Opera, and a Director of the Stamford Chamber Orchestra. Mr. Gerson previously served as a director of the foundation of Pharmacists and Corporate Americans for AIDS Education, the Pharmaceutical Advertising Council, the Nutrition Research Foundation and as a Trustee of the Chemotherapy Foundation. He was also on the boards of Penn Dixie Industries and Continental Steel Corporation.

During the fiscal year ended July 31, 2001, there were four formal meetings of the Board of Directors, several actions by unanimous consent and several informal meetings. The Board of Directors has an Audit Committee and Stock Option Committee. The Audit Committee had two formal meetings and the Stock Option Committee had one formal meetings in fiscal 2001.

The Audit Committee is authorized to review proposals of the Company's auditors regarding annual audits, recommend the engagement or discharge of the auditors, review recommendations of such auditors concerning accounting

principles and the adequacy of internal controls and accounting procedures and practices, to review the scope of the annual audit, to approve or disapprove each professional service or type of service other than standard auditing services to be provided by the auditors, and to review and discuss the audited financial statements with the auditors. Its members are Messrs. Sias, Delucca and Gerson.

The Stock Option Committee has the plenary authority in its discretion to determine the purchase price of the Common Stock issuable upon the exercise of each option, to determine the employees to whom, and the time or times at which, options shall be granted and the number of shares to be issuable upon the exercise of each option, to interpret the plans, to prescribe, amend and rescind rules and regulations relating to them, to determine the term and provisions of the respective option agreements and to make all other determinations deemed necessary or advisable for the administration of the plans. Its members are Messrs. Sias and Delucca.

The Company does not have a formal Executive Committee or Nominating Committee of the Board of Directors.

2.4

(b) Executive Officers - The following table sets forth the names and positions of all of the current executive officers of the Company:

<TABLE>

Name

Position

<S>
Elazar Rabbani, Ph.D.
Shahram K. Rabbani
Barry W. Weiner
Dean Engelhardt, Ph.D.
Norman E. Kelker, Ph.D.
Herbert B. Bass
Barbara E. Thalenfeld, Ph.D.
David C. Goldberg
</TABLE>

<C>
Chief Executive Officer, Chairman of the Board of Directors
Chief Operating Officer, Secretary, Treasurer
President
Executive Vice President
Senior Vice President
Vice President of Finance
Vice President, Corporate Development
Vice President, Business Development

DR. ELAZAR RABBANI (age 57) has served as President and a Director of the Company since its organization in 1976. Dr. Rabbani received his B.A. degree from New York University in Chemistry and his Ph.D. degree in Biochemistry from Columbia University. He is a member of the American Society for Microbiology.

SHAHRAM K. RABBANI (age 49) has served as Chief Operating Officer, Secretary, and Treasurer of the Company since November 1996, as Executive Vice President from September 1981 to November 1996 and as Vice President, Treasurer and a Director of the Company since its organization. Mr. Rabbani received a B.A. degree in chemistry from Adelphi University.

BARRY W. WEINER (age 51) has served as President of the Company since November 1996 and as a Director of the Company since its organization. Mr. Weiner has served as an Executive Vice President of the Company from September 1981 to November 1996, as a Vice President of the Company from the Company's organization to November 1996 and as Secretary of the Company from March 1980 to November 1996. He was employed by Colgate-Palmolive Company, New York, New York from August 1974 until March 1980, when he joined the Company on a full-time basis. Mr. Weiner received his B.S. degree in Economics from New York University and M.B.A. from Boston University. Mr. Weiner is a Director of the New York State Biotechnology Association.

DR. DEAN ENGELHARDT (age 61) has served as Executive Vice President since July 13, 2000, as Senior Vice President since January 1989, and as Vice President since September 1981 Prior to joining the Company he was Associate Professor of Microbiology at Columbia University College of Physicians and Surgeons. He obtained his Ph.D. from Rockefeller University.

DR. NORMAN E. KELKER (age 62) has been a Vice President of the Company since September 1981. Effective January 1, 1989, he was promoted to Senior Vice President. From 1975 until he joined the Company, Dr. Kelker was an Associate Professor in the Department of Microbiology of the New York University School of Medicine. He holds a Ph.D. from Michigan State University.

HERBERT B. BASS (age 53) is Vice President of Finance of the Company. Prior to his promotion, Mr. Bass was the Corporate Controller of Enzo. Before joining Enzo in 1986, Mr. Bass held various positions at Danziger & Friedman, Certified Public Accountants, from 1979 to 1986, the most recent of which was audit manager. For the preceding seven years he held various positions at Berenson & Berenson, C.P.A.'s. Mr. Bass holds a Bachelor degree in Business Administration from Baruch College.

DR. BARBARA E. THALENFELD (age 61) is Vice President of Corporate Development and has been with Enzo since 1982. Prior to joining the Company she held an NIH research fellowship at Columbia University. She received a Ph.D. from Hebrew University-Hadassah Medical Center and an M.S. from Yale University.

DAVID C. GOLDBERG (age 44) is Vice President of Business Development. Prior to joining Enzo in 1985, he was employed at DuPont NEN Products. He received an M.S. from Rutgers University and an MBA from New York University.

Dr. Elazar Rabbani and Shahram K. Rabbani are brothers and Barry W. Weiner is their brother-in-law.

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#### Item 11. Executive Compensation

The information required under this item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission on or before November 28, 2001 and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The information required under this item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission on or before November 28, 2001 and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions

The information required under this item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission on or before November 28, 2001 and is incorporated herein by reference.

PART IV

- Item 14. Exhibits, Financial Statement Schedules, and Reports on Form 8-K
- (a) (1) Consolidated Financial Statements
  Consolidated Balance Sheets July 31, 2001 and 2000
  Consolidated Statements of OperationsYears ended July 31, 2001, 2000 and 1999
  Consolidated Statements of Stockholders' EquityYears ended July 31, 2001, 2000 and 1999
  Consolidated Statements of Cash FlowsYears ended July 31, 2001, 2000 and 1999
  Notes to Consolidated Financial Statements.
  - (2) Financial Statement Schedule Schedule II - Valuation and Qualifying Accounts

All other schedules have been omitted because the required information is included in the consolidated financial statements or the notes thereto or because they are not required.

