UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 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, 2004

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 001-09974

ENZO BIOCHEM, INC.

(Exact name of registrant as specified in its charter)

| New York | 13-2866202 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| 60 Executive Boulevard, Farmingdale, New York | 11735 |
| (Address of principal executive offices) | (Zip Code) |

(631) 755-5500

(Registrant's telephone number, including area code)

SECURITIES REGISTERED PURSUANT TO SECTION 12(B) OF THE ACT:

| (Title of Each Class) | (Name of Each Exchange on Which Registered) |
|---|---|
| Common Stock, $.01 par value | the New York Stock Exchange |

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.

[ ]

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act).

Yes [X] No [ ]

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of January 31, 2004, the last business of the registrant's most recently completed second fiscal quarter, was approximately $461,771,000. As of October 7, 2004, the Registrant had 30,864,800 shares of Common Stock outstanding.

Document Incorporated by Reference

Portions of the definitive Proxy Statement to be delivered to shareholders in connection with the Annual Meeting of Shareholders to be held January 20, 2005 are incorporated by reference into Part III.

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. Enzo 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 for modifying gene expression. These technologies are generally applicable to 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 platforms for our planned entry into the clinical diagnostics market. In addition, our work in gene analysis has led to the development of significant therapeutic product candidates, several of which are currently in clinical trials, and several are in preclinical studies. In the course of our research and development activities, we have built what we believe is a significant patent position (comprised of 42 issued U.S. patents, over 190 issued foreign patents and various 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 Life Sciences, Inc., Enzo Therapeutics, Inc., and Enzo Clinical Labs, Inc. These activities are: (1) research and development, manufacturing and marketing of biomedical research products and tools through Enzo Life Sciences 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 15 of the Notes to Consolidated Financial Statements.

The Company's primary sources of revenue have historically been from sales of research products utilized in life science research and from the clinical laboratory services provided to the healthcare community. For the fiscal years ended July 31, 2004 and 2003, respectively, approximately 31% and 44% of the Company's operating revenues were derived from product sales and approximately 69% and 56% were derived from clinical reference laboratory services.

MARKETS

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. The sequence of the human genome, comprising over 30,000 genes, has been identified. 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, microarrays, biochips, microspheres, 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.

We believe this market will grow as a result of:

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



CLINICAL DIAGNOSTICS

The clinical diagnostics market currently has been reported by industry sources to be greater than $20 billion. It is comprised of a broad range of tests such as clinical chemistry, microbiology, immunoassay, blood banking and cancer screening. Many of these tests employ traditional technologies, such as immunoassays and cell culture technologies, for the detection of diseases. Immunoassays are based on the use of antibodies directed against a specific target, or antigen, to detect that antigen in a patient sample. Cell culturing techniques involve the growth, isolation and visual detection of 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 throughput 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 recognized industry sources, the market for molecular diagnostic tools, assays and other products was estimated at $1.9 billion in 2002, and is forecast to grow to at least to $3.1 billion in 2005 as a result of:

- rising number of diagnostic tests being developed from discoveries in genome research;
- advances in formats and other technologies that automate and accelerate gene-based diagnostic testing;
- growing emphasis by the health care industry on early diagnosis and treatment of disease; and
- 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 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.

STRATEGY

Our objective is to be A leading developer and provider of medicines, as well as a leading developer and provider of the tools and diagnostics used to study and detect disease at the molecular level. There can be no assurance 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 to 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 medicines that regulate the 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.

MAXIMIZE OUR RESOURCES BY COLLABORATING WITH OTHERS IN RESEARCH AND COMMERCIALIZATION 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. During the current fiscal year Enzo, through Enzo Therapeutics, entered into two agreements with the University of Connecticut Health Center at Farmington, CT, to license and cooperatively develop novel therapeutics for the stimulation and enhancement of bone formation. The products emanating from this technology could provide therapy for bone disorders, including bone loss, fractures, abnormalities, diseases, and other applications. We also entered into a licensing agreement with Thomas Jefferson University, Philadelphia, PA for certain patents relating to the development of products within our therapeutic program.

Similarly, we seek to fully exploit the commercial value of our technology by partnering with for-profit enterprises in areas in order to act on opportunities that can be accretive to our efforts in accelerating our development program. In line with this strategy, during the past fiscal year Enzo acquired the assets of OraGen Corporation, Moorestown, New Jersey and a privately owned biotechnology company specializing in immune regulation technologies. This acquisition is expected to broaden our capabilities in the area of immunological regulation, particularly as it relates to the treatment of infectious diseases.

APPLY OUR BIOMEDICAL RESEARCH PRODUCTS TO THE CLINICAL DIAGNOSTICS MARKET

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, for the identification of such viruses as human papillomavirus, cytomegalovirus, and Epstein-Barr virus. 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

During fiscal 2004, Enzo Life Sciences continued to implement an aggressive marketing program designed to more directly service its end users, while simultaneously positioning the Company for product line expansion. The program involves continued increases in the direct field sales force, a comprehensive advertising campaign, increased attendance at top industry trade meetings, and publications in leading scientific journals, as well as the development of a new interactive web site. 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. During fiscal 2004, distribution agreements were in effect with, among others, Roche Diagnostic Systems, Amersham PLC, Perkin-Elmer Life Sciences and Affymetrix, Inc. The Company gave notice on October 28, 2003 that it was terminating its agreement with Affymetrix effective November 12, 2003. The Company received notice in the first quarter of 2004 that Amersham PLC was terminating its agreement with the Company. See Item 3. Legal Proceedings.

Research product revenue from Affymetrix represented approximately 0 %, 22% and 23% of the consolidated revenues in fiscal 2004, 2003 and 2002, respectively, under a non-exclusive distribution and supply agreement. Research product revenue from this major distributor accounted for approximately 0 % and 50% of the Company's total research product revenue in fiscal 2004 and 2003, respectively. At July 31, 2004 and 2003, of the Company's net accounts receivable no monies were included from this one major distributor. Research product revenue from Amersham represented approximately 0%, 1% and 1% of the consolidated revenues in fiscal 2004, 2003 and 2002, respectively, under a non-exclusive distribution and supply agreement. At July 31, 2004 and 2003, 0% and 2%, respectively, of the Company's net accounts receivable relate to amounts due from this distributor. Research product revenue from Perkin-Elmer represented approximately 8%, 4% and 6% of the consolidated revenues in fiscal 2004, 2003 and 2002, respectively, under a non-exclusive distribution and supply agreement. At July 31, 2004 and 2003, 5% and 3%, respectively, of the Company's net accounts receivable relate to amounts due from this distributor. Research product revenue from Roche represented approximately 8%, 6% and 5% of the consolidated revenues in fiscal 2004, 2003 and 2002, respectively, under a non-exclusive distribution and supply agreement. At July 31, 2004 and 2003, 0% and 6% respectively of the Company's net accounts receivable relate to amounts due from the this distributor. At July 31, 2004, the Company had written off $1.8 million against the amount due from this distributor. See Item 3. Legal Proceedings.

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.

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:

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

GENE REGULATION 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:

oEFFICIENT 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.

oIMMUNOLOGICALLY "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 Stealth Vectors(TM) 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 ultimately permit us to develop a genetic antisense product that is administered directly to the patient.

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

IMMUNE REGULATION.

oORAL IMMUNE REGULATION. 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 subject'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 active hepatitis caused by HBV and HCV infection, graft versus host disease and inflammatory bowel disease, including Crohn's Disease and ulcerative colitis.

oIMMUNE POTENTIATION. We have developed a new immunomodulator agent, EGS21, a beta-D-glucosylceramide (GC) compound, as a potential therapeutic for treating immune mediated diseases. GC is a glycolipid that has been shown by Enzo scientists and collaborators to modulate specific immune responses by acting on certain immune regulatory cells, and therefore is an important candidate drug in the treatment of various immune mediated diseases, such as Crohn's disease, hepatitis B, hepatitis C, non-alcoholic steatohepatitis (NASH) or fatty liver and HIV. We believe that GC could be utilized either as a

separate therapeutic or as an adjunct or combination treatment with our other platforms for the management of immune mediated disorders.



SMALL MOLECULE DEVELOPMENT

Enzo's newest therapeutic platform involves the development as pharmaceutical agents, of protein factors or associated peptides, as well as small molecules that interfere with protein-protein interactions. It has been shown recently that bone density is dependent on a homeostatic mechanism requiring the interaction of several protein factors. The interference of factor-factor interactions by small molecules can lead to significant increases in bone mass. Enzo is developing these observations to yield new pharmaceutical products for the management of osteoporosis and certain periodontal disorders.

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), HBV, cytomegalovirus (CMV) and chlamydia. We market these kits under the PATHOGENE(R) brand name. These kits target the pathology market.

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, 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 nucleic acid labeling and detections reagent and kits that are designed for the life sciences research market. The products are used by scientists to detect and identify genes in certain specific formats. Our line of kits for the labeling of nucleic acids for the study of specific gene expression are marketed under the BIOARRAY(R) brand name. This product line also includes a new kit for amplifying small quantities of genetic material as well as our new GENEBEAM(TM) system for gene detection and identification.

THERAPEUTIC DEVELOPMENT PROGRAMS

We have a number of therapeutic products 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) progressively disappear from the body. 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 the World Health Organization, there were 35-42 million individuals worldwide living with HIV infection during 2003. There were 5 million new infections and 3 million deaths from HIV during that same year. 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 may 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.

HGTV43(TM) GENE MEDICINE. Enzo's proprietary Stealth Vector(TM) HGTV43(TM) gene construct is the vehicle designed to carry and deliver anti-HIV-1 antisense RNA genes directed against the genes responsible for viral replication. HGTV43 is designed to deliver the antisense genes to targeted blood cells of subjects 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 academic collaborators, demonstrated resistance to HIV-1 in human immune cells into which the antisense genes had been inserted. Our Phase I clinical trial of the HIV-1 gene medicine is in the follow up phase. In this study, white blood cell precursors, known as stem cells, were collected from the subjects. These stem cells were then treated EX VIVO with our Stealth Vector(R) HGTV43(TM) transducing vector and infused into the subject. Results of the trial have shown that all subjects tolerated the procedure and that anti-HIV-1 antisense RNA continued to be expressed in the subjects' circulating white blood cells, the longest running subject at 54 months to date.

- all subjects tolerated the procedure;
- anti HIV-1 antisense RNA was detected in the circulation of subjects, the longest at 54 months to date;
- purified CD4+ cells from all evaluable subjects were tested for the presence of anti HIV-1 antisense RNA and these cells contained the antisense RNA;
- CD34+ cells from the bone marrow of all subjects were tested for the presence of anti HIV-1 antisense RNA between 6 months and 20 months after infusion and these cells contained the antisense RNA.

Based on these Phase I trial results demonstrating long-term survival and functioning of antisense RNA in white blood cells, including 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 to be conducted at New York Presbyterian Hospital-Cornell Medical Center was initiated early this year. Enzo'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) and Cornell's Institutional Review Board ("IRB".) 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.

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 VIRUS (HBV). We are developing HBV therapeutics utilizing our proprietary immune regulation technology.

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, of 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%).



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 a 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 subjects with chronic active hepatitis. Subjects received the medication three times a week for 20 - 30 weeks and were followed for an additional 20 weeks. Results of the trial have shown that:

- the drug was well tolerated in all subjects;
- 46% of subjects showed a decrease in HBV viral load and improvement in liver function tests;
- 33% of subjects showed a decrease in inflammation seen on liver biopsy;

Based on these results, the Company is going forward to bring the manufacturing in house preparing to begin a multi-center Phase II random-label double blind clinical study.

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.

HEPATITIS C VIRUS (HCV).

EHC18 IMMUNE REGULATION PRODUCT. We are using our proprietary 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 Phase I clinical trial conducted by physicians at the Liver Unit of Hadassah University Medical Center in Jerusalem, Israel has met its safety endpoints. Enzo is currently looking to the next level of study.

EGS21 IMMUNE POTENTIATION PRODUCT. EGS21, our immune potentiation product was tested for safety in a Phase I study in healthy human volunteers at the Hadassah-Hebrew University Medical Center. All subjects were followed by complete blood analysis and standard blood chemistries. All laboratory results were within normal limits and no treatment-related adverse events were observed during the treatment period or during the follow-up period. We are currently in the regulatory process at Hadassah Hospital for approval to begin a clinical study to test EGS21 for treatment of HCV infection.

NON-ALCOHOLIC STATOHEPATITIS (NASH)

Enzo is evaluating the use of EGS21 as a potential product for treatment of fatty liver or non alcoholic steatohepatitis (NASH). Fatty liver, often associated with a metabolic syndrome defined by hyperlipidemia, insulin resistance and obesity, can be demonstrated by imaging studies in 25% of the general population. Recent studies have suggested an immunologic basis for NASH. This condition is presently considered to be a risk factor for the development of non-alcoholic steatohepatitis (NASH), one of the top three causes of liver disease in the USA and a form of chronic hepatitis that is increasingly recognized as a predisposing condition for the development of liver cirrhosis. NASH is present in 20% of obese individuals and in 2.5% of the general population. Using experimental animal model systems, we showed that EGS21 had a beneficial effect on NASH and its associated metabolic syndrome in these experimental animals.

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.



There is currently no effective treatment for these diseases. Human subjects 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 not 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 completed a Phase II randomized double-blind clinical trial of ALEQUEL(TM) our innovative immune regulation medicine for treatment of Crohn's Disease. In this study, subjects were evaluated using the Crohn's Disease Activity Index (CDAI), a standard measure of the severity of the disease, with higher scores indicating more severe disease activity. The data showed that of the 58% of the evaluable subjects who had received the drug reached clinical remission (defined as a decrease to a CDAI of 150 or lower in 2 consecutive visits during the study period.) In comparison, 29% of evaluable subjects who had received the placebo reached clinical remission. Enzo plans to expand this study to broaden the diversity of the patient population.

This current trial followed a successful open label Phase I study and was based on successful preclinical results achieved in an animal model system. The preclinical 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. Currently, clinical studies are in development.

CLINICAL LABORATORY SERVICES

We operate a regional clinical reference laboratory that offers full diagnostic services to the greater New York and New Jersey medical community. The Company's clinical laboratory testing is utilized by physicians as an essential element in the delivery of healthcare services. Physicians use laboratory tests to assist in the detection, diagnoses, evaluation, monitoring and treatment of diseases and other medical conditions. Clinical laboratory testing is generally categorized as clinical testing and anatomic pathology testing. Clinical testing is performed on body fluids, such as blood and urine. Anatomic pathology testing is performed on tissues and other samples, such as human cells. Most clinical laboratory tests are considered routine and can be performed by most commercial clinical laboratories. Tests that are not routine and that require more sophisticated equipment and highly skilled personnel are considered esoteric tests.

The Company offers a comprehensive menu of 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.

We operate a clinical reference laboratory on Farmingdale, N.Y. and eighteen satellite patient service centers in the greater New York and New Jersey area. Patient service centers collect the specimens as requested by physicians. The specimens are sent through our in-house logistics department our main laboratory facility in Farmingdale, N.Y. 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 requisition 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 in some

instances, manually. Most routine testing is completed by early the next morning, and test results are reported to the ordering physician. These test results are either delivered by the Company's Logistic department or some physicians have computers and or



local printer capabilities to have reports printed out directly in their offices. Physicians who request that they be called with a result are so notified.