(3) Exhibits

The following documents are filed as Exhibits to this Annual Report on Form 10-K:

Exhibit No	Description
	Certificate of Incorporation, as amended March 17, 980. (1)
, ,	Tune 16, 1981 Certificate of Amendment of the Certificate of Incorporation. (2)
- ( - /	Certificate of Amendment to the Certificate of Encorporation. (11)
3 (d) E	Bylaws. (1)
10(a) 1	983 Incentive Stock Option Plan. (4)
10 (b) 1	993 Incentive Stock Option Plan. (5)
10(c) E	Employment Agreement with Elazar Rabbani. (5)

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10(e)	Employment Agreement with Barry Weiner. (5)
10(f)	1994 Stock Option Plan (6).
10 (g)	Agreement with Corange International Limited (Boehringer Mannheim) effective April 1994. (19) (7)
10(h)	Agreement with Amersham International effective February 1995. (7)
10(i)	Agreement with Dako A/S effective May 1995. (7)
10(j)	Agreement with Baxter Healthcare Corporation (VWR Scientific Products) effective September 1995. (7)
10(k)	Agreement with Yale University and amendments thereto $(7)$
10(1)	Agreement with The Research Foundation of the State of New York effective May 1987. (7)
10 (m)	1999 Stock Option Plan filed. (8)
10 (n)	Amendment to Elazar Rabbani's employment agreement. (9)
10(0)	Amendment to Shahram Rabbani's employment agreement. (9)
10 (p)	Amendment to Barry Weiner's employment agreement. (9)
10 (q)	Lease Addendum (9)
11	Computation of per-share earnings filed herewith.
21	Subsidiaries of the registrant: Enzo Clinical Labs, Inc., a New York corporation. Enzo Diagnostics, Inc., a New York corporation. Enzo Therapeutics, Inc., a New York corporation.
2.3	Consent of Independent Auditors filed herewith.

- (1) The exhibits were filed as exhibits to the Company's Registration Statement on Form S-18 (File No. 2-67359) and are incorporated herein by reference.
- (2) This exhibit was filed as an exhibit to the Company's Form 10-K for the year ended July 31, 1981 and is incorporated herein by reference.
- (3) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 1989 and is incorporated herein by reference.
- (4) This exhibit was filed with the Company's definitive proxy statement dated February 4, 1983 and is incorporated herein by reference.
- (5) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 1994 and is incorporated herein by reference.
- (6) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 1995 and is incorporated herein by reference.
- (7) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 1996 or previously filed amendment thereto and is incorporated herein by reference.

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- (8) This exhibit was filed with the Company's Registration Statement on Form S-8 (333-87153) and is incorporated herein by references.
- (9) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 2000 and is incorporated herein by reference.
- (a) These exhibits are subject to a confidential treatment request pursuant to Securities Exchange Act Rule 24b-2

- (b) The Company's Current Reports on Form 8-K filed during the quarter ended July 31, 2001 -- none
- (c) See Item 14(a)(3), above.

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#### SIGNATURES

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

ENZO BIOCHEM, INC.

Date: October 29, 2001 By: /s/ Elazar Rabbani Ph.D. \_\_\_\_\_

Chairman of the Board

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

By: Elazar Rabbani Ph.D. October 29, 2001

Elazar Rabbani

Chairman of Board of Directors (Principal Executive Officer)

By: Shahram K. Rabbani October 29, 2001

Shahram K. Rabbani, Chief Operating Officer, Secretary and Director (Principal Financial and

Accounting Officer)

October 29, 2001 By: Barry W. Weiner

Barry W. Weiner, President and Director

\_\_\_\_\_

John B. Sias, Director

By: John J. Delucca October 29, 2001

\_\_\_\_\_ John J. Delucca, Director

October 29, 2001 Bv: Irwin Gerson

Irwin Gerson, Director

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FORM 10-K, ITEM 14(a) (1) and (2)

ENZO BIOCHEM, INC.

LIST OF CONSOLIDATED FINANCIAL STATEMENTS AND FINANCIAL STATEMENT SCHEDULE

The following consolidated financial statements and financial statement schedule of Enzo Biochem, Inc. are included in Item 14(a):

Report of Independent Auditors	F-2
Consolidated Balance Sheets July 31, 2001 and 2000	F-3
Consolidated Statements of Operations Years ended July 31, 2001, 2000 and 1999	F-4
Consolidated Statements of Stockholders' Equity Years ended July 31, 2001, 2000 and 1999	F-5
Consolidated Statements of Cash Flows Years ended July 31, 2001, 2000 and 1999	F-6
Notes to Consolidated Financial Statements	F-8
Schedule II - Valuation and Qualifying AccountsYears ended July 31, 2001, 2000 and 1999	F-19

All other schedules for which prov5ision is made in the applicable accounting regulation of the Securities and Exchange Commission are not required under the related instructions or are inapplicable, and therefore have been omitted.

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# Report of Independent Auditors

Board of Directors and Stockholders Enzo Biochem, Inc.

We have audited the accompanying consolidated balance sheets of Enzo Biochem, Inc. (the "Company") as of July 31, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended July 31, 2001. Our audits also included the financial statement schedule listed in the Index at Item 14(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule 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 consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Enzo Biochem, Inc. at July 31, 2001 and 2000 and the consolidated results of its operations and its cash flows for each of the three years in the period ended July 31, 2001, in conformity with accounting principles generally accepted in the United States. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ Ernst & Young LLP

Melville, New York October 4, 2001

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ENZO BIOCHEM, INC. CONSOLIDATED BALANCE SHEETS July 31, 2001 and 2000

<TABLE> <CAPTION>

ASSETS

 <\$>	<c></c>	<c></c>
Current assets:  Cash and cash equivalents 51,027,000	\$ 58,671,000	\$
Accounts receivable, less allowance for doubtful accounts of \$6,526,000 in 2001 and \$5,890,000 in 2000	24,559,000	
20,211,200 Inventories 1,798,900	2,019,800	
Deferred taxes 3,609,700	1,708,500	
Prepaid taxes	350,200	
Other 1,071,100	1,132,300	
Total current assets 77,717,900	88,440,800	
Property and equipment, at cost less accumulated depreciation and amortization	2,670,600	
2,800,600  Cost in excess of fair value of net tangible assets acquired, less accumulated amortization of \$4,980,600 in 2001 and \$4,610,100 in 2000 8,193,200	7,822,700	
Deferred patent costs, less accumulated amortization of \$5,553,400 in 2001 and \$4,802,800 in 2000 4,047,900	3,865,200	
Other 126,800	131,800	
	\$102,931,100	\$
92,886,400	=========	·
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities: Trade accounts payable	\$ 2,039,500	\$
1,470,500 Income taxes payable		
375,700 Accrued legal fees	251,000	
664,600 Accrued payroll	322,300	
301,400 Other accrued expenses	734,400	
812,100		
Total current liabilities 3,624,300	3,347,200	
Deferred taxes 1,290,100	1,391,900	
Deferred liability 795,700	675 <b>,</b> 000	
Commitments and contingencies (Notes 5, 6, and 9)		
Stockholders' equity: Preferred Stock, \$.01 par value; authorized 25,000,000 shares; no shares issued or outstanding		
Common Stock, \$.01 par value; authorized 75,000,000 shares; shares issued and outstanding: 27,080,100 in 2001 and 25,583,700 in 2000	270,700	
255,800 Additional paid-in capital	133,136,100	
97,349,600 Accumulated deficit (10,429,100)	(35,889,800)	
Total stockholders' equity 87,176,300	97,517,000	
	\$102,931,100	\$
92,886,400		
======================================		

</TABLE>

<TABLE>

F-3

# ENZO BIOCHEM, INC. CONSOLIDATED STATEMENTS OF OPERATIONS Years ended July 31, 2001, 2000 and 1999

<table> <caption></caption></table>		
1999	2001	2000
<\$>	<c></c>	<c></c>
<c></c>		
Revenues: Research product revenues	\$ 23,195,800	\$ 18,553,500
\$ 16,278,600 Clinical laboratory services	35 210 100	31,475,100
28,040,800		
50,028,600 44,319,400	58,405,900	
Costs and expenses:		
Cost of research product revenues 7,883,700	6,925,200	7,521,700
Cost of clinical laboratory services 8,285,000	10,498,400	8,505,700
Research and development expense	6,080,800	5,430,900
4,427,000 Selling expense	3,856,300	
3,240,800 2,782,800 Provision for uncollectable accounts receivable	11,999,200	11,294,000
9,960,800  General and administrative expense	9.817.800	8 <b>,</b> 951 <b>,</b> 700
7,577,400		
	49,177,700	
44,944,800 40,916,700		
Income before interest income, and (provision) benefit for taxes on income 3,402,700	9,228,200	5,083,800
Interest income	3,003,000	
2,584,600 1,983,900		
<pre>Income before (provision) benefit for taxes on income 5,386,600</pre>	12,231,200	7,668,400
(Provision) benefit for taxes on income (1,043,700) 1,128,400	(5,418,400)	
Net income 6,624,700 \$ 6,515,000	\$ 6,812,800	\$
	========	
Not income non common change		
Net income per common share: Basic	\$ .25	\$
.25 \$ .25	========	
======== ========= Diluted	\$ .24	\$
.23 \$ .24		
Denominator for per share calculation:	06.000.000	
Basic 26,597.000 26,180,000	26,999,000	
	=========	
Diluted 28,335.000 26,751,000	28,126,000	
20,333.000 20,731,000		

\_\_\_\_\_

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Increase in common stock and paid-in capital due to exercise of stock options and warrants

</TABLE>

See accompanying notes.

# F-4 ENZO BIOCHEM, INC. CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY Years ended July 31, 2001, 2000 and 1999

<table> <caption></caption></table>				
Total	Common	Common	Additional	
Accumulated Stockholders'	Stock	Stock	Paid-in	
	Shares	Amount	Capital	
Deficit Equity				
<\$> <c></c>	<c></c>	<c></c>	<c></c>	<c></c>
Balance at July 31, 1998 \$(23,568,800) \$ 68,783,000	24,905,300	\$ 249,100	\$ 92,102,700	
Net income for the year ended July 31, 1999 6,515,000				6,515,000
Increase in common stock and paid-in capital due to exercise of stock options and warrants 162,500	34,200	300	162,200	
Issuance of stock for employee 401(k) plan 187,500	18,200	200	187,300	
Balance at July 31, 1999 (17,053,800) 75,648,000	24,957,700	249,600	92,452,200	
Net income for the year ended July 31, 2000 6,624,700				6,624,700
Increase in common stock and paid-in capital due to exercise of stock options and warrants 4,126,200	621,600	6,100	4,120,100	
Issuance of stock for employee 401(k) plan 201,600	4,400	100	201,500	
Increase in paid-in capital due to issuance of warrants as Compensation for services performed 100,000			100,000	
Tax benefit from stock options exercised 418,400			418,400	
<pre>Increase in paid-in capital due to stock issued     for services performed 57,400</pre>			,	
Balance at July 31, 2000 (10,429,100) 87,176,300	25,583,700	255 <b>,</b> 800	97,349,600	
Net income for the year ended July 31, 2001 6,812,800				6,812,800
5% stock dividend (fair value on date declared)	1,284,500	12,800	32,260,700	(32,273,500)

202,200

2,000 1,231,900

Issuance of stock for employee 401(k) plan 230,800	9,700	100	230,700	
Tax benefit from stock options exercised 1,780,000			1,780,000	
Increase in paid-in capital due to stock issued for services performed 283,200			283,200	
Balance at July 31, 2001 \$(35,889,800) \$ 97,517,000	27,080,100	\$ 270,700	\$133,136,100	
	========	=======	========	========

</TABLE>

See accompanying notes.