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 89% at July 31, 2004 and 83% at July 31, 2003, 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 clinical laboratory's accounts receivable is limited due to the diversity of the Company's client base and to the various numbers of insurance carriers and the numerous individual patient accounts. As is standard in the health care industry, substantially all of the Company's clinical laboratory's accounts receivable are with numerous third party insurance carriers and individual patient accounts. 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 years ended July 31, 2004, 2003 and 2002 were approximately 19%, 11% and 10%, respectively, of the Company's total revenue. The clinical reference laboratory industry is characterized by a significant amount of uncollectible accounts receivable related to the inability to receive accurate and timely billing information in order to forward it on to the third party payors for reimbursement, and the inaccurate information received from the covered individual patients for unreimbursed unpaid amounts. The Company's provision for uncollectible accounts receivable is within historical expectations.

Billing for laboratory services is complicated. Depending on the billing arrangement and applicable law, we must bill various payers, such as patients, insurance companies, Medicare and employer groups, all of which have different requirements. Auditing for compliance with applicable laws and regulations as well as, internal compliance policies and procedures adds further complexity to the billing process. We depend on healthcare providers to provide billing information to us. When this information is missing or the incorrect billing information is provided on our requisitions we perform the tests and attempt to obtain any missing information and correct the billing information received from the healthcare provider. This slows the invoicing process and generally increases the aging of our accounts receivable. Additional factors complicating the billing process include:

- pricing differences between our fee schedules and the reimbursement rates of the payers;
- disputes with payers as to which party is responsible for payment; and
- disparity in coverage and information requirements among various payers.

We incur significant additional costs as a result of our participation in Medicare, as billing and reimbursement for clinical laboratory testing is subject to considerable and complex federal and state regulations. These additional costs include those related to: (1) complexity added to our billing processes; (2) training and education of our employees and customers; (3) compliance and legal costs; and (4) costs related to, among other factors, medical necessity denials and advance beneficiary notices. The Centers for Medicare & Medicaid Services, or CMS (formerly the Health Care Financing Administration), establishes procedures and continuously evaluates and implements changes in the reimbursement process.

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 25 years of dedicated focus in this area. We conduct our research and other product development efforts through internal research and collaborative relationships. In the fiscal years ended July 31, 2004, 2003 and 2002, the Company incurred costs of $8,078,000, $8,311,000 and $6,179,000, respectively, for research and development activities.

INTERNAL RESEARCH PROGRAMS

A staff of 33 professionals and scientists performs our internal

research and development activities, centered in Farmingdale, New York. 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.



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.

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. We market the clinical laboratory services to our customers through our direct sales force, customer service and patient service representatives.

We focus our sales efforts on obtaining and retaining profitable accounts. We also have an active account management process to evaluate the profitability of all of our accounts. Where appropriate, we change the service levels and terminate accounts that are not profitable.

DIRECT SALES AND MARKETING EFFORT

We internally market our products through our catalogue and direct field sales and a professional sales management team as well as through our e-commerce web site. 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.

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. During fiscal 2004, we have distribution agreements with Perkin-Elmer Life Sciences & Roche Diagnostics Systems, among other companies. Enzo Life Sciences is focusing on a strategic initiative to expand its direct sales to the end user. See Item 3. Legal Proceedings.

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. Some of these competitors are larger than we are and 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 than we are 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. A broad portfolio of issued patents and pending patent applications supports our core technology platforms. 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 2004 we owned or licensed 42 U.S. and over 190 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. There can be no assurance; 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 the collaborating party might obtain a patent, 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 University 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 there under 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 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. The FDA on a case-by-case basis currently reviews each protocol. The FDA has published "Points to Consider" guidance documents with respect to the development of gene medicine protocols. The National Institutes 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. There can be no assurance regarding 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 product. 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 there can be no assurance 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 might 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 the FDA approves our biological or other drug products for marketing, we must continue to comply with the cGMP regulations. The 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 our collaborators or us are likely to be regulated by the FDA as medical devices. Unless an exemption

applies, medical devices must receive either "510(k) clearance" or pre-market approval ("PMA") 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 pre-market 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 "pre-amendment" 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, it's 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 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. Furthermore, 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 imposition 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, post market 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 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 REGULATIONS

The clinical laboratory industry is subject to significant federal and state regulation, including inspections and audits by governmental agencies. Governmental authorities may impose fines or criminal penalties or take other actions to enforce laws and regulations, including revoking a clinical laboratory's federal certification to operate a clinical laboratory operation. Changes in regulation may increase the costs of performing clinical laboratory tests, increase the administrative requirements of claims or decrease the amount of reimbursement. Our Clinical Laboratory and (where applicable) patient service centers are licensed and accredited by the appropriate federal and state agencies. CLIA (The Clinical Laboratory Improvement Act of 1967, and the Clinical Laboratory Improvement Amendments of 1988) regulates virtually all clinical laboratories by requiring that they be certified by the federal government and comply with various operational, personnel and quality requirements intended to ensure that their clinical laboratory testing services are accurate, reliable and timely. CLIA does not preempt state laws that are more stringent than federal laws. Many clinical laboratories 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.

CLIA places all tests into one of three categories of complexity (waived, moderate complexity and high complexity) and establishes varying requirements depending upon the complexity category of the test performed. A 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 Secretary of Health and Human Services ("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.

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.

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 LABORATORY REIMBURSEMENT

Billing and reimbursement for clinical laboratory testing is subject to significant and complex federal and state regulation. Penalties for violations of laws relating to billing federal healthcare programs and for violations of federal fraud and abuse laws include: (1) exclusion from participation in Medicare/Medicaid programs; (2) asset forfeitures; (3) civil and criminal fines and penalties; and (4) the loss of various licenses, certificates and authorizations necessary to operate some or all of a clinical laboratory's business. The Company is not aware of any material violations.

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, health maintenance organizations 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, commercial insurer and health maintenance organizations 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.

Containment of health care costs, including reimbursement for clinical laboratory services, has been a focus of ongoing governmental activity. In 1984, Congress established the Medicare fee schedule for clinical laboratory services, which is applicable to patients covered under Part B of the Medicare program as well as patients receiving Medicaid. Clinical laboratories must bill Medicare directly for the services provided to Medicare beneficiaries and may only collect the amounts permitted under this fee schedule. Reimbursement to clinical laboratories under the Medicare Fee Schedule has been steadily declining since its inception. Furthermore, and Medicare have mandated use of the Physicians Current Procedural Terminology ("CPT") for coding of laboratory services which has altered the way we bill these programs for some of our services, thereby reducing the reimbursement that we receive.

In March 1996, HCFA (now, the Center for Medicare and Medicaid Services or CMS) 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. Because a significant portion of our costs is fixed, these Medicare reimbursement reductions and changes have a direct adverse effect on our net earnings and cash flows.

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. In addition, reimbursement disapprovals by the third party payors, commercial insures and health maintenance organizations, reductions or delays in the establishment of reimbursement rates, and carrier limitations on the insurance coverage of the Company's services or the use of the Company as a service provider could have a negative effect on the Company's future revenues.

ANTI FRAUD AND ABUSE LAWS

Existing Federal laws governing Medicare, as well as state laws, also regulate certain aspects of the relationship between healthcare providers, including clinical laboratories and their referral sources such as physicians, hospitals and other laboratories. One provision of these laws, known as the "Anti-Kickback Law," contains extremely broad proscriptions. Violation of this provision may result in criminal penalties, exclusion from Medicare, and significant civil monetary penalties. Under another Federal law, known as the "Stark" law or "self-referral prohibition," physicians who have an investment or compensation relationship with an entity furnishing clinical laboratory services (including anatomic pathology and clinical chemistry services) may not, subject to certain exceptions, refer clinical laboratory testing for Medicare patients to that entity. Similarly, laboratories may not bill Medicare or Medicaid or any other party for services furnished pursuant to a prohibited referral. Violation of these provisions may result in disallowance of Medicare for the affected testing services, as well as the imposition of civil monetary penalties. New York State also has laws similar to the Federal Stark and Anti-Kickback laws.

The Federal Stark laws, and New York State law, have also placed

restrictions on the supplies and other items that laboratories may provide to their clients. These laws specify that laboratories may only provide clients with items or devices that are used solely to collect, transport or store specimens for the laboratory or to communicate results or tests. Items such as biopsy needles, snares and reusable needles are specifically prohibited from being supplied by laboratories to their clients. These laws represent a significant deviation from practices that previously occurred throughout the industry. The Company has put in place procedures to ensure compliance with these laws and restrictions and believes that it is in compliance with these laws.

In February 1997, the OIG released a model compliance plan for laboratories. One key aspect of the model compliance plan is an emphasis on the responsibilities of laboratories to notify physicians that Medicare covers only medically necessary services. These requirements, and their likely effect on physician test ordering habits, focus on chemistry tests, especially routine tests, rather than on anatomic pathology services or the non-automated tests, which make up the majority of the Company's business measured in terms of net revenues. Nevertheless, they potentially could affect physicians test ordering habits more broadly. The Company is unable to predict whether, or to what extent, these developments may have an impact or the utilization of the Company's services.

The Company seeks to structure its arrangements with physicians and other customers to be in compliance with the anti-kickback, Stark and state laws, and to keep up-to-date on developments concerning their application by various means, including consultation with legal counsel. In addition, in order to address these various Federal and state laws, the Company has developed its



own Corporate Compliance Program based upon the OIG' model program. The Company's Program focuses on establishing clear standards, training and monitoring of the Company's billing and coding practices. Furthermore, as part of this Program, the Company's Corporate Compliance Committee meets on a regular basis to review various operations and relationships as well as to adopt policies addressing these issues.

However, the Company is unable to predict how the laws described above will be applied in the future, and no assurances can be given that its arrangements or processes will not become subject to scrutiny under these laws.

CONFIDENTIALITY OF HEALTH INFORMATION

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") was signed into law on August 21, 1996, and it includes "administrative simplification" provisions designed to standardize common electronic transactions in health care and to protect the security and privacy of health information. Congress' purpose in promulgating HIPAA was to increase the efficiency of health care transactions while, at the same time, protecting the confidentiality of patient information. Final regulations have been adopted for electronic transaction, privacy and security standards. Further, final regulations adopting a national employer identifier to be used in electronic health care transactions have been finalized. These provisions have very broad applicability and they specifically apply to health care providers, which include physicians and clinical laboratories.

The electronic transaction standards regulations create guidelines for certain common health care transactions. With certain exceptions, these standards require that when we conduct certain transactions electronically with another provider, clearinghouse or health plan we must comply with the standards set forth in the regulations. The regulations establish standard data content and format for submitting electronic claims and other administrative health transactions. All health care providers will be able to use the electronic format to bill for their services and all health plans and providers will be required to accept standard electronic claims, referrals, authorizations, and other transactions. The Company believes it is in compliance with these standards. Despite the initial costs, the use of uniform standards for all electronic transactions could lead to greater efficiency in processing claims and in handling health care information.

The privacy regulations, which went into effect in April 2003, create specific requirements for the use and disclosure of protected health information ("PHI"). We are required to maintain numerous policies and procedures in order to comply with these requirements. Furthermore, we need to continuously ensure that there mechanisms to safeguard the PHI, which is used or maintained in any format (E.G., oral, written, or electronic). Failure to comply with these requirements can result in criminal and civil penalties.

The security regulations, which were finalized on February 20, 2003 and go into effect in April 20, 2005, require us to ensure the confidentiality, integrity and availability of all electronic protected health information ("EPHI") that we create, receive, maintain, or transmit. We have some flexibility to fashion our own security measures to accomplish these goals, but, in general, the starting point is to determine what security measures we need to

take. The security regulations strongly emphasize that we must conduct an accurate and thorough assessment of the potential risks and vulnerabilities of the confidentiality, integrity and availability of our EPHI and then document our response to the various security regulations on the basis of that assessment. We will also be required to create additional policies and procedures in order to comply with these requirements.

Complying with the electronic transaction, privacy and security rules will require significant effort and expense for virtually all entities that conduct health care transactions electronically and handle patient health information. We have already implemented almost all of the requirements of the privacy and electronic transactions standards and will now focus on the security regulations; however, at this time, because we have not yet completed the required security risk assessment, we are unable to estimate the total cost or impact of the regulations.

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.



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 Federal Drug Enforcement Administration regulates the use of controlled substances in testing for drugs of abuse. 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 the Occupational Safety and Health Act, the Resource 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 with these laws 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 of 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, 2004, we employed 238 full-time and 24 part-time employees. Of the full-time employees, 33 were engaged in research, development, manufacturing, administrative support and marketing of research products and 189 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

Information systems are used extensively in virtually all aspects of our business, including laboratory testing, billing, customer service, logistics, and management of medical data. Our success depends, in part, on the continued and uninterrupted performance of our information technology, or IT systems. Computer systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures that we have taken to prevent unanticipated problems that could affect our IT systems,



sustained or repeated system failures that interrupt our ability to process test orders, deliver test results or perform tests in a timely manner could adversely affect our reputation and result in a loss of customers and net revenues.

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 with distinction, by the CAP.

AVAILABLE INFORMATION

We make available free of charge on or through our Internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports, if any, filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as soon as reasonably practicable after they are electronically filed with, or furnished to, the Securities and Exchange Commission. Our Internet website address is www.enzo.com and you can find these reports under "Investor Information - SEC Filings." The SEC also maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, which may be accessed at http://www.sec.gov. The public may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. To obtain information on the operation of the Public Reference Room, you may call the SEC at 1-800-SEC-0330.

DIRECTORS AND EXECUTIVE OFFICERS

The following sets forth certain information with regard to directors and executive officers of the Company.

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 sub caption "Executive Officers." The Company has a classified Board of Directors consisting of three classes.

JOHN B. SIAS (age 77) has been a Director of the Company since January 1982. Mr. Sias had been President and Chief Executive Officer of Chronicle Publishing Company from April 1993 to September 2000. 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 61) has been a Director of the Company since January 1982. From 2003 to 2004, Mr. Delucca was Executive Vice President and Chief Financial Officer of REL Consulting Group. Mr. Delucca had been the Chief Financial Officer & Executive Vice President, Finance & Administration of Coty, Inc., from January 1999 to January 2002. 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. Before that, he was a Vice President and Treasurer of the Avco Corporation, which was acquired by Textron.



IRWIN C. GERSON (age 74) has been a Director of the Company since May 8, 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 Bachelor of Science in Pharmacy from Fordham University and an MBA from the NYU Graduate School of Business Administration. He is a director of Andrx Corporation, a NASDAQ listed company which specializes in proprietary drug delivery technologies. From 1990-1999, he was Chairman of the Council of Overseers of the Arnold and Marie Schwartz College of Pharmacy and has served as a trustee of The Albany College of Pharmacy and Long Island University.

MELVIN F. LAZAR, CPA (age 65) has been a Director of the Company since August 1, 2002. Mr. Lazar was a founding partner of the public accounting firm of Lazar, Levine & Felix (LLP) from 1969 until October 2002. Mr. Lazar and his firm served the business and legal communities for over 30 years. He is an expert on the topic of business valuations and merger and acquisition activities. Mr. Lazar is a board member and chairman of the audit committee of Arbor Realty Trust, Inc. (ABR:NYSE). Arbor is a real estate investment trust (REIT) formed to invest in real estate related bridge and mezzanine loans, preferred equity investments and other real estate related assets. Mr. Lazar is a board member and serves as the Chairman of the Audit Committee of privately owned Active Media Services, Inc., the largest corporate barter company in the nation. Mr. Lazar is also a board member and serves as the Chairman of the Audit Committee of Ceco Environmental Corp., which is a provider of innovative solutions to industrial ventilating and air quality problems. Mr. Lazar holds a Bachelor of Business Administration degree from The City College of New York (Baruch College).