# F-5 ENZO BIOCHEM, INC. CONSOLIDATED STATEMENTS OF CASH FLOWS Years ended July 31, 2001, 2000 and 1999

<table></table>		
<caption></caption>	2001	2000
1999		
<\$>	<c></c>	<c></c>
<pre><c> Cash flows from operating activities:</c></pre>		
Net income	\$ 6,812,800	\$ 6,624,700
\$ 6,515,000	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	, , , , ,
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization of property and equipment 883,300	1,131,200	832,100
Amortization of costs in excess of fair value of net		
tangible assets acquired	370,500	370,500
370,500 Amortization of deferred patent costs	750 <b>,</b> 600	722,400
677,800	730,000	722,400
Provision for uncollectible accounts receivable 9,960,800	11,999,200	11,294,000
Deferred income tax provision (benefit)	2,003,000	255,400
(1,550,000)		400.000
Issuance of warrants as compensation for services performed		100,000
Issuance of stock as compensation for services performed	283,200	57,400
Accretion of interest on note receivable		
(58, 400)		
Issuance of stock for employee 401(k) plan	230,800	201,600
187,500  Tax benefit from stock options exercised	1,780,000	418,400
	1,700,000	410,400
Deferred liabilities	(120,700)	
(94,800) (64,500)		
Changes in operating assets and liabilities:		
Note receivable - litigation settlement		
5,000,000		
Accounts receivable before provision for uncollectible amounts	(16,347,000)	(16,497,500)
(10,772,100) Inventories	(220,900)	
(372,200) (33,700)	(220, 300)	
Prepaid taxes	(350,200)	
Other current assets (2,800)	(61,200)	160,600
Trade accounts payable and accrued expenses	504,000	246,200
(199, 300)	,	,
Income taxes payable	(375,700)	75 <b>,</b> 700
136,000 Accrued legal fees	(413,600)	599,600
noctuca togat 1663	(413,000)	333,000

15,000 Accrued (62,600)	1 payroll 4,200	20,900	
Total a	djustments 4,554,300	1,184,100	
11,069,300 			

 Net cash provided by operating activities | 7,996,900 | 4,931,500 |(Continued on following page.)

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ENZO BIOCHEM, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years ended July 31, 2001, 2000, and 1999

<table></table>		
<caption></caption>		
4000	2001	2000
1999		
<\$>	<c></c>	<c></c>
<0>		
Cash flows from investing activities:		
Capital expenditures	\$ (1,013,900)	\$ (790,500)
\$ (1,137,600)		
Patent costs deferred	(567,900)	
(458,400) (431,000) Security deposits	(5,000)	200
21,200	(3,000)	200
21/200		
Net cash used by investing activities	(1,586,800)	(1,248,700)
(1,547,400)		
Cash flows from financing activities:		
Payments of obligations under capital leases		
(8,900)		
Proceeds from the exercise of stock options and warrants	1,233,900	4,126,200
162,500		
Net cash provided by financing activities	1 233 900	4,126,200
153,600	1,233,300	1,120,200
Net increase in cash and cash equivalents	7,644,000	7,809,000
9,675,500		
Cash and cash equivalents at the beginning of the year	51.027.000	43,218,000
33,542,500	,,	,,
	A 50 651 000	A 51 005 000
Cash and cash equivalents at the end of the year	\$ 58,671,000	\$ 51,027,000
\$ 43,218,000		
========		

See accompanying notes.

</TABLE>

Note 1 - Business and summary of significant accounting policies

Business

Enzo Biochem, Inc. (the "Company") is engaged in research, development, manufacturing and marketing of diagnostic and research products based on genetic engineering, biotechnology and molecular biology. These products are designed for the diagnosis of and/or screening for infectious diseases, cancers, genetic defects and other medically pertinent diagnostic information. The Company is conducting research and development activities in the development of therapeutic products based on the Company's technology platform of genetic modulation and immune modulation. The Company also operates a clinical reference laboratory that offers and provides diagnostic medical testing services to the health care community.

Summary of significant accounting policies

Principles of consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany transactions and balances have been eliminated.

Cash and cash equivalents

The Company considers all highly liquid debt instruments purchased with maturities of three months or less to be cash equivalents.

Cash equivalents consist of short-term debt securities of domestic companies that the Company intends to hold to maturity that range from August 2001 to October 2001. The market values of these securities, as determined by quoted sources, aggregated \$57,954,300 and \$49,789,900 at July 31, 2001 and 2000, respectively, and approximated cost at the respective dates.

Concentration of credit risk

Approximately 82% at July 31, 2001 and 2000, of the Company's net accounts receivable relates to its clinical reference laboratory business which operates in the New York Metropolitan area. The Company believes that the concentration of credit risk with respect to accounts receivable is limited due to the diversity of the Company's client base. However, the Company provides services to certain patients covered by various third-party payors, including the Federal Medicare program. Revenue, net of contractual allowances, from direct billings under the Federal Medicare program during the year ended July 31, 2001 was approximately 15% of the Company's total revenue. For the years ended July 31, 2000 and 1999 there were no payors with revenue, net of contractual allowances from direct billings, accounting for more than 10% of the Company's total revenues.

No individual distributor accounted for more than 10% of the Company's research product revenue during fiscal 2001. Research product revenue from one major distributor represented approximately 16% and 22% of the consolidated revenues in fiscal 2000 and 1999, respectively, under a non-exclusive distribution and supply agreement. At July 31, 2000, 5% of the Company's net accounts receivable relate to amounts due from the one major distributor.

Inventories

Inventories are stated at the lower of cost (first-in, first-out method) or  $\max$ 

Property and equipment

Property and equipment is stated at cost, and depreciated on the straight-line and accelerated methods over the estimated useful lives of the assets. Leasehold improvements are amortized over the term of the related leases or estimated useful lives of the assets, whichever is shorter.

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ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2001, 2000 and 1999

Note 1 - Business and summary of significant accounting policies (Cont'd)

Amortization of intangible assets

The cost in excess of fair value of net tangible assets acquired is being amortized on the straight-line method over periods of fifteen to forty years.

Patent costs

The Company has filed applications for United States and foreign patents covering certain aspects of its technology. The costs incurred in filing such applications have been deferred and are amortized over the estimated useful lives of the patents beginning upon issue. Costs related to unsuccessful patent applications are expensed.

#### Revenue Recognition

Revenues from services from the clinical reference laboratory are recognized when services are provided. The Company's revenue is based on amounts billed or billable for services rendered, net of contractual adjustments and other arrangements made with third-party payors to provide services at less than established billing rates. Revenues from research product sales are recognized when the products are shipped.

#### Reimbursement Contingencies

Laws and regulations governing Medicare are complex and subject to interpretation for which action for noncompliance includes fines, penalties and exclusion from the Medicare programs. The Company believes that it is in compliance with all applicable laws and regulations and is not aware of any pending or threatened investigations involving allegations of potential wrongdoing.

# Shipping and Handling Costs

Research product revenue shipping and handling costs included in selling expense amounted to approximately \$279,000, \$179,000 and \$141,000 for fiscal years ended July 31, 2001, 2000 and 1999, respectively.

#### Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amount of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and amounts of income and expenses during the reporting period. Actual results could differ from those estimates.