MARCUS A. CONANT, M.D. (age 68) was appointed to the board as of July 1, 2004. Dr. Conant, received his B.S. and M.D. degrees from Duke University. He was an exchange student at Hammersmith Hospital in London, England and held an Elective Fellowship in Biochemistry at the London Hospital. Dr. Conant has been the recipient of numerous awards, and has served as a member of or consultant to a broad array of scientific societies and associations, community organizations and government committees and has authored or co-authored more than 70 published papers. Dr. Conant is a Clinical Professor at the University of California San Francisco (UCSF) and has been on the faculty of UCSF since 1967. He currently serves as Chairman of the Board of the Conant Foundation, an HIV/AIDS education and research foundation based in San Francisco. Dr. Conant served as principal investigator for Enzo's Phase I clinical trial of its gene medicine for HIV-1 infection.

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

<TABLE>
<CAPTION>

| NAME | POSITION |
|---|---|
| <S> | <C> |
| Elazar Rabbani, Ph.D. | Chief Executive Officer, Chairman of the Board of Directors |
| Shahram K. Rabbani | Chief Operating Officer, Secretary, Treasurer |
| Barry W. Weiner | President, Chief Financial Officer |

| | |
|---|---|
| Dean Engelhardt, Ph.D. | Executive Vice President |
| Norman E. Kelker, Ph.D. | Senior Vice President |
| Herbert B. Bass | Vice President of Finance |
| Barbara E. Thalenfeld, Ph.D. | Vice President, Corporate Development |
| David C. Goldberg | Vice President, Business Development |

</TABLE>

DR. ELAZAR RABBANI (age 60) Enzo Biochem's founder has served as the Company's Chairman of the Board of Directors and Chief Executive Officer since its inception in 1976. Dr. Rabbani has authored numerous scientific publications in the field of molecular biology, in particular, nucleic acid labeling and detection. He is also the lead inventor of many of the company's pioneering patents covering a wide range of technologies and products. Dr. Rabbani received his Bachelor of Arts degree from New York University in Chemistry and his Ph.D. in Biochemistry from Columbia University. He is a member of the American Society for Microbiology.

SHAHRAM K. RABBANI (age 52) Chief Operating Officer, Treasurer, Secretary and Director, is a founder and has been with the Company since its inception. He is also President of Enzo Clinical Labs. Mr. Rabbani serves on the New York State Clinical Laboratory Association, a professional board. Mr. Rabbani is a trustee of Adelphi University and serves as Chairman of its audit committee. He received a Bachelor of Arts Degree in Chemistry from Adelphi University, located in Long Island, New York.

BARRY W. WEINER (age 54) President, Chief Financial Officer and Director, is a founder of Enzo Biochem, Inc. He has served as the Company's President since 1996, and previously held the position of Executive Vice President. Before his employment with Enzo, he worked in several managerial and marketing positions at the Colgate Palmolive Company. Mr. Weiner is a Director of



the New York Biotechnology Association. He received his Bachelor of Arts degree in Economics from New York University and a Master of Business Administration in Finance from Boston University.

DR. DEAN ENGELHARDT (age 64) Executive Vice President has held this position since July 2000. Since joining the Company in 1981, Dr. Engelhardt has held several other executive and scientific positions within Enzo Biochem. In addition, Dr. Engelhardt has authored many papers in the area of nucleic acid synthesis and protein production and has been a featured presenter at numerous scientific conferences and meetings. He holds a Ph.D. degree in Molecular Genetics from Rockefeller University.

DR. NORMAN E. KELKER (age 65) Senior Vice President has held this position since 1989. Before this, he was the Company's Vice President for Scientific Affairs. Dr. Kelker has authored numerous scientific papers and presentations in the biotechnology field. He is a member of American Society of Microbiology and the American Association of the Advancement of Science. Dr. Kelker received his Ph.D. in Microbiology and Public Health from Michigan State University.

HERBERT B. BASS (age 56) Vice President of Finance for the Company and is also Senior Vice President of Enzo Clinical Labs. Before his promotion in 1989 to Vice President of Finance, Mr. Bass served as the Corporate Controller of the Company. Mr. Bass has been with The Company since 1986. From 1977 to 1986, Mr. Bass held various positions at Danziger and Friedman, Certified Public Accountants, the most recent of which was audit manager. For the preceding seven (7) years, he held various positions at Berenson & Berenson, Certified Public Accountants. Mr. Bass received a Bachelor of Business Administration degree in Accounting from Bernard M. Baruch College, in New York City.

DR. BARBARA E. THALENFELD (age 64) Vice President of Corporate Development for Enzo Biochem and Vice President of Clinical Affairs for Enzo Therapeutics. Dr. Thalenfeld has been employed with the Company since 1982. She has authored over 20 scientific papers in the areas of molecular biology and genetics, and is a member of the American Society of Gene Therapy, the Association of Clinical Research Professionals, and the Drug Development Association. Dr. Thalenfeld received her Ph.D. at the Institute of Microbiology at Hebrew University in Jerusalem, Israel and a Master of Science degree in Molecular Biology from Yale University. She also completed a Post Doctoral Fellowship in the Department of Biological Sciences at Columbia University.

DAVID C. GOLDBERG (age 47) Vice President of Business Development for Enzo Biochem and Senior Vice President of Enzo Clinical Labs has been employed with the company since 1985. He has held several managerial positions within Enzo Biochem. Mr. Goldberg also held management and marketing positions with DuPont-NEN and Gallard Schlesinger Industries before joining the Company. He received a Master of Science degree in Microbiology from Rutgers University and a Master of Business Administration in Finance from New York University.

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

FORWARD-LOOKING AND CAUTIONARY STATEMENTS

This Annual Report contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact, including, without limitation, the statements under "Management's Discussion and Analysis of Financial Condition and Results of Operations" are "forward-looking statements." Forward-looking statements may include the words "believes," "expects," "plans," "intends," "anticipates," "continues" or other similar expressions. These statements are based on the Company's current expectations of future events and are subject to a number of risks and uncertainties that may cause the Company's actual results to differ materially from those described in the forward-looking statements. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, estimated or projected. These factors and uncertainties include, among others:

(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.

(l) Inability to obtain patent protection or secure and maintain proprietary positions on its technology.

(m) Dependence on new technologies for our product development and dependence on product candidates in early stages 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.

(p) Fluctuations in quarterly results resulting from uneven customer order flow.

These and other risks and uncertainties are disclosed from time to time in the Company's filings with the Securities and Exchange Commission, in the Company's press releases and in oral statements made by or with the approval of authorized personnel. The Company assumes no obligation to update any forward-looking statements as a result of new information or future events or developments.

Item 2. PROPERTIES

The following are the principal facilities of the Company:

<TABLE>
<CAPTION>
Location | Principal | Approximate Floor | Approximate | Expiration

| - -------- | Operations | Area (sq. ft.) | Annual Base Rent | Date |
|---|---|---|---|---|
| <S> | <C> | <C> | <C> | <C> |
| 60 Executive Blvd Farmingdale, N.Y. | Corporate headquarters, clinical laboratory, research and manufacturing facilities (See note 6 of Notes to Consolidated Financial Statements) | 43,000 | $1,138,000 | November 30, 2004 |
| 527 Madison Ave New York, NY | Executive office | 6,400 | $367,000 | December 31, 2008 |

</TABLE>

We believe that the current facilities are suitable and adequate for the Company's current operating needs and the production capacity in such facilities is substantially being utilized.



Item 3. LEGAL PROCEEDINGS

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. On July 15, 2002, the Court of Appeals for the Federal Circuit reversed the judgment of invalidity and remanded the case to the district court for further proceedings. In March 2003, settlements were reached with bioMerieux and Chugai; the settlements did not have a material monetary impact on the Company. In July 2004, the district court again granted another motion by the remaining defendants (Gen-Probe and Becton Dickinson) that all claims of the Company's patent are invalid. The Company has filed an appeal of that judgment. There can be no assurance that the Company will be successful in the on-going proceedings. However, even if the Company is not successful, management does not believe that there will be a significant adverse monetary impact to the Company.

On March 6, 2002, the Company was named, along with certain of its officers and directors among others, in a complaint entitled Lawrence F. Glaser and Maureen Glaser, individually and on behalf of Kimberly, Erin, Hannah, and Benjamin Glasser v. Hyman Gross, Barry Weiner, Enzo Biochemical Inc., Elazar Rabbani, Shahram Rabbani, John Delucca, Dean Engelhardt, Richard Keating, Doug Yates and Docs 1-50, in the U.S. District Court for the Eastern District of Virginia. The complaint was filed by an investor in the Company who has filed for bankruptcy protection and his family. The complaint alleged securities and common law fraud and breach of fiduciary duty and seeks in excess of $150 million in damages. On August 22, 2002, the complaint was voluntarily dismissed; however a new substantially similar complaint was filed at the same time. On October 21, 2002, the Company and the other defendants filed a motion to dismiss the complaint, and the plaintiffs responded by amending the complaint and dropping their claims against defendants Keating and Yates. On November 18, 2002, the Company and the other defendants again moved to dismiss the Amended Complaint. On July 16, 2003, the Court issued a Memorandum Opinion dismissing the Amended Complaint in its entirety with prejudice. Plaintiffs thereafter moved for reconsideration but the Court denied the motion on September 8, 2003. The plaintiffs subsequently appealed to the Fourth Circuit and that appeal is presently pending. The Company does not believe that the complaint has any merit and was correctly dismissed, and intends to continue to defend the complaint vigorously in any event.

In March 2002, Enzo Life Sciences, a subsidiary of the Company, filed suit (the "Litigation") in the United States District Court for the District of Delaware against Digene Corp., charging it with infringing the Company's U.S. Patent No. 6,221,581, (the "581 Patent") which concerns a novel process for detecting nucleic acids of interest. On May 31, 2002, Digene filed counterclaims in that suit against Enzo Life Sciences and the Company, including business tort counterclaims relating to the `581 patent. On October 13, 2004, the Company, its wholly owned subsidiary Enzo Life Sciences, Inc. ("Enzo Life Sciences") and Digene Corporation ("Digene") entered into a Settlement and License Agreement (the "Agreement") and a Joint Stipulation and Order of Dismissal with Prejudice (the "Stipulation"). The Agreement provides for (i) the full and final settlement of the Litigation and (ii) the grant to Digene of a non-exclusive, worldwide, royalty-bearing license with respect to such `581 Patent and the remaining patents in the '581 patents global family. The '581 patent is set to expire on April 24, 2018. Pursuant to the Agreement Digene is irrevocably required to pay Enzo Life Sciences an aggregate of $30.5 million of which Life Sciences received U.S. $16 million (the "First Payment") from Digene on October 14, 2004. Digene will pay to Enzo U.S. $16.5 million (subject to the $2 million

credit discussed below) ("Additional Irrevocable Payments"); $2.5 million of which shall be paid by November 14, 2005 and $3.5 million per year by November 14 of each of 2006, 2007, 2008 and 2009. In addition, Digene shall pay Enzo Life Sciences Running Royalties on Net Sales of Licensed Products. Each Additional Irrevocable Payment is fully creditable by Digene against the Running Royalties that are due under the Agreement. Digene at its discretion may credit $2 million of the First Payment against either the payment required to be paid by Digene by November 14, 2005 or the Running Royalties due Enzo Life Sciences under the Agreement. The Stipulation which will be filed with the Court by October 15, 2004 dismisses with prejudice all claims, counterclaims and defenses brought or raised by any party to the Litigation.

In October 2002, the Company filed suit in the United States District Court of the Southern District of New York against Amersham plc, Amersham Biosciences, Perkin Elmer, Inc., Perkin Elmer Life Sciences, Inc., Sigma-Aldrich Corporation, Sigma Chemical Company, Inc., Molecular Probes, Inc. and Orchid Biosciences, Inc. In January 2003, the Company amended its complaint to include defendants Sigma Aldrich Co. and Sigma Aldrich, Inc. The counts set forth in the suit are for breach of contract; patent infringement; unfair competition under state law; unfair competition under federal law; tortious interference with business relations; and fraud in the inducement of contract. The complaint alleges that these counts arise out of the defendants' breach of distributorship agreements with the Company concerning labeled nucleotide products and technology, and the defendants' infringement of patents covering the same. In April, 2003, the Court directed that individual complaints be filed separately against each defendant. A number of the defendants have answered the individual complaints and asserted a variety of affirmative defenses and counterclaims. Fact discovery is currently



scheduled to close on May 6, 2005. The Court will conduct a claim construction hearing on June 28, 2005. There can be no assurance that the Company will be successful in this litigation. However, even if the Company is not successful, management does not believe that there will be a significant adverse monetary impact to the Company.

On October 28, 2003, the Company and Enzo Life Sciences, Inc., a subsidiary of the Company, filed suit in the United States District Court of the Eastern District of New York against Affymetrix, Inc. The Complaint alleges that Affymetrix improperly transferred or distributed substantial business assets of the Company to third parties, including portions of the Company's proprietary technology, reagent systems, detection reagents and other intellectual property. The Complaint also charges that Affymetrix failed to account for certain shortfalls in sales of the Company's products, and that Affymetrix improperly induced collaborators and customers to use the Company's products in unauthorized fields or otherwise in violation of the agreement. The Complaint seeks full compensation from Affymetrix to the Company for its substantial damages, in addition to injunctive and declaratory relief to prohibit, among other things, Affymetrix's unauthorized use, development, manufacture, sale, distribution and transfer of the Company's products, technology, and/or intellectual property, as well as to prohibit Affymetrix from inducing collaborators, joint venture partners, customers and other third parties to use the Company's products in violation of the terms of the agreement and the Company's rights. Subsequent to the filing of the Complaint against Affymetrix, Inc. referenced above, on or about November 10, 2003, Affymetrix, Inc. filed its own complaint against the Company and its subsidiary, Enzo Life Sciences, Inc., in the United States District Court for the Southern District of New York, seeking among other things, declaratory relief that Affymetrix, Inc., has not breached the parties' agreement, that it has not infringed certain of Enzo's Patents, and that certain of Enzo's patents are invalid. The Affymetrix complaint also seeks damages for alleged breach of the parties' agreement, unfair competition, and tortuous interference, as well as certain injunction relief to prevent alleged unfair competition and tortuous interference. The Company does not believe that the complaint has any merit and intends to defend vigorously. Affymetrix also moved to transfer venue of Enzo's action to the Southern District of New York, where other actions commenced by Enzo were pending as well as Affymetrix's subsequently filed action. On January 30, 2004, Affymetrix's motion to transfer was granted. Accordingly, the Enzo and Affymetrix actions are now both pending in the Southern District of New York. Pleadings have not been completed and discovery has not commenced.

On June 2, 2004 Roche Diagnostic GmbH and Roche Molecular Systems, Inc. (collectively "Roche") filed suit in the U.S. District Court of the Southern District of New York against Enzo Biochem, Inc. and Enzo Life Sciences, Inc. (collectively "Enzo"). The complaint was filed after Enzo rejected Roche's latest cash offer to settle Enzo's claims for, INTER ALIA, alleged breach of contract and misappropriation of Enzo's assets. The complaint seeks declaratory judgment (i) of patent invalidity with respect to Enzo's 4,994,373 patent, (ii) of no breach by Roche of its 1994 Distribution and Supply Agreement with Enzo (the "1994 Agreement"), (iii) that non-payment by Roche to Enzo for certain sales of Roche products does not constitute a breach of the 1994 Agreement, and (iv) that Enzo's claims of ownership to proprietary inventions, technology and products developed by Roche are without basis. In addition, the suit claims tortious interference and unfair competition. The Company does not believe that the complaint has merit and intends to vigorously respond to such action with

appropriate affirmative defenses and counterclaims.

On June 7, 2004, the Company and its wholly-owned subsidiary, Enzo Life Sciences, Inc., filed suit in the United States District Court for the District of Connecticut against Applera Corporation and its wholly-owned subsidiary Tropix, Inc. The complaint alleges infringement of six patents (relating to DNA sequencing systems, labelled nucleotide products, and other technology). Yale University is the owner of four of the patents and the Company is the exclusive licensee. Accordingly, Yale is also a plaintiff in the lawsuit. Yale and Enzo are aligned in protecting the validity and enforceability of the patents. Enzo Life Sciences is the owner of the remaining two patents. The complaint seeks permanent injunction and damages (including treble damages for wilful infringement). Defendants answered the complaint on July 29, 2004. The answer pleads affirmative defences of invalidity, estoppel and laches and asserts counterclaims of non-infringement and invalidity. A trial date has not been set. Discovery commences on September 15, 2004. There can be no assurance that the Company will be successful in this litigation. Even if the Company is not successful, management does not believe that there will be a significant adverse monetary impact on the Company.

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, 2004.



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 |
|---|---|---|
| 2003 Fiscal Year (August 1, 2002 to July 31, 2003): | | |
| 1st Quarter | $16.40 | $11.64 |
| 2nd Quarter | $15.86 | $12.76 |
| 3rd Quarter | $15.23 | $11.50 |
| 4th Quarter | $30.10 | $14.78 |
| 2004 Fiscal Year (August 1, 2003 to July 31, 2004): | | |
| 1st Quarter | $22.45 | $17.35 |
| 2nd Quarter | $20.95 | $15.85 |
| 3rd Quarter | $19.88 | $14.20 |
| 4th Quarter | $15.69 | $12.57 |

As of October 7, 2004, the Company had approximately 1,171 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 October 5, 2004 payable November 15, 2004 to shareholders of record as of October 25, 2004. The Company declared a 5% stock dividend on June 10, 2003 payable July 14, 2003 to shareholders of record as of June 30, 2003. The Company declared a 5% stock dividend on January 23, 2002 payable February 27, 2002 to shareholders of record as of February 2, 2002. The per share data has been adjusted retroactively to reflect the stock dividend declared on October 5, 2004. The consolidated balance sheet and consolidated statement of stockholders' equity do not give retroactive effect to the dividend declared October 5, 2004. The shares and per share data have been adjusted to retroactively reflect the stock dividends in fiscal 2003 and 2002. The Company recorded a charge to accumulated deficit and a credit to common stock and additional paid-in capital in the amounts of approximately $37,709,000 and $26,988,000 in fiscal 2003 and fiscal 2002 and fiscal 2001, respectively, which reflects the fair value of the dividends on the dates of declaration.

EQUITY COMPENSATION PLAN DISCLOSURE

The following table summarizes equity compensation plans approved by security holders and equity compensation plans that were not approved by security holders as of July 31, 2004:

<TABLE>
<CAPTION>

| Number of Securities | | Number of securities remaining |
|---|---|---|

| Plan category | To be Issued Upon Exercise of outstanding options, warrants and rights | Weighted-Average Exercise Price of outstanding options, warrants and rights | future issuance under equity compensation plans (excluding securities reflected in column (a) |
|---|---|---|---|
| | (a) | (b) | (c) |
| Equity compensation plans (stock options) approved by security holders | 2,856,801 | $11.86 | 238,780 |
| Equity compensation plans not Approved by security holders | --- | --- | --- |
| Total | 2,856,801 | $11.86 | 238,780 |



Item 6. SELECTED FINANCIAL DATA

The selected operating results for the years ended July 31, 2004, 2003 and 2002 and the financial position data as of July 31, 2004 and 2003, have been derived from the Company's audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The selected operating results for the years ended July 31, 2001 and 2000, and the selected financial position data as of July 31, 2002, 2001 and 2000 are derived from the Company's audited consolidated financial statements which are not included in this Annual Report on Form 10-K.

The following tables summarize the Company's consolidated statement of operations and balance sheet data. This information should be read together with the discussion in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the Company's consolidated financial statements and notes to those statements included elsewhere in this Annual Report on Form 10-K.

<TABLE>
<CAPTION>

| | For the Years Ended July 31, | | | | |
|---|---|---|---|---|---|
| | (In thousands, except per share data) | | | | |
| | 2004 | 2003 | 2002 | 2001 | 2000 |
| <S> | <C> | <C> | <C> | <C> | <C> |
| OPERATING RESULTS: | | | | | |
| Operating revenues | $41,644 | $52,767 | $54,015 | $52,266 | $42,847 |
| Interest income | 1,152 | 1,355 | 1,350 | 3,003 | 2,585 |
| (Loss) income before benefit (provision) for taxes on income | (11,080) | 5,725 | 10,340 | 12,231 | 7,668 |
| Benefit (provision) for taxes on income | 4,848 | (1,881) | (3,417) | (5,418) | (1,044) |
| Net (loss) income | $(6,232) | $3,844 | $6,923 | $6,813 | $6,624 |

| | | | | | |
|---|---|---|---|---|---|
| Basic net (loss) income per common share: | $(.20) | $0.12 | $0.22 | $0.22 | $0.22 |
| Diluted net (loss) income per common share: | $(.20) | $0.12 | $0.21 | $0.21 | $0.20 |
| Denominator for per share calculation: | | | | | |
| Basic | 31,700 | 31,399 | 31,359 | 31,254 | 30,789 |
| Diluted | 31,700 | 32,175 | 32,327 | 32,558 | 32,802 |
| FINANCIAL POSITION: | | | | | |
| Working capital | $92,259 | $97,723 | $92,772 | $85,094 | $74,094 |
| Total assets | $110,334 | $115,878 | $109,291 | $102,931 | $92,886 |
| Stockholders' equity | $104,166 | $109,380 | $104,733 | $97,517 | $87,176 |

</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 "Forward-Looking and Cautionary Statements." 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.

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. Enzo also provides clinical laboratory services to the medical community. In addition, our work in gene analysis has led to our development of significant therapeutic product candidates, several of which are currently in clinical trials, and several are in preclinical studies.



The business activities of the Company are performed by the Company's three wholly owned subsidiaries. These activities are: (1) research and development, manufacturing and marketing of biomedical research products and tools through Enzo Life Sciences 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 15 of the Notes to Consolidated Financial Statements.

The Company's source of revenue has been from the direct sales of research products of labeling and detection reagents for the genomics and sequencing markets, as well as through non-exclusive distribution agreements with other companies. Another source of revenue has been from the clinical laboratory service market. Clinical laboratory services are provided to patients covered by various third party insurance programs, including Medicare and self payors for the services provided. The clinical laboratory is subject to seasonal fluctuations in operating results. Volume of testing generally declines during the summer months, the year-end holiday periods and other major holidays. In addition, volume declines due to inclement weather may reduce net revenues. Therefore, comparison of the results of successive quarters may not accurately reflect trends or results for the full year. For the fiscal years ended July 31, 2004 and 2003, respectively, approximately 31% and 44% of the Company's operating revenues were derived from research product sales and approximately 69% and 56% were derived from clinical laboratory services. Research product revenue from Affymetrix represented approximately 0 %, 22% and 23% of the consolidated revenues in fiscal 2004, 2003 and 2002, respectively, under a non-exclusive distribution and supply agreement. Research product revenue from this major distributor accounted for approximately 0 % and 50% of the Company's total research product revenue in fiscal 2004 and 2003, respectively. At July 31, 2004 and 2003, of the Company's net accounts receivable no monies were included from this one major distributor. Research product revenue from Amersham represented approximately 0%, 1% and 1% of the consolidated revenues in fiscal 2004, 2003 and 2002, respectively, under a non-exclusive distribution and supply agreement. At July 31, 2004 and 2003, 0% and 2%, respectively, of the Company's net accounts receivable relate to amounts due from this distributor. Research product revenue from Perkin-Elmer represented approximately 8%, 4% and 5% of the

consolidated revenues in fiscal 2004, 2003 and 2002, respectively, under a non-exclusive distribution and supply agreement. At July 31, 2004 and 2003, 5% and 3%, respectively, of the Company's net accounts receivable relate to amounts due from this distributor. Research product revenue from Roche represented approximately 8%, 6% and 8% of the consolidated revenues in fiscal 2004, 2003 and 2002, respectively, under a non-exclusive distribution and supply agreement. At July 31, 2004 and 2003, 0% and 6% respectively of the Company's net accounts receivable relate to amounts due from the this distributor. At July 31, 2004, the Company had written off $1.8 million against the amount due from this distributor. See Item 3. Legal Proceedings. The following is a table outlining the above for the respective consolidated fiscal years:

<TABLE>
<CAPTION>

| | % of Revenue | | | % of Accounts Receivable | |
|---|---|---|---|---|---|
| | 2004 | 2003 | 2002 | 2004 | 2003 |
| <S> | <C> | <C> | <C> | <C> | <C> |
| Affymetrix | 0% | 22% | 23% | 0% | 0% |
| Perkin-Elmer | 8% | 4% | 6% | 5% | 3% |
| Amersham | 0% | 1% | 1% | 0% | 2% |
| Roche | 8% | 6% | 5% | 0% | 6% |

</TABLE>

LIQUIDITY AND CAPITAL RESOURCES

At July 31, 2004, our cash and cash equivalents of $54.5 million and marketable securities of $17.2 million totaled $71.7 million, a decrease of $6.7 million from July 31, 2003. We had working capital of $92.3 million at July 31, 2004 compared to $97.7 million at July 31, 2003. On October 14, 2004 the Company received $16 million from Digene Corporation in connection with execution of a settlement and license agreement. See Item 3. Legal Proceeding.

Net cash used in operating activities for the year ended July 31, 2004 was approximately $5.6 million as compared to net cash provided by operating activities of $12.1 million for the year ended July 31, 2003. The decrease in net cash provided by operating activities from fiscal 2003 to fiscal 2004 was primarily due to a net loss in the current year offset by the net change in operating assets and liabilities compared to the prior year.

Net cash used in investing activities decreased approximately $12.5 million from fiscal 2003, primarily as a result of a decrease in the purchase of marketable securities in the current year.

Net cash provided by financing activities increased by $.3 million from fiscal 2003 primarily as a result of the increase in proceeds from the exercise of stock options.



Net accounts receivable of $14.8 million and $17.3 million represented 130 days and 119 days of operating revenues at July 31, 2004 and 2003, respectively. The change in net accounts receivable is due to a decrease in accounts receivable at the clinical reference laboratory of approximately $1.3 million and a decrease of research products accounts receivable of approximately $1.2 million. The decrease in the clinical laboratory receivable is primarily due to the decrease in revenue. The decrease in the research products accounts receivable is primarily due to the decrease in revenue from one specific distributor of research products. The Company had written off $1.8 million against the open accounts receivable due from this one distributor in the fourth quarter of 2004.

The Company has entered into various real estate operating leases with both related and unrelated parties. See Note 6 to the Consolidated Financial Statements for a further description of these various leases.

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. See Note 10 to the Consolidated Financial Statement.

The total future payments under the Company's contractual obligations as of July 31, 2004 are as follows:

<TABLE>
<CAPTION>

| | Payments Due by Period | | | |
|---|---|---|---|---|
| | Total | Less Than 1 Year | 1-3 Years | 4-5 Years |
| <S> | <C> | <C> | <C> | <C> |
| Operating Leases | $1,393,000 | $705,000 | $498,000 | $190,000 |
| Total Contractual Cash Obligations | $1,393,000 | $705,000 | $498,000 | $190,000 |

</TABLE>

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.

CRITICAL ACCOUNTING POLICIES

GENERAL

The Company's discussion and analysis of its financial condition and results of operations are based upon Enzo Biochem, Inc. consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses; these estimates and judgments also affect related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to contractual allowance, allowance for uncollectible accounts, intangible assets and income taxes. The Company bases its estimates on experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

REVENUE RECOGNITION

Revenues from the clinical laboratory are recognized as services are rendered upon completion of the testing process for a specific patient and reported to the ordering physician. 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, exclusive of certain non-exclusive distribution agreements, are recognized when the products are shipped.

The Company has certain non-exclusive distribution agreements, which provide for consideration to be paid to the distributors for the manufacture of certain products. The Company records such consideration provided to distributors under these non-exclusive distribution agreements as a reduction to research product revenues. The revenue from these non-exclusive distribution agreements are recognized when shipments are made to their respective customers and reported to the Company.



CONTRACTUAL ALLOWANCES

The percentage of the Company's revenues derived from Medicare, third party payers, commercial insurers and managed care patients continue to increase. The Medicare regulations and various managed care contracts are often complex and may include multiple reimbursement mechanisms for different types of services provided in our clinical laboratory. We estimate the allowance for contractual allowances on a payer-specific basis given our interpretation of the applicable regulations and historical calculations. However, the services authorized and provided and related reimbursement are often subject to interpretation that could result in payments that differ from our estimates. Additionally, updated regulations occur frequently necessitating continual review and assessment of the estimation process by management.

ALLOWANCE FOR DOUBTFUL ACCOUNTS

The Company's ability to collect outstanding receivables from third party payers is critical to its operating performance and cash flows. The primary collection risk lies with uninsured patients or patients for whom primary insurance has paid but a patient portion remains outstanding. The

Company estimates the allowance for doubtful accounts primarily based upon the age of the accounts since invoice date. The Company continually monitors its accounts receivable balances and utilizes cash collections data to support the basis for its estimates of the provision for doubtful accounts. Significant changes in payer mix or regulations could have a significant impact on the Company's results of operations and cash flows. In addition, the Company has implemented a process to estimate and review the collectibles of its receivables based on the period they have been outstanding. Historical collection and payor reimbursement experience is an integral part of the estimation process related to reserves for doubtful accounts. The Company also assesses the current state of its billing functions in order to identify any known collection or reimbursement issues in order to assess the impact, if any, on the reserve estimates, which involves judgment. The Company believes that the collectibility of its receivables is directly linked to the quality of its billing processes, most notably, those related to obtaining the correct information in order to bill effectively for the services provided. Revisions in reserve for doubtful accounts estimates are recorded as an adjustment to bad debt expense. The Company believes that its collection and reserves processes, along with the close monitoring of its billing processes, helps reduce the risk associated with material revisions to reserve estimates resulting from adverse changes in collection and reimbursement experience and billing operations.

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 carry forwards and other items be reduced by a valuation allowance where it is more likely than not 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.

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.