### Income Taxes

The Company accounts for income taxes under the liability method of accounting for income taxes. Under the liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. The liability method requires that any tax benefits recognized for net operating loss carryforwards and other items be reduced by a valuation allowance where it is more likely than not that the benefits may not be realized. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Under the liability method, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

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ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2001, 2000 and 1999

Note 1 - Business and summary of significant accounting policies (Cont'd)

# Impairment of Long-Lived Assets

The Company evaluates the requirement to recognize impairment losses on long-lived assets used in operations when indicators of impairment are present and the undiscounted cash flows estimated to be generated by those assets are less than the assets' carrying amount. Company management believes that no impairment to its long-lived assets has occurred.

# Reclassifications

Certain prior year balances have been reclassified to conform with the 2001 presentation.

# Recently Issued Accounting Pronouncements

In December 1999, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin No. 101 "Revenue Recognition" ("SAB 101"), which provides guidance on the recognition, presentation and disclosure of revenue in financial

statements filed with the SEC. SAB 101 outlines the basic criteria that must be met to recognize revenue and provides guidance for disclosures related to revenue recognition policies. The Company implemented SAB 101 in the fourth quarter of fiscal 2001, and such implementation did not have an effect on the timing of when the Company recognizes revenue.

In April 2001, the Financial Accounting Standards Board's Emerging Issues Task Force (EITF or Task Force) reached a consensus on Issue 00-25, "Vendor Statement Characterization of Consideration paid by vendors to retailers". The consensus addresses whether consideration paid by vendors to retailers should be classified as a reduction of sales or as a cost or expense. This consensus is effective for fiscal quarters beginning after December 15, 2001 (the Company's April 2002 quarter). The Company has certain non-exclusive distribution agreements which provide for consideration to be paid to the distributors for the manufacture of certain products. Such amounts are included in cost of research product revenues. The Company is currently reviewing the consensus to determine the impact, if any, that the consensus may have on the way the Company reports certain non-exclusive distribution agreement revenues and contract manufacturing costs.

In June 2001, the Financial Accounting Standards Board issued SFAS No. 141, Business Combinations and No. 142, Goodwill and Other Intangible Assets. Statement 141 requires business combinations initiated after June 30, 2001 to be accounted for using the purchase method of accounting, and broadens the criteria for recording intangible assets separate from goodwill. SFAS No. 142 requires the discontinuance of amortization of goodwill and intangible assets with indefinite useful lives, subject to an annual review for impairment. Other intangible assets will continue to be amortized over their estimated useful lives. The provisions of the statement will be adopted by the Company on August 1, 2002. Although the Company is in the process of assessing the impact of adopting Statement No. 142, based upon its current level of goodwill and qualifying intangible assets, management expects the adoption to reduce its fiscal 2003 annualized amortization expense by approximately \$370,000.

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# ENZO BIOCHEM, INC. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS July 31, 2001, 2000 and 1999

Note 1 - Business and summary of significant accounting policies (Cont'd)

# Stock Dividend

The Company declared a 5% stock dividend on January 16, 2001 payable March 20, 2001 to shareholders of record as of February 27, 2001. The shares and per share data have been adjusted to retroactively reflect this stock dividend. The Company recorded a charge to accumulated deficit and a credit to common stock and additional paid-in capital in the amount of approximately \$32,274,000, which reflects the fair value of the dividend on the date of declaration.

Net income per share

The Company reported basic and diluted earnings per share in accordance with SFAS No. 128, "Earnings Per Share" ("SFAS No. 128"). Basic earnings per share excludes any dilutive effects of options and warrants. Diluted earnings includes the dilutive effects of common stock equivalents such as stock options and warrents.

The following table sets forth the computation of basic and diluted net income per share pursuant to SFAS No. 128.

<TABLE>

Denominator:
Denominator for basic net income per common share-weighted-average

Effect of dilutive employee and director stock options and

	warrants	1.127.000	1,738,000	
571,000		1,121,000	1,700,000	
,				
	Denominator for diluted net income			
	per share-adjusted			
	weighted-average shares	28,126,000	28,335,000	
26,751,	000			
		========	=========	
======	=====			
	Basic net income per share	\$ .25	\$ .25	\$
.25				
		========	========	
	====			
		<u> </u>	<b>A</b> 0.2	
0.4	Diluted net income per share	\$ .24	\$ .23	Ş
.24				
		=========	========	
======	====			

</TABLE>

(a) In fiscal 1999, potentially dilutive employee and director stock options and warrants that have been excluded from this amount because they are anti-dilutive amounted to 724,000.

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ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2001, 2000 and 1999

Note 2 - Supplemental disclosure for statement of cash flows

In the years ended July 31, 2001, 2000 and 1999, the Company paid cash for income taxes of approximately \$2,267,000,\$294,000 and \$286,000 respectively.

Note 3 - Inventories

At July 31, 2001 and 2000 inventories consist of:

2001	2000		
85 <b>,</b> 700	\$ 94,800		
1,035,300	1,040,000		
898,800	664,100		
2,019,800	\$ 1,798,900		
	85,700 1,035,300 898,800		

Note 4 - Property and equipment

At July 31, 2001 and 2000 property and equipment consist of:

	2001	2000
Laboratory machinery and equipment Leasehold improvements Office furniture and equipment	\$ 1,471,200 2,223,400 4,152,300	\$ 2,551,600 2,470,800 5,107,600
Accumulated depreciation and amortization	7,846,900 5,176,300	10,130,000 7,329,400
	\$ 2,670,600	\$ 2,800,600
	=========	=========

# Note 5 - Lease obligations

Enzo Clinical Labs, Inc. ("Enzo Clinical Labs"), a wholly-owned subsidiary of the Company, leases its office and laboratory space under several leases that expire between December 31, 2001 and November 30, 2004. Certain officers of the Company own the building that Enzo Clinical Labs uses as its main facility. In addition to the minimum annual rentals of space, this lease is subject to an escalation clause. Rent expense under this lease approximated \$1,055,000, \$1,017,000 and \$986,000 in fiscal 2001, 2000 and 1999, respectively.

The Company has various other operating leases for office and laboratory space,

which expire through fiscal 2006.