RESULTS OF OPERATIONS

<TABLE>
<CAPTION>

| | Comparative financial data for the years ended July 31, | | | | |
|---|---|---|---|---|---|
| | 2004 | Increase (Decrease) | 2003 | Increase (Decrease) | 2002 |
| | (in thousands) | | | | |
| <S> | <C> | <C> | <C> | <C> | <C> |
| Revenues: | | | | | |
| Research product sales | $12,972 | ($10,281) | $23,253 | ($2,710) | $25,963 |
| Clinical laboratory services | 28,672 | (842) | 29,514 | 1,462 | 28,052 |
| Total revenue | $41,644 | (11,123) | $52,767 | (1,248) | $54,015 |
| Costs and expenses: | | | | | |
| Cost of research products | 2,518 | (871) | 3,389 | 1,552 | 1,837 |
| Cost of laboratory services | 10,586 | 993 | 9,593 | (516) | 10,109 |
| Research & development | 8,078 | (233) | 8,311 | 2,132 | 6,179 |
| Selling expense | 4,335 | 829 | 3,506 | 263 | 3,243 |
| General & administrative | 10,032 | 1,441 | 8,591 | 1,233 | 7,358 |
| Provision for uncollectible A/R | 11,987 | 2,642 | 9,345 | (4,843) | 14,188 |
| Legal expenses | 6,340 | 679 | 5,661 | 3,550 | 2,111 |
| Total costs and expenses | $53,876 | 5,480 | $48,396 | 3,371 | $45,025 |
| Operating (loss) income | $(12,232) | $(16,603) | $4,371 | $(4,619) | $8,990 |

</TABLE>

FISCAL 2004 COMPARED TO FISCAL 2003

Revenues from operations for the fiscal year ended July 31, 2004 were $41.6 million a decrease of $11.1 million over revenues from operations for the fiscal year ended July 31, 2003. This decrease was due to a decrease of $10.3 million in revenues from our research product sales operations and decrease of $.8 million in revenues from clinical reference laboratory operation over revenues for such activities in fiscal 2004.

The decrease in research product sales resulted primarily from a decrease in direct sales of research products of labeling and detection reagents for the genomics and sequencing markets related to shipments to Affymetrix a major distributor. Research product revenue from this one major distributor accounted for approximately 0% and 50% of the Company's total research product revenues in fiscal 2004 and 2003, respectively. See Item 3. Legal Proceedings.

The decrease of clinical laboratory services revenue was due primarily to the recent downward trends that had indicated a decrease in the reimbursements rates from the Medicare Program, certain third party payors and HMO's. Clinical laboratory services are provided to patients covered by various third party payor programs, including Medicare and health maintenance organizations ("HMO's"). Billings for services are included in revenue net of allowances for contractual discounts and allowances paid for differences between the amounts billed and the estimated amount to be paid. The effect of such reduced reimbursement rates have been reflected in fiscal 2004. The clinical laboratory is subject to seasonal fluctuations in operating results. Volume of testing generally declines during the summer months, the year-end holiday periods and other major holidays. In addition, volume declines due to inclement weather may reduce net revenues. Therefore, comparison of the results of successive quarters may not accurately reflect trends or results for the full year.

The cost of research products sold decreased by $.9 million from the prior fiscal year. This decrease was primarily due to the decrease in research product revenue based on the termination of a contract with one major distributor.

The cost of clinical laboratory services increased by $1.0 million during this period primarily due to an increase in costs with certain esoteric tests and costs related to performing more testing in house.

Research and development expenses decreased by approximately $.2 million as a result of a decrease in the expenses related to the clinical trial activities and other research projects.

Selling expenses increased by $.8 million during this fiscal year, as compared to the prior year's fiscal year. This increase was primarily due to an increase in both the sales personnel and marketing expenditures for research product sales and clinical laboratory services.

The Company's provision for uncollectible accounts receivable increased by $2.6 million to $11.9 million from $9.3 million as compared to last year. At the clinical laboratory division the percentage of the provision for uncollectible accounts receivable as a relationship to revenue increased to 35.7% this fiscal year as compared to 29.6% for last year. These increases were primarily due to



the change in the mix of payors during the current fiscal year. The company wrote off $1.8 million of an uncollectible receivable from one of its distributors at the Life Science division this fiscal year. See Item 3. Legal Proceedings.

The Company's legal expenses increased by $.6 million to $6.3 million from $5.7 million as compared to the previous year. This increase is primarily due to the increase in patent infringement proceedings and the increase in the overall legal activities on these infringement proceedings.

General and administrative expenses increased by $1.4 million due to an increase at the clinical lab in the information technology expenditures and the in-house legal patent costs.

Interest income was comparable to the prior fiscal year.

In fiscal 2004, we recorded a benefit for income taxes of $4.8 million, based upon an $11.1 million loss before benefit for taxes on income in the current year as compared to a provision for income taxes of $1.9 million in fiscal 2003, which were based on the combined effective federal, state and local income tax rates.

Net accounts receivable from our clinical laboratory operations of $13.1 million and $14.4 million represented an average of 167 days and 174 days of operating revenues at July 31, 2004 and 2003, respectively.

Loss before provision for taxes on income from the research and

development segment activities and related costs was $1.3 million in fiscal 2004, as compared to income before provision for taxes on income of $9.4 million in fiscal 2003. The decrease in the profit resulted primarily from a decrease in direct sales of research products of labeling and detection reagents for the genomics and sequencing markets to Affymetrix a major distributor. Loss before provision for taxes on income from the clinical reference laboratories segment amounted to a $1.5 million for fiscal 2004, as compared to income of $3.0 million for fiscal 2003. The decrease in income before taxes for the clinical laboratory segment was primarily due to the reduction in reimbursement rates from third party payors. Loss before provision for taxes on income at the other segment amounted to a loss of $8.3 million for fiscal 2004, as compared to a loss of $6.7 million for fiscal 2003, due to the increase in legal expenses in fiscal 2004.

FISCAL 2003 COMPARED TO FISCAL 2002

Revenues from operations for the fiscal year ended July 31, 2003 were $52.8 million a decrease of $1.2 million over revenues from operations for the fiscal year ended July 31, 2002. This decrease was due to a decrease of $2.7 million in revenues from our research product sales operations offset by an increase of $1.5 million in revenues from clinical reference laboratory operation over revenues for such activities in fiscal 2003.

The decrease in research product sales resulted primarily from a decrease in direct sales of research products of labeling and detection reagents for the genomics and sequencing markets related to shipments to one major distributor. Research product revenue from this one major distributor accounted for approximately 50% and 49% of the Company's total research product revenues in fiscal 2003 and 2002, respectively.

The increase of clinical laboratory services revenue was due primarily to increase volume of higher priced esoteric tests. Clinical laboratory services are provided to patients covered by various third party payor programs, including Medicare and health maintenance organizations ("HMO's"). Billings for services are included in revenue net of allowances for contractual discounts and allowances paid for differences between the amounts billed and the estimated amount to be paid. Recent trends had indicated a decrease in the collection rates from the Medicare Program, certain third party payors and HMO's. The effect of such reduced collection rates have been reflected in fiscal 2003. The clinical laboratory is subject to seasonal fluctuations in operating results. Volume of testing generally declines during the summer months, the year-end holiday periods and other major holidays. In addition, volume declines due to inclement weather may reduce net revenues. Therefore, comparison of the results of successive quarters may not accurately reflect trends or results for the full year.

Although, research product revenue decreased for the fiscal year, the cost of research products sold increased by $1.6 million to $3.4 million from the prior fiscal year. This increase was primarily due to the increase in reagent costs, the expansion of the manufacturing, processing capabilities and an increase in headcount in these areas, due to the unusually high volume of the orders shipped in the first quarter of fiscal 2003 to one major distributor that did not continue for the balance of fiscal 2003.

The cost of clinical laboratory services decreased by $.5 million during this period primarily due to a reduction in personnel costs and the improved efficiency of performing certain esoteric tests in-house that reduced certain other expenses.



Research and development expenses increased by approximately $2.1 million as a result of an increase in the expenses related to the clinical trial activities and other research projects.

Selling expenses increased by $.3 million during this fiscal year, as compared to the prior year's fiscal year. This increase was primarily due to costs associated with the unusually high volume of the orders shipped in the first quarter of fiscal 2003 to one major distributor of research products.

General and administrative expenses increased by $1.2 million due to the increase in overall insurance costs of professional, directors & officers, liability insurance premiums and an increase in data processing personnel costs.

The Company's legal expenses increased by $3.6 million to $5.7 million from $2.1 million as compared to the previous year. This increase is primarily due to the increase in patent infringement proceedings and the increase in the overall legal activities on these infringement proceedings.

The Company's provision for uncollectible accounts receivable decreased by $5.5 million to $8.7 million from $14.2 million as compared to last year at the clinical laboratory division. The percentage of the provision for uncollectible accounts receivable as a relationship to revenue decreased to 30.8% this fiscal year as compared to 50.6% for last year. These decreases were primarily due to the change in the mix of payors and improved collection

procedures and the effect of the canceled HMO contract last year. In addition, during the current fiscal year, the Company wrote off $.6 million as an uncollectible receivable from one of its distributors at the Life Science division.

Interest income was comparable to the prior fiscal year.

In fiscal 2003 and 2002, we recorded a provision for income taxes of $1.8 and $3.4 million, respectively, which was based on the combined effective federal, state and local income tax rates.

Net accounts receivable from our clinical laboratory operations of $14.4 million and $13.8 million represented an average of 174 days and 180 days of operating revenues at July 31, 2003 and 2002, respectively.

Income before provision for taxes on income from the research and development segment activities and related costs was $9.4 million in fiscal 2003, as compared to income before provision for taxes on income of $16.6 million in fiscal 2002. The decrease in the profit resulted primarily from a decrease in direct sales of research products of labeling and detection reagents for the genomics and sequencing markets to one specific customer. Income before provision for taxes on income from the clinical reference laboratories segment amounted to a $3.0 million for fiscal 2003, as compared to a loss of $3.8 million for fiscal 2002. The increase in income before taxes for the clinical laboratory segment was primarily due to the increase in revenue from an increase in higher gross margin reimbursement and an increase in volume of esoteric tests being ordered by physicians. These esoteric tests have higher pricing levels as compared to the regular tests performed at the laboratory.

The Company does not have any "off-balance sheet arrangements" as such term is defined in Item 303(a) (4) of Regulation S-K.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company believes that it does not have any material exposure to market risk associated with interest rate risk, foreign currency exchange rate risk, commodity price risk, equity price risk, or other market risks.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The response to this item is submitted in a separate section of this report. See Item 15(a) (1) and (2)

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.



Item 9A. CONTROLS AND PROCEDURES

Quarterly Evaluation of the Company's Disclosure Controls and Internal Controls. As of the end of the period covered by this Annual Report on Form 10-K, the Company evaluated the effectiveness of the design and operation of its "disclosure controls and procedures" ("Disclosure Controls"), and its "internal controls and procedures for financial reporting" ("Internal Controls"). This evaluation (the "Controls Evaluation") was done under the supervision and with the participation of our chief executive officer ("CEO") and chief financial officer ("CFO"). Rules adopted by the Securities and Exchange Commission ("SEC") require that in this section of the Annual Report we present the conclusions of the CEO and the CFO about the effectiveness of our Disclosure Controls and Internal Controls based on and as of the date of the Controls Evaluation.

Disclosure Controls and Internal Controls. As provided in Rule 13a-14 of the General Rules and Regulations under the Securities and Exchange Act of 1934, as amended, Disclosure Controls are defined as meaning controls and procedures that are designed with the objective of insuring that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, designed and reported within the time periods specified by the SEC's rules and forms. Disclosure Controls include, within the definition under the Exchange Act, and without limitation, controls and procedures to insure that information required to be disclosed by us in our reports is accumulated and communicated to our management, including our CEO and CFO, as appropriate to allow timely decisions regarding disclosure. Internal Controls are procedures which are designed with the objective of providing reasonable assurance that (1) our transactions are properly authorized; (2) our assets are safeguarded against unauthorized or improper use; and (3) our transactions are properly recorded and reported, all to permit the preparation of our financial statements in conformity with generally accepted accounting principles.

Scope of the Controls Evaluation. The evaluation made by our CEO and CFO of our Disclosure Controls and our Internal Controls included a review of the controls' objectives and design, the controls' implementation by the Company and the

effect of the controls on the information generated for use in this Annual Report. In the course of the Controls Evaluation, we sought to identify data errors, control problems or acts of fraud and to confirm that appropriate corrective action, including process improvements, were being undertaken. This type of evaluation will be done on a quarterly basis so that the conclusions concerning controls effectiveness can be reported in our Quarterly Reports on Form 10-Q and Annual Report on Form 10-K. The overall goals of these various evaluation activities are to monitor our Disclosure Controls and our Internal Controls and to make modifications as necessary; our intent in this regard is that the Disclosure Controls and the Internal Controls will be maintained as dynamic systems that change (including with improvements and corrections) as conditions warrant.

Among other matters, we sought in our evaluation to determine whether there were any "significant deficiencies" or "material weaknesses" in the Company's Internal Controls, or whether the Company had identified any acts of fraud involving personnel who have a significant role in the Company's Internal Controls. In the professional auditing literature, "significant deficiencies" are referred to as "reportable conditions"; these are control issues that could have a significant adverse effect on the ability to record, process, summarize and report financial data in the financial statements. A "material weakness" is defined in the auditing literature as a particularly serious reportable condition where the internal control does not reduce to a relatively low level the risk that misstatements caused by error or fraud may occur in amounts that would be material in relation to the financial statements and not be detected within a timely period by employees in the normal course of performing their assigned functions. We also sought to deal with other controls matters in the Controls Evaluation, and in each case if a problem was identified, we considered what revision, improvement and/or correction to make in accord with our on-going procedures. In fiscal 2004, we have established an internal "Hotline" for employees to report to the audit committee acts of fraud in the financial reporting process.

In accord with SEC requirements, our CEO and CFO each have confirmed that, during the most recent fiscal quarter and since the date of the Controls Evaluation to the date of this Annual Report, there have been no significant changes in Internal Controls or in other factors that have materially affected, or are reasonably likely to materially affect, the Company's Internal Controls, including any corrective actions with regard to significant deficiencies and material weaknesses.

Conclusions. Based upon the Controls Evaluation, our CEO and CFO have each concluded that, our Disclosure Controls are effective to ensure that material information relating to the Company and its consolidated subsidiaries is made known to management, including the CEO and CFO, particularly during the period when our periodic reports are being prepared, and that our Internal Controls are effective to provide reasonable assurance that our financial statements are fairly presented in conformity with generally accepted accounting principles.



Item 9B. OTHER INFORMATION

On October 13, 2004, the Company, its wholly owned subsidiary Enzo Life Sciences, Inc. ("Enzo Life Sciences") and Digene Corporation ("Digene") entered into a Settlement and License Agreement (the "Agreement") and a Joint Stipulation and Order of Dismissal with Prejudice (the "Stipulation"). The Agreement provides for (i) the full and final settlement of the Litigation and (ii) the grant to Digene of a non-exclusive, worldwide, royalty-bearing license with respect to such `581 Patent and the remaining patents in the '581 patents global family. The '581 patent is set to expire on April 24, 2018. Pursuant to the Agreement Digene is irrevocably required to pay Enzo Life Sciences an aggregate of $30.5 million of which Life Sciences received U.S. $16 million (the "First Payment") from Digene on October 14, 2004. Digene will pay to Enzo U.S. $16.5 million (subject to the $2 million credit discussed below) ("Additional Irrevocable Payments"); $2.5 million of which shall be paid by November 14, 2005 and $3.5 million per year by November 14 of each of 2006, 2007, 2008 and 2009. In addition, Digene shall pay Enzo Life Sciences Running Royalties on Net Sales of Licensed Products. Each Additional Irrevocable Payment is fully creditable by Digene against the Running Royalties that are due under the Agreement. Digene at its discretion may credit $2 million of the First Payment against either the payment required to be paid by Digene by November 14, 2005 or the Running Royalties due Enzo Life Sciences under the Agreement. The Stipulation which will be filed with the Court by October 15, 2004 dismisses with prejudice all claims, counterclaims and defenses brought or raised by any party to the Litigation.

PART III

Item 10. DIRECTORS AND EXECUTIVE OFFICERS

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 26, 2004 and is incorporated herein by reference.