Total consolidated rent expense incurred by the Company during fiscal 2001, 2000 and 1999 was approximately \$1,631,000, \$1,547,000 and \$1,527,000 respectively. Minimum annual rentals under operating lease commitments for fiscal years ending July 31 are as follows:

2002	1,414,000
2003	1,395,000
2004	1,155,000
2005	398,000
2006	37,000
	4,399,000
	========

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ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2001, 2000 and 1999

Note 6 - Litigation

Patent Infringement

In 1993, the Company filed suit in U.S. district court against Calgene, Inc., alleging that Calgene's "Flavr Savr" tomato infringed several of the Company's patents concerning antisense technology. After a trial, the district court ruled against the Company, ruling that claims of these patents were invalid and not infringed. In September 1999, the U.S. Court of Appeals for the Federal Circuit affirmed the decision of the district court. On August 10, 2001, the case was dismissed pursuant to stipulation of the parties, with each party to bear its own costs and attorneys' fees. No significant adverse monetary impact to the Company occurred.

In June 1999, the Company filed suit in the United States District Court for the Southern District of New York against Gen-Probe Incorporated, Chugai Pharma U.S.A., Inc., Chugai Pharmaceutical Co., Ltd., bioMerieux, Inc., bioMerieux SA, and Becton Dickinson and Company, charging them with infringing the Company's U.S. Patent 4,900,659, which concerns probes for the detection of the bacteria that causes gonorrhea. On January 26, 2001, the court granted the defendants' motion for summary judgment that the Company's patent is invalid. The grant of summary judgment is being appealed to the Court of Appeals for the Federal Circuit. The appeal proceedings are at an early stage. There can be no assurance that the Company will be successful in these proceedings. However, even if the Company is not successful, management does not believe that there will be a significant adverse monetary impact.

Note 7 - Income taxes

The tax (provision) benefit is calculated under the provisions of SFAS No. 109.

<TABLE>

<caption></caption>	2001	2000	
1999			
<\$>	<c></c>	<c></c>	<c></c>
Current			
Federal	\$ (2,783,400)	\$ (616,300)	\$
(108,000)			
State and local	(632 <b>,</b> 000)	(172,000)	
(313,600)			
Deferred	(2,003,000)	(255,400)	
1,550,000	( , , ,	(,,	
(Provision) benefit for income taxes	\$ (5,418,400)	\$ (1,043,700)	\$
1,128,400			
	========	========	

</TABLE>

Current Federal income taxes provided for in fiscal 2001 are based on regular tax, and in fiscal 2000 and 1999 are based on the alternative minimum tax method.

Deferred income taxes arise from temporary differences between the tax basis of assets and liabilities and their reported amounts in the financial statements.

The components of deferred income taxes are as follows:

<TABLE> <CAPTION>

</TABLE>

2000	2001	
2000		
<\$>	<c></c>	<c></c>
Deferred tax assets:		
Provision for uncollectable accounts		
Receivable	\$ 1,612,900	\$
914,500		
Net operating loss carry forwards		
2,023,400	105.000	
Alternative minimum tax credits	105,800	
742,500 Other	202 200	
332,800	293,200	
332,000		
	2,011,900	
4,013,200	2,011,300	
Deferred tax liability:		
Deferred patent costs	(1,695,300)	
(1,693,600)		
Net deferred tax asset	\$ 316,600	\$
2,319,600		

2001

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# ENZO BIOCHEM, INC. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS July 31, 2001, 2000 and 1999

# Note 7 - Income taxes (Cont'd)

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax asset will be realized. The ultimate realization of the deferred tax asset is dependent upon the generation of future taxable income. Management considers scheduled reversals of deferred tax liabilities, projected future taxable income and tax planning strategies which can be implemented by the Company in making this assessment. The Company had provided a full valuation allowance for the net deferred tax asset at July 31, 1997. In fiscal 2000 and 1999, management reversed a portion of the deferred tax asset valuation allowance as management considered that it was more likely than not that a portion of the deferred tax asset would be realized. The valuation allowance was decreased \$2,570,000 in fiscal 2000 to zero. The valuation allowance decreased \$3,928,000 in fiscal 1999.

The provision (benefit) for income taxes were at rates different from U.S. federal statutory rates for the following reasons:

	2001	2000	1999
Federal statutory rate	34%	34%	34%
Expenses not deductible for income tax return purposes	1%	4%	4 %
State income taxes, net of federal tax deduction and	10	40	40
change in deferred tax asset valuation reserve	9%	9%	
Change in deferred tax asset valuation reserve and benefits recognized from net operating losses		(33%)	(59%)
	44%	14%	(21%)

# Note 8 - Stock options and warrants

The Company follows the disclosure provisions of SFAS No. 123. SFAS No. 123 defines a fair value method of accounting for the issuance of stock options and other equity instruments. Under the fair value method, compensation cost is measured at the grant date based on the fair value of the award and is recognized over the service period, which is usually the vesting period. Pursuant to SFAS No. 123, companies are encouraged, but are not required, to adopt the fair value method of accounting for employee stock-based transactions. Companies are also permitted to continue to account for such transactions under Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to

Employees" ("APB 25"), but are required to disclose in a note to the consolidated financial statements proforma net income and per share amounts as if the Company had applied the new method of accounting. SFAS No. 123 also requires increased disclosures for stock-based compensation arrangements.

The Company has elected to comply with APB 25, in accounting for its stock options because, as discussed below, the alternative fair value accounting provided for under SFAS No. 123, requires use of option valuation models which were not developed for use in valuing employee stock options. Under APB 25, because the exercise price of the Company's employee stock options equals the market price of the underlying stock on the data of grant, no compensation expense is recognized.

The Company has an incentive stock option plan and a restricted stock incentive plan and has issued other options and warrants, as described below.

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# ENZO BIOCHEM, INC. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS July 31, 2001, 2000 and 1999

Note 8 - Stock options and warrants (Cont'd)

Incentive stock option plan

The Company has an incentive stock option plan ("1983 plan") under which the Company may grant options for up to 1,093,956 shares of common stock. No additional options may be granted under the 1983 plan. The exercise price of options granted under such plan is equal to or greater than fair market value of the common stock on the date of grant. The Company has stock option plans ("1993 plan" and "1994 plan") under which the Company may grant options for up to 1,823,260 shares (1993 plan) and for up to 1,154,731 shares (1994 plan) of common stock. No additional options may be granted under the 1993 plan or the 1994 plan. In fiscal 1999, the Company set up a new incentive stock option plan ("1999 plan") under which the Company may grant up to 997,500 shares of common stock. The options granted pursuant to the plans may be either incentive stock options or nonstatutory options. To date, the Company has only granted incentive stock options under these plans.