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 26, 2004 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 26, 2004 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 26, 2004 and is incorporated herein by reference.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

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 26, 2004 and is incorporated herein by reference.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a) (1) Consolidated Financial Statements
Consolidated Balance Sheets - July 31, 2004 and 2003
Consolidated Statements of Operations-
Years ended July 31, 2004, 2003 and 2002
Consolidated Statements of Stockholders' Equity-



Years ended July 31, 2004, 2003 and 2002
Consolidated Statements of Cash Flows-
Years ended July 31, 2004, 2003 and 2002 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 |
|---|---|
| 3(a) | Certificate of Incorporation, as amended March 17, 1980. (1) |
| 3(b) | June 16, 1981 Certificate of Amendment of the Certificate of Incorporation. (2) |
| 3(c) | Certificate of Amendment to the Certificate of Incorporation. (11) |
| 3(d) | Bylaws. (1) |
| 10(a) | 1983 Incentive Stock Option Plan. (4) |
| 10(b) | 1993 Incentive Stock Option Plan. (5) |
| 10(c) | Employment Agreement with Elazar Rabbani. (5) |
| 10(d) | Employment Agreement with Shahram Rabbani. (5) |
| 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(l) | 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(o) | Amendment to Shahram Rabbani's employment agreement. (9) |
| 10(p) | Amendment to Barry Weiner's employment agreement. (9) |



| | |
|---|---|
| 10(q) | Lease Addendum (9) |
| 10(r) | Code of Ethics filed herewith. |
| 10(s) | Settlement and License Agreement with Digene Corporation effective as of September 30, 2004 filed herewith (10) |
| 10(t) | Joint Stipulation and Order of Dismissal with Prejudice dated October , 2004 filed herewith (10). |
| 21 | Subsidiaries of the registrant:<br>Enzo Clinical Labs, Inc., a New York corporation.<br>Enzo Life Sciences, Inc., a New York corporation.<br>Enzo Therapeutics, Inc., a New York corporation. |
| 23 | Consent of Independent Registered Public Accounting Firm filed herewith. |
| 31(a) | Certification of CEO Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 filed herewith. |
| 31(b) | Certification of CFO Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 filed herewith. |
| 32(a) | Certification of CEO Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 filed herewith. |
| 32(b) | Certification of CFO Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 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.

(8) This exhibit was filed with the Company's Registration Statement on Form S-8 (333-87153) and is incorporated herein by reference.

(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.

(10) These exhibits are subject to a confidential treatment request pursuant to the Securities Exchange Act Rule 24b-2.

(b) See Item 15(a)(3), above.
(c) See Item 15(a)(2), above.

**********



S I G N A T U R E S

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 14, 2004 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: /s/ Elazar Rabbani Ph.D. October 14, 2004
Elazar Rabbani
Chairman of Board of Directors
(Principal Executive Officer)

By: /s/ Shahram K. Rabbani October 14, 2004
Shahram K. Rabbani,
Chief Operating Officer, Secretary
and Director

By: /s/ Barry W. Weiner October 14, 2004
Barry W. Weiner,
President, Chief Financial Officer, and Director

By: /s/ John B. Sias October 14, 2004
John B. Sias, Director

By: /s/ John J. Delucca October 14, 2004
John J. Delucca, Director

By: /s/ Irwin Gerson October 14, 2004
Irwin Gerson, Director

By: /s/ Melvin F. Lazar October 14, 2004
Melvin F. Lazar, Director

Marcus A. Conant, Director



FORM 10-K, ITEM 15(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 15(a):

All other schedules for which provision 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.



## Report of Registered Public Accounting Firm

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, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended July 31, 2004. Our audits also included the financial statement schedule listed in the Index at Item 15(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 standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Enzo Biochem, Inc. at July 31, 2004 and 2003 and the consolidated results of their operations and their cash flows for each of the three years in the period ended July 31, 2004, in conformity with United States generally accepted accounting principles. 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 7, 2004, except for Note 14
and the third paragraph of Note 7,
as to which the date is October 14, 2004



## ENZO BIOCHEM, INC
## CONSOLIDATED BALANCE SHEETS

JULY 31, 2004 AND 2003

<TABLE>
<CAPTION>

| ASSETS | 2004 | 2003 |
|---|---|---|
| <S> | <C> | <C> |
| Current assets: | | |
| Cash and cash equivalents ..... | $54,499,100 | $63,267,600 |

| | | |
|---|---|---|
| Marketable securities | 17,241,500 | 15,154,100 |
| Accounts receivable, less allowance for doubtful accounts of $5,503,000 in 2004 and $4,900,000 in 2003 | 14,794,400 | 17,266,400 |
| Income tax receivable | 3,906,900 | 542,300 |
| Inventories | 3,434,300 | 3,421,800 |
| Prepaid expenses | 1,832,500 | 2,232,900 |
| Deferred taxes | 1,974,800 | 1,013,800 |
| Total current assets | 97,683,500 | 102,898,900 |
| Property and equipment, at cost less accumulated depreciation and amortization | 2,414,600 | 2,199,800 |
| Goodwill | 7,452,000 | 7,452,000 |
| Deferred patent costs, less accumulated amortization of $8,383,600 in 2004 and $7,097,200 in 2003 | 2,624,500 | 3,166,200 |
| Other | 159,600 | 161,000 |
| | $110,334,200 | $115,877,900 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Trade accounts payable | $2,092,300 | $1,321,000 |
| Accrued legal fees | 2,050,500 | 1,915,200 |
| Other accrued expenses | 711,600 | 551,000 |
| Accrued research and development expenses | 225,000 | 453,400 |
| Accrued payroll | 258,100 | 703,000 |
| Deferred rent | 86,700 | 232,300 |
| Total current liabilities | 5,424,200 | 5,175,900 |
| Deferred taxes | 444,200 | 1,234,800 |
| Deferred rent | --- | 87,000 |
| Long term payable | 300,000 | --- |
| Commitments and contingencies | | |
| 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: 30,864,800 in 2004 and 29,975,100 in 2003 | 308,600 | 299,800 |
| Additional paid-in capital | 205,920,000 | 199,081,800 |
| Less treasury stock at cost, 349,900 shares | (5,668,900) | --- |
| Accumulated deficit | (96,148,000) | (89,916,400) |
| Accumulated other comprehensive loss | (245,900) | (85,000) |
| Total stockholders' equity | 104,165,800 | 109,380,200 |
| | $110,334,200 | $115,877,900 |

</TABLE>



See accompanying notes.

ENZO BIOCHEM, INC.
CONSOLIDATED STATEMENT OF OPERATIONS

YEARS ENDED JULY 31, 2004, 2003 AND 2002

<TABLE>
<CAPTION>

| | 2004 | 2003 | 2002 |
|---|---|---|---|
| <S> | <C> | <C> | <C> |
| Revenues: | | | |
| Research product revenues | $12,972,200 | $23,253,100 | $25,963,400 |
| Clinical laboratory services | 28,672,200 | 29,513,900 | 28,051,700 |
| | 41,644,400 | 52,767,000 | 54,015,100 |
| Costs and expenses: | | | |
| Cost of research product revenues | 2,517,800 | 3,388,900 | 1,837,100 |
| Cost of clinical laboratory services | 10,586,200 | 9,592,900 | 10,109,500 |
| Research and development expense | 8,078,300 | 8,311,200 | 6,178,600 |

| | | | |
|---|---|---|---|
| Selling expense | 4,334,900 | 3,506,100 | 3,242,800 |
| Provision for uncollectible accounts receivable | 11,986,500 | 9,345,300 | 14,188,400 |
| Legal expense | 6,339,900 | 5,661,000 | 2,111,000 |
| General and administrative expense | 10,032,300 | 8,591,300 | 7,358,200 |
| | 53,875,900 | 48,396,700 | 45,025,600 |
| (Loss) income before interest income and benefit (provision) for taxes on income | (12,231,500) | 4,370,300 | 8,989,500 |
| Interest income | 1,151,800 | 1,355,000 | 1,350,400 |
| (Loss) income before benefit (provision) for taxes on income | (11,079,700) | 5,725,300 | 10,339,900 |
| Benefit (provision) for taxes on income | 4,848,100 | (1,881,300) | (3,417,100) |
| Net (loss) income | ($6,231,600) | $3,844,000 | $6,922,800 |
| Net (loss) income per common share: | | | |
| Basic | $(0.20) | $0.12 | $0.22 |
| Diluted | $(0.20) | $0.12 | $0.21 |
| Denominator for per share calculation: | | | |
| Basic | 31,700,000 | 31,399,000 | 31,359,000 |
| Diluted | 31,700,000 | 32,175,000 | 32,327,000 |

</TABLE>



See accompanying notes

ENZO BIOCHEM, INC
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

YEARS ENDED JULY 31, 2004, 2003 AND 2002

<TABLE>
<CAPTION>

| | Common Stock Shares | Treasury Stock Shares | Common Stock Amount | Treasury Stock Amount | Additional Paid-in Capital | Accumulated Deficit | Accumulated Other Compre-hensive Loss | Total Stock-holders' Equity |
|---|---|---|---|---|---|---|---|---|
| <S> | <C> | <C> | <C> | <C> | <C> | <C> | <C> | <C> |
| Balance at July 31, 2001 | 27,080,100 | --- | $270,700 | --- | $133,136,100 | $(35,889,800) | --- | $97,517,000 |
| Net income for the year ended July 31, 2002 | --- | --- | --- | --- | --- | 6,922,800 | --- | 6,922,800 |
| 5% stock dividend (fair value on date declared) | 1,353,500 | --- | 13,600 | --- | 26,974,000 | (26,987,600) | --- | --- |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Payment of cash for fractional shares for the 5% stock dividend | --- | --- | --- | --- | --- | (96,600) | -- | (96,600) |
| Increase in common stock and paid-in capital due to exercise of stock options | 15,200 | --- | 200 | --- | 127,800 | --- | -- | 128,000 |
| Tax benefit from stock options exercised | --- | --- | --- | --- | 15,000 | --- | -- | 15,000 |
| Issuance of stock for employee 401(k) plan | 11,000 | --- | 100 | --- | 246,900 | --- | -- | 247,000 |
| Balance at July 31, 2002 | 28,459,800 | --- | 284,600 | --- | 160,499,800 | (56,051,200) | -- | 104,733,200 |
| Net income for the year ended July 31, 2003 | --- | --- | --- | --- | --- | 3,844,000 | -- | 3,844,000 |
| Net unrealized loss on available for-sale securities, net of tax | --- | --- | --- | --- | --- | --- | ($85,000) | (85,000) |
| Comprehensive income | | | | | | | | 3,759,000 |
| 5% stock dividend (fair value on date declared) | 1,423,600 | --- | 14,300 | --- | 37,694,900 | (37,709,200) | -- | --- |
| Increase in common stock and paid-in capital due to exercise of stock options | 73,300 | --- | 700 | --- | 630,100 | --- | -- | 630,800 |
| Issuance of stock for employee 401(k) plan | 18,400 | --- | 200 | --- | 257,000 | --- | -- | 257,200 |
| Balance at July 31, 2003 | 29,975,100 | --- | 299,800 | --- | 199,081,800 | (89,916,400) | (85,000) | 109,380,200 |
| Net loss for the year ended July 31, 2004 | --- | --- | --- | --- | --- | (6,231,600) | -- | (6,231,600) |
| Net unrealized loss on available for-sale securities, net of tax | --- | --- | --- | --- | --- | --- | (160,900) | (160,900) |
| Comprehensive loss | | | | | | | | (6,392,500) |
| Purchase of treasury stock | --- | 349,900 | --- | $(5,668,900) | --- | --- | -- | (5,668,900) |
| Increase in common stock and paid-in capital due to exercise of stock options | 873,900 | --- | 8,700 | --- | 6,556,100 | --- | -- | 6,564,800 |
| Issuance of stock for employee 401(k) plan | 15,800 | --- | 100 | --- | 282,100 | --- | -- | 282,200 |
| Balance at July 31, 2004 | 30,864,800 | 349,900 | $308,600 | $(5,668,900) | $205,920,000 | $(96,148,000) | $(245,900) | $104,165,800 |

</TABLE>



See accompanying notes

ENZO BIOCHEM, INC
CONSOLIDATED STATEMENT OF CASH FLOWS

YEARS ENDED JULY 31, 2004, 2003 AND 2002

<TABLE>

<CAPTION>

| | 2004 | 2003 | 2002 |
|---|---|---|---|
| <S> | <C> | <C> | <C> |
| Cash flows from operating activities: | | | |
| Net (loss) income | ($6,231,600) | $3,844,000 | $6,922,800 |
| Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities: | | | |
| Depreciation and amortization of property and equipment | 1,076,000 | 1,058,000 | 989,900 |
| Amortization of costs in excess of fair value of net tangible assets acquired | | --- | 370,700 |
| Amortization of deferred patent costs | 1,285,500 | 750,000 | 793,600 |
| Provision for uncollectible accounts receivable | 11,986,500 | 9,345,300 | 14,188,400 |
| Deferred income tax provision | (1,650,700) | (128,100) | 720,000 |
| Issuance of stock for employee 401(k) plan | 282,200 | 257,200 | 247,000 |
| Tax benefit from stock options exercised | --- | --- | 15,000 |
| Deferred rent | (232,600) | (195,400) | (160,300) |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable before provision for uncollectible amounts | (9,514,500) | (6,344,200) | (9,896,900) |
| Inventories | (12,500) | 768,400 | (2,170,400) |
| Prepaid expenses | 400,400 | (741,900) | (358,700) |
| Income taxes receivable | (3,364,600) | 1,426,300 | (1,618,400) |
| Trade accounts payable and accrued expenses | 931,900 | (374,700) | (527,200) |
| Accrued research and development expenses | (228,400) | 453,400 | -- |
| Accrued legal fees | 135,300 | 1,775,200 | (111,000) |
| Accrued payroll | (444,900) | 227,100 | 153,600 |
| Total adjustments | 649,600 | 8,276,600 | 2,635,300 |
| Net cash (used in) provided by operating activities | (5,582,000) | 12,120,600 | 9,558,100 |
| Cash flows from investing activities: | | | |
| Capital expenditures | (1,303,800) | (956,700) | (620,400) |
| Patent costs deferred | (443,800) | (353,900) | (490,700) |
| Purchase of marketable securities | (2,349,000) | (15,293,400) | -- |
| Security deposits | 1,400 | (14,800) | (14,400) |
| Net cash used in investing activities | (4,095,200) | (16,618,800) | (1,125,500) |
| Cash flows from financing activities: | | | |
| Payment for fractional shares of stock dividend | --- | --- | (96,600) |
| Proceeds from the exercise of stock options | 895,700 | 630,800 | 128,000 |
| Proceeds from insurance loss | 13,000 | --- | -- |
| Net cash provided by financing activities | 908,700 | 630,800 | 31,400 |
| Net (decrease) increase in cash and cash equivalents | (8,768,500) | (3,867,400) | |

| | | | |
|---|---|---|---|
| 8,464,000 | | | |
| Cash and cash equivalents at the beginning of the year ..... | 63,267,600 | 67,135,000 | 58,671,000 |
| Cash and cash equivalents at the end of the year ..... | $54,499,100 | $63,267,600 | $67,135,000 |

</TABLE>



See accompanying notes

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

JULY 31, 2004, 2003 AND 2002

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 through October 2004. The market values of these securities, as determined by quoted sources, aggregated $54,449,100 and $63,267,600 at July 31, 2004 and 2003, respectively, and approximated cost at the respective dates.

MARKETABLE SECURITIES

The Company invests funds that are not required for immediate operating needs both in income bond mutual funds and in a diversified portfolio of debt securities. Management determines the appropriate classification of these marketable securities at the time of purchase and reevaluates such designation as of each balance sheet date. The Company classifies its marketable securities as "available for sale" and, accordingly, carries these investments at their aggregate fair values. Unrealized gains or losses, net of tax, on these marketable securities are included as a separate component of stockholders' equity. Realized gains & losses and declines in value judged to be other-than-temporary on the marketable securities are included in investment income. The cost of securities sold is based on the specific identification method.

CONCENTRATION OF CREDIT RISK

Financial instruments that subject the Company to significant concentrations of credit risk primarily consist of cash and cash equivalents, marketable securities and the net accounts receivable. The Company's cash equivalents and marketable securities are invested in financial instruments with high credit ratings.

Approximately 89% at July 31, 2004 and 83% at July 31, 2003, 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 clinical laboratory's accounts receivable is limited due to the diversity of the Company's client base and to the various numbers of insurance carriers and the numerous individual patient accounts. As is standard in the health care industry, substantially all

of the Company's clinical laboratory's accounts receivable is with numerous third party insurance carriers and individual patient accounts. 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 years ended July 31, 2004, 2003 and 2002 were approximately 19%, 11% and 10%, respectively, of the Company's total revenue. The clinical reference laboratory industry is characterized by a significant amount of uncollectible accounts receivable related to the inability to receive accurate and timely billing information in order to forward it to the third party payors for reimbursement, and the inaccurate information received from the covered individual patients for unreimbursed unpaid amounts. The Company's provision for uncollectible accounts receivable is within historical expectations.





NOTE 1 - BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONT'D)

Research product revenue from one major distributor represented approximately 0%, 22% and 23% of the consolidated revenues in fiscal 2004, 2003 and 2002, respectively, under a non-exclusive distribution and supply agreement. Research product revenue from this one major distributor accounted for approximately 0% and 50% of the Company's total research product revenues in fiscal 2004 and 2003, respectively.

INVENTORIES

Inventories are stated at the lower of cost (first-in, first-out) or market. Work-in-process and finished goods inventories consist of material, labor, outside processing costs and manufacturing overhead.

PROPERTY AND EQUIPMENT

Property and equipment is stated at cost, and depreciated on the straight-line basis 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.

PATENT COSTS

The Company capitalizes certain legal costs directly incurred in pursuing patent applications as deferred patent costs under its research and development segment. When such applications result in an issued patent, the related costs are amortized over a ten year period, using the straight-line method. The Company reviews its issued patents and pending patent applications, and if it determines to abandon a patent application or that an issued patent no longer has economic value, the unamortized balance in deferred patent costs relating to that patent is immediately expensed.

REVENUE RECOGNITION

The Company has certain non-exclusive distribution agreements, which provide for consideration to be paid to the distributors for the manufacture of certain products. In accordance with EITF 00-25 and EITF 01-09, the Company records such consideration provided to distributors under these non-exclusive distribution agreements as a reduction to research product revenues. The revenue from these non-exclusive distribution agreements are recognized when shipments are made from the distributors to their respective customers and reported to the Company.

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, excluding certain non-exclusive distribution agreement revenues, 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 $384,000, $414,000 and $325,000 for fiscal years ended July 31, 2004, 2003 and 2002, respectively.





NOTE 1 - BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONT'D)

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.

RECLASSIFICATIONS

Certain amounts in prior years have been reclassified to conform to current year presentation.

GOODWILL AND OTHER INTANGIBLES

The Company follows the provisions of the Financial Accounting Standards Board ("FASB") Statement No. 142 ("SFAS 142"), Goodwill and Other Intangibles. Under SFAS 142, goodwill is no longer subject to amortization over its estimated useful life. Rather, goodwill is subject to at least an annual assessment for impairment by applying a fair-value based test. Additionally, an acquired intangible asset should be separately recognized if the benefit of the intangible asset is obtained through contractual or other legal rights, or if intangible asset can be sold, transferred, licensed, rented or exchanged, regardless of the acquirer's intent to do so. All of the Company's goodwill is related to their clinical reference laboratory segment. The Company adopted SFAS No. 142 as of August 1, 2002 and has performed the requisite impairment testing. The Company has performed their annual impairment testing on the first day of the fourth quarter of their fiscal year. Based on this testing, there is no impairment to the goodwill recorded on the accompanying balance sheet.

SFAS 142 requires the disclosure of net income and earning per share computed on a pro forma basis by reversing the goodwill amortized in the periods presented. Such pro forma disclosures are required in the period of adoption and thereafter until all periods presented reflect goodwill accounted for in accordance with SFAS 142. The goodwill amortized in the year ended July 31, 2002 was $370,700. Therefore, had SFAS 142 been effective prior to August 1, 2002, the Company's net income would have been $7,293,500 for the year ended July 31, 2002. Basic net income per share would have been $.24 for the year ended July 31, 2002. Diluted net income per share would have been $.24 for the year ended July 31, 2002.

IMPAIRMENT OF LONG-LIVED ASSETS

The Company accounts for its investments in long-lived assets in accordance with FASB Statement No. 144 ("SFAS No. 144"), Accounting for the Impairment or Disposal of Long-Lived Assets and Long-Lived Assets. The Company adopted SFAS No. 144 on August 1, 2002. SFAS No. 144 requires a company to review its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Factors the Company considers important, which could trigger an impairment review, include, among others, the following:

- a significant adverse change in the extent or manner in which a long-lived asset is being used;

- a significant adverse change in the business climate that could affect the value of a long-lived asset; and

- a significant decrease in the market value of assets.





NOTE 1 - BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONT'D)

If the Company determines that the carrying value of long-lived assets may not be recoverable, based upon the existence of one or more of the above indicators of impairment, the Company compares the carrying value of the asset group to the undiscounted cash flows expected to be generated by the group. If the carrying value exceeds the undiscounted cash flows, an impairment charge may be needed. To determine the amount of the impairment charge, the Company compares the carrying value of the applicable asset group to its fair value. If the fair value is less than the carrying value, such amount is recognized as an impairment charge. As of July 31, 2004 the Company has not recorded an impairment charge.

STOCK DIVIDEND

The Company declared a 5% stock dividend on October 5, 2004 payable November 15, 2004 to shareholders of record as of October 25, 2004. The Company declared a 5% stock dividend on June 10, 2003 payable July 14, 2003 to shareholders of record as of June 30, 2003. The Company declared a 5% stock dividend on January 23, 2002 payable February 27, 2002 to shareholders of record as of February 2, 2003. The per share data has been adjusted retroactively to reflect the stock dividend declared on October 5, 2004. The consolidated balance sheet and consolidated statement of stockholders' equity do not give effect to the dividend declared October 5, 2004. The shares and per share data have been adjusted to retroactively reflect the stock dividends in fiscal 2003 and 2002. The Company recorded a charge to accumulated deficit and a credit to common stock and additional paid-in capital in the amounts of approximately $37,709,000 and $26,988,000 in fiscal 2003 and fiscal 2002, respectively, which reflects the fair value of the dividends on the dates of declaration.

NET (LOSS) INCOME PER SHARE

The Company applies SFAS No. 128, "Earnings per Share." SFAS No. 128 establishes standards for computing and presenting earnings per share. Basic net (loss) income per share represents net (loss) income divided by the weighted average number of common shares outstanding during the period. The dilutive effect of potential common shares, consisting of outstanding stock options, is determined using the treasury stock method in accordance with SFAS No. 128. Diluted weighted average shares outstanding for 2004 do not include the potential common shares from stock options because to do so would have been antidilutive. Accordingly, basic and diluted net loss per share is the same. The number of potential common shares excluded from the calculation of diluted earnings per share during the year ended July 31, 2004 was 798,349 shares.

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

<TABLE>
<CAPTION>

| | 2004 | 2003 | 2002 |
|---|---|---|---|
| <S> | <C> | <C> | <C> |
| Numerator: | | | |
| Net (loss) income for numerator for basic and diluted net income per common share | $(6,231,600) | $3,844,000 | $6,922,800 |
| Denominator: | | | |
| Denominator for basic net income per common share-weighted-average shares | 31,700,000 | 31,399,000 | 31,359,000 |
| Effect of dilutive employee and director stock options and warrants | --- | 776,000 | 968,000 |
| Denominator for diluted net income per share-adjusted weighted-average shares | 31,700,000 | 32,175,000 | 32,327,000 |
| Basic net (loss) income per share | $(.20) | $.12 | $.22 |
| Diluted net (loss) income per share | $(.20) | $.12 | $.21 |

</TABLE>

NOTE 1 - BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONT'D)

Basic earnings per share have been computed using the weighted-average number of shares of common stock outstanding. Diluted earnings per share has been computed using the basic weighted-average shares of common stock issued plus outstanding stock options, in the periods in which such options have a dilutive effect under the treasury stock method.

STOCK COMPENSATION PLANS

The Company accounts for stock option grants to employees under the recognition and measurement principles of APB Opinion No. 25, "Accounting for Stock Issued to Employees," and related Interpretations. Under APB No. 25, because the exercise price of the Company's employee stock options equals the market price of the underlying stock on the date of grant, no compensation expense is recorded.

Pro forma information regarding net (loss) income applicable to common stockholders is required by FASB Statement No. 123 ("SFAS 123"), "Accounting for Stock-Based Compensation," which also requires that the information be determined as if the Company has accounted for its stock options under the fair value method of that statement. For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period. The fair value for these options was estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions used for all grants in the years ended July 31, 2004, 2003, and 2002: no dividend yield, weighted-average expected life of the option of seven years, risk-free interest rate ranges of 3% to 6.88% and a volatility of .74, ..77 and .78 for all grants.

The Company follows the provisions of FASB Statement No. 148 ("SFAS 148"), "Accounting for Stock-Based Compensation - Transition and Disclosure." SFAS No. 148 amends SFAS No. 123, "Accounting for Stock-Based Compensation," to provide alternative methods of transition to SFAS No. 123's fair value method of accounting for stock-based employee compensation. SFAS No. 148 also amends the disclosure provisions of SFAS No. 123 to require disclosure in the summary of significant accounting policies of the effects of an entity's accounting policy with respect to stock-based employee compensation on reported net income. While SFAS No. 148 does not amend SFAS No. 123 to require companies to account for employee stock options using the fair value method, the disclosure provisions of SFAS No. 148 are applicable to all companies with stock-based employee compensation, method of SFAS No. 123 or the intrinsic value method of APB No. 25. The Company adopted SFAS No. 148 effective January 31, 2004.

The following table illustrates the effect on net (loss) income if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based (loss) compensation:

<TABLE>
<CAPTION>

| Year ended July 31, | 2004 | 2003 | 2002 |
|---|---|---|---|
| <S> | <C> | <C> | <C> |
| Reported net (loss) income | ($6,231,600) | $3,844,000 | $6,922,800 |
| Stock compensation expense included in net income | --- | --- | --- |
| Pro forma compensation expense | (3,239,800) | (3,010,900) | (2,597,800) |
| Pro forma net (loss) income | ($9,471,400) | $833,100 | $4,325,000 |
| Pro forma (loss) earnings per share: | | | |
| Basic | ($.30) | $.03 | $.14 |
| Diluted | ($.30) | $.03 | $.14 |

</TABLE>



NOTE 2 - SUPPLEMENTAL DISCLOSURE FOR STATEMENT OF CASH FLOWS

In the years ended July 31, 2004, 2003 and 2002, the Company paid cash for income taxes of approximately $219,000, $583,000 and $4,300,000 respectively.

In fiscal 2004, certain officers exercised 769,290 shares of incentive stock options. The officers surrendered 349,932 of previously owned shares of the Company's common stock to be utilized to exercise the stock options. The Company recorded the 349,932 of surrendered shares as treasury stock of approximately $5.6 million as a non cash transaction.

In fiscal 2004, the Company purchased the assets of a privately held company for $650,000, of which 350,000 was paid in cash during fiscal 2004 and the remaining $300,000 is to be paid in two $150,000 installments on the 18 and 36 month anniversary date of the acquisition. The $300,000 is a non-cash transaction at July 31, 2004.

NOTE 3 - MARKETABLE SECURITIES

The following is a summary of available for-sale securities at July 31, 2004 and 2003:

<TABLE>
<CAPTION>

| | Fiscal Years Ended July 31, | | Unrealized Holding Gain (Loss) Years Ended July 31, | |
|---|---|---|---|---|
| | 2004 | 2003 | 2004 | 2003 |
| <S> | <C> | <C> | <C> | <C> |
| Income bond mutual fund | $15,401,300 | $15,154,100 | $(132,300) | $(139,300) |
| Marketable securities | | | | |
| U.S. Government and agency securities | 1,063,100 | --- | --- | --- |
| Corporate and other debt securities | 777,100 | | (129,400) | --- |
| (Average of remaining maturity of approximately four months at July 31, 2004) | $17,241,500 | $15,154,100 | $(261,700) | ($139,300) |

</TABLE>

There were no realized gains during fiscal 2004 and 2003 on the Company's marketable securities.

The following is a summary of income tax effects relating to other comprehensive income (loss):

<TABLE>
<CAPTION>

| | Before-Tax Amount | Tax (Expense) or Benefit | Net-of-Tax Amount |
|---|---|---|---|
| <S> | <C> | <C> | <C> |
| Fiscal 2004 unrealized loss ..... | ($261,700) | $100,800 | ($160,900) |
| Fiscal 2003 unrealized loss ..... | (139,300) | 54,300 | (85,000) |
| Cumulative balance at July 31, 2004... | ($401,000) | $155,100 | ($245,900) |

</TABLE>

NOTE 4 - INVENTORIES

At July 31, 2004 and 2003 inventories consist of:

| | 2004 | 2003 |
|---|---|---|
| Raw materials..... | $124,900 | $167,900 |
| Work in process..... | 2,188,000 | 2,057,900 |
| Finished products..... | 1,121,400 | 1,196,000 |
| | $3,434,300 | $3,421,800 |

NOTE 5 - PROPERTY AND EQUIPMENT

At July 31, 2004 and 2003 property and equipment consist of:

<TABLE>
<CAPTION>

| | 2004 | 2003 |
|---|---|---|
| <S> | <C> | <C> |
| Laboratory machinery and equipment..... | $1,901,900 | $1,866,700 |
| Leasehold improvements..... | 2,543,400 | 2,327,400 |
| Office furniture and equipment..... | 5,650,300 | 4,896,500 |
| | 10,095,600 | 9,090,600 |
| Accumulated depreciation and amortization..... | 7,681,000 | 6,890,800 |
| | $2,414,600 | $2,199,800 |

</TABLE>

NOTE 6 - LEASE OBLIGATIONS

The Company leases its office and laboratory space under several leases that expire between November 30, 2004 and December 2008. Certain officers / directors of the Company own the building that the Company uses as its main facility for laboratories and research and manufacturing. In addition to the minimum annual rentals of space, this lease is subject to an escalation clause. Rent expense under this lease approximated $1,370,000, $1,302,000 and $1,238,000 in fiscal 2004, 2003 and 2002, respectively.

The Company has various other operating leases for office and laboratory space, which expire through fiscal 2009.