A summary of the information pursuant to the Company's stock options plans for the years ended July 31, 2001, 2000 and 1999 under SFAS No. 123 is as follows:

<TABLE> <CAPTION>

		2001		2000		1999
- Average		Weighted - Average		Weighted - Average		Weighted
Average	Options	Exercise Price	Options	Exercise Price	Options	Exercise
Price	1		-1		11	
<s></s>	<c></c>	<c></c>	<c></c>	<c></c>	<c></c>	<c></c>
Outstanding at beginning of						
year	2,305,091	\$ 9.60	2,835,986	\$ 8.55	2,277,714	\$
8.71	0.04 0.50			0.4.45	500 585	
Granted 8.01	381,250	14.96	88,200	24.17	633 <b>,</b> 675	
Exercised	(207,865)	5.67	(600,233)	6.70	(27,754)	
5.70	( , , , , , , , , , , , , , , , , , , ,		( ,		( , - ,	
Terminated	(3,930)	14.94	(18,862)	11.36	(47,649)	
12.76						
Outstanding at						
end of year	2,474,546	\$10.74	2,305,091	\$ 9.60	2,835,986	\$
8.55						
	=======		=======		=======	
Exercisable at						
end of year	1,701,398	\$ 9.75	1,632,188	\$ 8.97	1,882,842	\$
8.00						
	=======		=======		=======	

Weighted average fair value of options granted during year \$14.96 \$18.57 \$5.52

</TABLE>

The following table summarizes information for stock options outstanding at July 31, 2001:

<TABLE> <CAPTION>

</TABLE>

Options Outstanding Options Exercisable \_\_\_\_\_ -----\_\_\_\_\_ Weighted-Average Range of Exercise Remaining Weighted-Average Weighted-Average prices Shares Contractual Life Exercise Price Shares Exercise Price \_\_\_\_\_ \_\_\_\_\_ \_\_\_\_\_ ---\_\_\_\_\_ <C> <S> <C> <C> <C> <C> \$1.23 \$1.23 .32 years 289 \$1.23 \$3.70 6,078 .79 years 3.70 6,078 3.70 1,171,926 7.68 \$6.27 - \$9.36 4.49 years 1,032,650 \$9.65 - \$13.49 790,497 6.25 years 11.65 596,249 11.99 459,256 7.03 years \$14.96 - \$16.63 15.04 58,257 16.98 \$23.51 - \$28.27 30,750 9.64 years 25.83 15,750 8.46 years 41.73 7,875 \$41.73 41.73

1,701,398

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2,474,546

ENZO BIOCHEM, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

July 31, 2001, 2000 and 1999

Note 8 - Stock options and Warrants (cont'd)

Incentive stock options generally become exercisable at 25% per year after one year and expire ten years after the date of grant.

Pro-forma information regarding net income and net income per share is required by SFAS No. 123, and has been determined as if the Company had accounted for its stock options under the fair value method of that statement. The fair value for these options was estimated at the date of grant using a Black-Sholes option pricing model with the following assumptions: risk free interest rate ranging from 4.54% to 6.88%; no dividend yield; volatility factor of the expected market price of the Company's common stock of .80, .80 and .68 for grants during fiscal year ended July 31, 2001, 2000 and 1999, respectively and a weighted-average expected life of the options of 7 years at July 31, 2001, 2000 and 1999.

The Black-Sholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company's stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period. The Company's pro forma information is as follows:

	2	001	2	000	1	999
	_		-		-	
Pro forma net income:	\$4,3	98,000	\$4,2	78,000	\$4,4	26,000
Pro forma net income per share:						
Basic	\$	.16	\$	.16	\$	.17
Diluted	\$	.16	\$	.15	\$	.17

The SFAS No. 123 method of accounting has not been applied to options granted

prior to August 1, 1995. As a result, the pro forma compensation cost may not be representative of that to be expected in future years.

Restricted stock incentive plan

The Company has a restricted stock incentive plan whereby the Company may award up to 243,101 shares of its common stock. Under the terms of the plan, any shares issued are restricted in regard to sales and transfers for a period of five years after award. Such restrictions begin to expire at 25% per year after the second year of ownership. As of July 31, 2001, the Company has not awarded any shares of common stock under this plan.

#### Warrants

In November 1991, the Company issued warrants to purchase 312,386 shares of common stock with an exercise price of \$1.64 per share expiring ten years after the date of issue. In fiscal 2000 and 1999, 7,833 and 8,190 of these warrants were exercised, respectively. In fiscal 1996, the Company issued warrants to purchase 94,347 shares of common stock with an exercise price ranging from \$8.63 to \$15.11 per share which expire five years after the date of issue. In fiscal 2000, 44,615 of these warrants were exercised and 25,423 were canceled. As of July 31, 2001 and 2000, there are no warrants outstanding.

\*\*\*\*\*

As of July 31, 2001, the Company has reserved 4,209,894 shares under the arrangements described above.

Note 9 - Commitments

The company has an exclusive licensing agreement to an invention covered by licensed patents. Under this agreement, the Company is required to make certain minimum royalty payments of \$200,000 per year through the life of the patents.

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ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2001, 2000 and 1999

# Note 10 - Employee benefit plan

The Company has a qualified Salary Reduction Profit Sharing Plan (the "Plan") for eligible employees under Section 401(k) of the Internal Revenue Code. The Plan provides for voluntary employee contributions through salary reduction and voluntary employer contributions at the discretion of the Company. For the years ended July 31, 2001, 2000 and 1999, the Company has authorized employer contributions of 50% of the employees' contribution up to 6% of the employees' compensation in Enzo Biochem, Inc. common stock. The 401(k) employer contributions expense was \$230,800, \$201,600 and \$187,500 in fiscal years 2001, 2000, and 1999, respectively.

Note 11 - Quarterly financial data (unaudited)

Unaudited quarterly financial data (in thousands, except per share amounts) for fiscal 2001 and 2000 is summarized as follows:

<TABLE>

	October	Three Months Ended 27 31, 2000 January 31, 2001		April 30, 2001 July		31, 2001		
<s> Revenues</s>	<c></c>	13,859	<c></c>	13,876	<c></c>	15,201	<c></c>	15,470
Gross profit		9,941		9,839		10,899		10,303
Income before (provision) benefit for taxes on income		2,987		2,801		3 <b>,</b> 335		3,108
Net income	\$	1,673	\$	1,565	\$	1,861	\$	1,714
Basic income per common share	\$	0.06	\$	0.06	\$	0.07	\$	0.06
Diluted income per common share	\$	0.05	\$	0.06	\$	0.07	\$	0.06

	October	31, 1999	January 31, 2000 April 30, 2000		July 31, 2000			
<s> Revenues</s>	<c></c>	11,612	<c></c>	11,564	<c></c>	12,579	<c></c>	14,274
Gross profit		7,634		7,937		8,592		9,838
<pre>Income before (provision) benefit for taxes on income</pre>		1,614		1,575		2,033		2,446
Net income	\$	1,517	\$	1,520	\$	2,003	\$	1,585
Basic income per common share	\$	0.05	\$ =====	0.06	\$ =====	0.08	\$	0.06
Diluted income per common share	\$	0.05	\$ =====	0.05	\$	0.07	\$	0.06

</TABLE>

# F-17 ENZO BIOCHEM, INC. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS July 31, 2001, 2000 and 1999

#### Note 12 - Segment Information

he Company has two reportable segments: research and development and clinical reference laboratories. The Company's research and development segment conducts research and development activities as well as selling products derived from these activities. The clinical reference laboratories provide diagnostic services to the health care community. The Company evaluates performance based on income before (provision) benefit for taxes on income. The accounting policies of the reportable segments are the same as those described in the summary of significant accounting policies. Costs excluded from income before (provision) benefit for taxes on income and reported as other consist of corporate general and administrative costs which are not allocable to the two reportable segments. Management of the Company assesses assets on a consolidated basis only and therefore, assets by reportable segment has not been included in the reportable segments below.

The following financial information (in thousands) represents the reportable segments of the Company:

<TABLE> <CAPTION>

<pre><caption> Laboratories</caption></pre>	Research and Development						Clinical Reference			
	Fiscal Year Ended July 31,						Fiscal Year Ended			
July 31,	2	2001	:	2000		1999	:	2001	2	000
1999										
<pre><s> <c> Operating revenues:</c></s></pre>	<c></c>		<c></c>		<c></c>		<c></c>		<c></c>	
Research product revenues	\$	23,196	\$	18,554	\$	16,279				
Clinical laboratory services 31,475 \$ 28,041							\$	35,210	\$	
Cost and expenses:										
Cost of research product revenues		6 <b>,</b> 925		7 <b>,</b> 522		7,884				
Cost of clinical laboratory services 8,285								10,498		8,506
Research and development expense		6,081		5,431		4,427				
Depreciation and amortization 1,188		856		814		744		1,397		1,111
Interest income 23										
<pre>Income before (provision) benefit for     taxes on income 3,720 \$ 2,363</pre>	\$	8,290	\$	3,840	\$	2,661	\$	3,795	\$	

<CAPTION>

Other Consolidated

	Fiscal Year Ended July 31,						Fiscal Year Ended			
July 31,	2.0	01	2	2000	1	.999		2001	2000	
1999										
<pre><s> <c> Operating revenues:</c></s></pre>	<c></c>		<c></c>		<c></c>		<c></c>		<c></c>	
Research product revenues 18,554 \$ 16,279							\$	23,196	\$	
Clinical laboratory services 31,475 28,041								35 <b>,</b> 210		
Cost and expenses:										
Cost of research product revenues 7,884								6,925	7,522	
Cost of clinical laboratory services 8,285								10,498	8,506	
Research and development expense 4,427								6,081	5,431	
Depreciation and amortization 1,925 1,932								2,253		
Interest income 2,585 1,984	\$	3,003	\$	2 <b>,</b> 585	\$	1,961		3,003		
<pre>Income before (provision) benefit for     taxes on income 7,668 \$ 5,387</pre>	\$	146	\$	108	\$	363	\$	12,231	\$	

#### </TABLE>

The Company's reportable segments are determined based on the services they performed and the products they sell, not on the geographic area in which they operate. The Company's clinical reference laboratories segment operates 100% in the United States with all revenue derived from this country. The research and development segment earns revenue both in the United States and foreign countries. The following is a summary of research and development revenues attributable to customers located in the United States and foreign countries:

	2001	2000	1999
United States Foreign Countries	\$ 14,256 8,940	\$ 8,076 10,478	\$ 3,813 12,466
	\$ 23,196	\$ 18,554	\$ 16,279

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ENZO BIOCHEM, INC.
SCHEDULE II - VALUATION
AND QUALIFYING ACCOUNTS
Years ended July 31, 2001, 2000, and 1999

<TABLE> <CAPTION>

		Additions					
Delana	Balance at Beginning	Charged (credited) to costs	Charged to other	(Additions)			
Balance at Description end of period	of period	and expenses	accounts	Deductions			
<\$> <c></c>	<c></c>	<c></c>	<c></c>	<c></c>			

2001 Allowance for doubtful accounts receivable \$ 6,526,000	\$ 5,890,000	\$ 11,999,000	 \$ 11,363,000 (1)
2000 Allowance for doubtful accounts receivable \$ 5,890,000	\$ 6,027,000	\$ 11,294,000	 \$ 11,431,000 (1)
Allowance for deferred tax valuation	\$ 2,570,000	\$ (2,570,000)	 
1999 Allowance for doubtful accounts receivable \$ 6,027,000	\$ 5,148,500	\$ 9,960,800	 \$ 9,082,300 (1)
Allowance for deferred tax valuation \$ 2,570,000			

 \$ 6,498,000 | \$ (1,550,000) | \$ 2,378,000 |(1) Write-off of uncollectable accounts receivable.

Exhibit 23

#### Consent of Independent Auditors

We consent to the incorporation by reference in the Registration Statements (Forms S-3, No. 333-15533, 33-58736, 33-60229, 33-78760, 33-72170, 33-68542) and (Forms S-8 No. 33-45348, 33-75466, 33-88826 and 333-87153) of Enzo Biochem, Inc. and in the related Prospectus of our report dated October 4, 2001, with respect to the consolidated financial statements and schedule of Enzo Biochem, Inc. included in this Annual Report (Form 10-K) for the fiscal year ended July 31, 2001.

/s/ Ernst & Young LLP

Melville, New York October 26, 2001