Total consolidated rent expense incurred by the Company during fiscal 2004, 2003 and 2002 was approximately $1,801,000, $1,742,000 and $1,710,000 respectively. Minimum annual rentals under operating lease commitments for fiscal years ending July 31 are as follows:

| | |
|---|---|
| 2005 | $705,000 |
| 2006 | $288,000 |
| 2007 | $210,000 |
| 2008 | $169,000 |
| 2009 | $21,000 |
| | $1,393,000 |

NOTE 7 - LITIGATION

PATENT INFRINGEMENT

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. On July 15, 2002, the Court of Appeals for the Federal Circuit reversed the judgment of invalidity and remanded the case to the district court for further proceedings. In March 2003, settlements were reached with bioMerieux and Chugai; the settlements did not have a material monetary impact on the Company. In July 2004, the district court again granted another motion by the remaining defendants (Gen-Probe and Becton Dickinson) that all claims of the Company's patent are invalid. The Company has filed an appeal of that judgment. There can be no assurance that the Company will be successful in the on-going proceedings. However, even if the Company is not successful, management does not believe that there will be a significant adverse monetary impact to the Company.



ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

JULY 31, 2004, 2003 AND 2002

On March 6, 2002, the Company was named, along with certain of its officers and directors among others, in a complaint entitled Lawrence F. Glaser and Maureen Glaser, individually and on behalf of Kimberly, Erin, Hannah, and Benjamin Glasser v. Hyman Gross, Barry Weiner, Enzo Biochemical Inc., Elazar Rabbani, Shahram Rabbani, John Delucca, Dean Engelhardt, Richard Keating, Doug Yates and Docs 1-50, in the U.S. District Court for the Eastern District of Virginia. The complaint was filed by an investor in the Company who has filed for bankruptcy protection and his family. The complaint alleged securities and common law fraud and breach of fiduciary duty and seeks in excess of $150 million in damages. On August 22, 2002, the complaint was voluntarily dismissed; however a new substantially similar complaint was filed at the same time. On October 21, 2002, the Company and the other defendants filed a motion to dismiss the complaint, and the plaintiffs responded by amending the complaint and dropping their claims against defendants Keating and Yates. On November 18, 2002, the Company and the other defendants again moved to dismiss the Amended Complaint. On July 16, 2003, the Court issued a Memorandum Opinion dismissing the Amended Complaint in its entirety with prejudice. Plaintiffs thereafter moved for reconsideration but the Court denied the motion on September 8, 2003. The plaintiffs subsequently appealed to the Fourth Circuit and that appeal is presently pending. The Company does not believe that the complaint has any merit and was correctly dismissed, and intends to continue to defend the complaint vigorously in any event.

In March 2002, Enzo Life Sciences, a subsidiary of the Company, filed suit in the United States District Court for the District of Delaware against Digene Corp., charging it with infringing the Company's U.S. Patent No. 6,221,581 B1, which concerns a novel process for detecting nucleic acids of interest. On May 31, 2002, Digene filed counterclaims in that suit against Enzo Life Sciences and the Company, including business tort counterclaims relating to the `581 patent. On October 13, 2004, the Company, its wholly owned subsidiary Enzo Life Sciences, Inc. ("Enzo Life Sciences") and Digene Corporation ("Digene") entered into a Settlement and License Agreement (the "Agreement") and a Joint Stipulation and Order of Dismissal with Prejudice (the "Stipulation"). The Agreement provides for (i) the full and final settlement of the Litigation and (ii) the grant to Digene of a non-exclusive, worldwide, royalty-bearing license with respect to such `581 Patent and the remaining patents in the '581 patents global family. The '581 patent is set to expire on April 24, 2018. Pursuant to the Agreement Digene is irrevocably required to pay Enzo Life Sciences an aggregate of $30.5 million of which Life Sciences received U.S. $16 million (the "First Payment") from Digene on October 14, 2004. In addition, Digene has irrevocable agreed to pay to Enzo U.S. $16.5 million (subject to the $2 million credit discussed below) ("Additional Irrevocable Payments"); $2.5 million of which shall be paid by November 14, 2005 and $3.5 million per year by November 14 of each of 2006, 2007, 2008 and 2009. Digene will pay to Enzo Life Sciences Running Royalties on Net Sales of Licensed Products. Each Additional Irrevocable Payment is fully creditable by Digene against the Running Royalties that are due under the Agreement. Digene at its discretion may credit $2 million of the First Payment against either the payment required to be paid by Digene by November 14, 2005 or the Running Royalties due Enzo Life Sciences under the Agreement. The Stipulation which will be filed with the Court by October 15, 2004 dismisses with prejudice all claims, counterclaims and defenses brought or raised by any party to the Litigation.

In October 2002, the Company filed suit in the United States District Court of the Southern District of New York against Amersham plc, Amersham Biosciences, Perkin Elmer, Inc., Perkin Elmer Life Sciences, Inc., Sigma-Aldrich Corporation, Sigma Chemical Company, Inc., Molecular Probes, Inc. and Orchid Biosciences, Inc. In January 2003, the Company amended its complaint to include defendants Sigma Aldrich Co. and Sigma Aldrich, Inc. The counts set forth in the suit are for breach of contract; patent infringement; unfair competition under state law; unfair competition under federal law; tortious interference with business relations; and fraud in the inducement of contract. The complaint alleges that these counts arise out of the defendants' breach of distributorship agreements with the Company concerning labeled nucleotide products and technology, and the defendants' infringement of patents covering the same. In April, 2003, the Court directed that individual complaints be filed separately against each defendant. A number of the defendants have answered the individual complaints and asserted a variety of affirmative defenses and counterclaims. Fact discovery is currently scheduled to close on May 6, 2005. The Court will conduct a claim construction hearing on June 28, 2005. There can be no assurance that the Company will be successful in this litigation. However, even if the Company is not successful, management does not believe that there will be a significant adverse monetary impact to the Company.

On October 28, 2003, the Company and Enzo Life Sciences, Inc., a subsidiary of the Company, filed suit in the United States District Court of the Eastern District of New York against Affymetrix, Inc. The Complaint alleges that Affymetrix improperly transferred or distributed substantial business assets of the Company to third parties, including portions of the Company's proprietary technology, reagent systems, detection reagents and other intellectual property. The Complaint also charges that Affymetrix failed to account for certain shortfalls in sales of the Company's products, and that Affymetrix improperly induced collaborators and customers to use the Company's products in unauthorized fields or otherwise in violation of the agreement. The Complaint seeks full compensation from Affymetrix to the Company for its substantial damages, in addition to injunctive and declaratory relief to prohibit, among other things, Affymetrix's unauthorized use, development, manufacture, sale, distribution and transfer of the Company's products, technology, and/or intellectual property, as well as to prohibit Affymetrix from inducing collaborators, joint venture partners, customers and other third parties to use the Company's products in violation of the terms of the agreement and the Company's rights. Subsequent to the filing of the Complaint against Affymetrix, Inc. referenced above, on or about November 10, 2003, Affymetrix, Inc. filed its own complaint against the Company and its subsidiary, Enzo Life Sciences, Inc., in the United States District Court for the Southern District of New York, seeking among other things, declaratory relief that Affymetrix, Inc., has not breached the parties' agreement, that it has not infringed certain of Enzo's Patents, and that certain of Enzo's patents are invalid. The Affymetrix complaint also seeks damages for alleged breach of the parties' agreement, unfair competition, and tortuous interference, as well as certain injunction relief to prevent alleged unfair competition and tortuous interference. The Company does not believe that the complaint has any merit and intends to defend vigorously. Affymetrix also moved to transfer venue of Enzo's action to the Southern District of New York, where other actions commenced by Enzo were pending as well as Affymetrix's subsequently filed action. On January 30, 2004, Affymetrix's motion to transfer was granted. Accordingly, the Enzo and Affymetrix actions are now both pending in the Southern District of New York. Pleadings have not been completed and discovery has not commenced.

On June 2, 2004 Roche Diagnostic GmbH and Roche Molecular Systems, Inc. (collectively "Roche") filed suit in the U.S. District Court of the Southern District of New York against Enzo Biochem, Inc. and Enzo Life Sciences, Inc. (collectively "Enzo"). The complaint was filed after Enzo rejected Roche's latest cash offer to settle Enzo's claims for, INTER ALIA, alleged breach of contract and misappropriation of Enzo's assets. The complaint seeks declaratory judgment (i) of patent invalidity with respect to Enzo's 4,994,373 patent, (ii) of no breach by Roche of its 1994 Distribution and Supply Agreement with Enzo (the "1994 Agreement"), (iii) that non-payment by Roche to Enzo for certain sales of Roche products does not constitute a breach of the 1994 Agreement, and (iv) that Enzo's claims of ownership to proprietary inventions, technology and products developed by Roche are without basis. In addition, the suit claims tortious interference and unfair competition. The Company does not believe that the complaint has merit and intends to vigorously respond to such action with appropriate affirmative defenses and counterclaims.

On June 7, 2004, the Company and its wholly-owned subsidiary, Enzo Life Sciences, Inc., filed suit in the United States District Court for the District of Connecticut against Applera Corporation and its wholly-owned subsidiary Tropix, Inc. The complaint alleges infringement of six patents (relating to DNA sequencing systems, labelled nucleotide products, and other technology). Yale University is the owner of four of the patents and the Company is the exclusive licensee. Accordingly, Yale is also a plaintiff in the lawsuit. Yale and Enzo are aligned in protecting the validity and enforceability of the patents. Enzo Life Sciences is the owner of the remaining two patents. The complaint seeks permanent injunction and damages (including treble damages for wilful infringement). Defendants answered the complaint on July 29, 2004. The answer pleads affirmative defences of invalidity, estoppel and laches and asserts counterclaims of non-infringement and invalidity. A trial date has not been set. Discovery commences on September 15, 2004. There can be no assurance that the Company will be successful in this litigation. Even if the Company is not successful, management does not believe that there will be a significant adverse monetary impact on the Company.





NOTE 8 - INCOME TAXES

The Company accounts for income taxes under the provisions of SFAS No. 109 "Accounting for Income Taxes".

<TABLE>
<CAPTION>

| | 2004 | 2003 | 2002 |
|---|---|---|---|

| <S> | <C> | <C> | <C> |
|---|---|---|---|
| Current | | | |
| Federal | ($3,288,000) | $1,828,000 | $2,211,600 |
| State and local | 191,500 | 181,400 | 485,500 |
| Deferred | (1,751,600) | (128,100) | 720,000 |
| (Benefit) provision for income taxes... | $(4,848,100) | $1,881,300 | $3,417,100 |

</TABLE>

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>

| <S> | 2004 <C> | 2003 <C> |
|---|---|---|
| Current deferred tax assets: | | |
| Provision for uncollectible accounts receivable... | $1,072,500 | $837,100 |
| State and local taxes carry forward losses ..... | 720,900 | --- |
| Other ..... | 181,400 | 176,700 |
| Current deferred tax assets ..... | 1,974,800 | 1,013,800 |
| Non current deferred tax liability: | | |
| Deferred patent costs ..... | (906,800) | (1,234,800) |
| Non current deferred tax asset: | | |
| Depreciation ..... | 462,000 | --- |
| Non current deferred tax liability, net ..... | (444,800) | (1,234,800) |
| Net deferred tax asset (liability) ..... | $1,530,600 | ($221,000) |

</TABLE>

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or the entire 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 that can be implemented by the Company in making this assessment.

The provisions for income taxes were at rates different from U.S. federal statutory rates for the following reasons:

<TABLE>
<CAPTION>

| <S> | 2004 <C> | 2003 <C> | 2002 <C> |
|---|---|---|---|
| Federal statutory rate ..... | (34%) | 34% | 34% |
| Expenses not deductible for income tax return purposes ..... | 3% | 2% | 2% |
| State income taxes, net (benefit) of federal tax deduction ..... | (4%) | 3% | 5% |
| Benefit of foreign sales ..... | (2%) | (4%) | (4%) |
| Fixed asset basis difference..... | (8%) | --- | --- |
| Benefit of tax credits ..... | --- | --- | (4%) |
| Other ..... | 1% | (2%) | --- |
| | (44%) | 33% | 33% |

</TABLE>

NOTE 9 - STOCKHOLDERS' EQUITY

TREASURY STOCK

In fiscal 2004, certain officers exercised 769,290 shares of incentive stock options. The officers surrendered 349,932 of previously owned shares of the Company's common stock to be utilized to exercise the stock options. The Company recorded the 349,932 of surrendered shares as treasury stock of approximately $5.6 million as a non cash transaction.

NOTE 9 - STOCKHOLDERS' EQUITY (CON'T)

INCENTIVE STOCK OPTION PLAN

The Company has incentive stock option plans ("1993 plan" and "1994 plan") under which the Company may grant options for up to 2,110,650 shares (1993 plan) and up to 1,336,745 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 options plan ("1999 plan") under which the Company may grant up to 2,202,244 shares of common stock. The exercise price of options granted under such plans is equal to or greater than fair market value of the common stock on the date of grant. The options granted pursuant to the plans may be either incentive stock options or no statutory 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 option plan for the years ended July 31, 2004, 2003 and 2002 under SFAS No. 123 is as follows:

<TABLE>
<CAPTION>

| | 2004 | | 2003 | | 2002 | |
|---|---|---|---|---|---|---|
| | Options | Weighted-Average Exercise Price | Options | Weighted-Average Exercise Price | Options | Weighted-Average Exercise Price |
| <S> | <C> | <C> | <C> | <C> | <C> | <C> |
| Outstanding at beginning of year | 3,397,087 | $9.88 | 2,841,401 | $9.38 | 2,864,595 | $8.85 |
| Granted | 428,925 | $17.02 | 661,225 | $11.76 | 26,046 | $20.20 |
| Exercised | (917,539) | $7.16 | (79,838) | $6.85 | (17,630) | $7.33 |
| Terminated | (51,672) | $10.13 | (25,701) | $12.51 | (31,611) | $10.69 |
| Outstanding at end of year | 2,856,801 | $11.86 | 3,397,087 | $9.88 | 2,841,401 | $9.38 |
| Exercisable at end of year | 1,770,492 | $10.54 | 2,490,003 | $8.98 | 2,297,908 | $8.81 |
| Weighted average fair value of options granted during year | | $12.40 | | $8.49 | | $14.18 |

</TABLE>

The following table summarizes information for stock options outstanding at July 31, 2004:

<TABLE>
<CAPTION>

| Options Outstanding | | | | Options Exercisable | |
|---|---|---|---|---|---|
| Range of Exercise Prices | Shares | Weighted-Average Remaining Contractual Life | Weighted-average Exercise Price | Shares | Weighted-average Exercise Price |
| <S> | <C> | <C> | <C> | <C> | <C> |
| $5.42-8.08 | 390,660 | 3.32 years | $6.00 | 390,660 | $6.00 |
| $8.32-12.25 | 1,741,557 | 5.52 years | $11.09 | 1,168,734 | $11.08 |
| $12.93-14.36 | 644,708 | 1.98 years | $15.92 | 135,563 | $15.92 |

</TABLE>

| | | | | | |
|---|---|---|---|---|---|
| $20.20-24.42 | 61,643 | 7.00 years | $21.42 | 57,302 | $21.42 |
| $36.05 | 18,232 | 5.45 years | $36.05 | 18,232 | $36.05 |
| | 2,856,801 | | | 1,770,492 | |

</TABLE>

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





NOTE 9 - STOCKHOLDERS' EQUITY (CON'T)

RESTRICTED STOCK INCENTIVE PLAN

The Company has a restricted stock incentive plan whereby the Company may award up to 281,420 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, 2004, the Company has not awarded any shares of common stock under this plan.

**********

As of July 31, 2004, the Company has reserved 3,640,359 shares under the arrangements described above.

NOTE 10 - 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.

NOTE 11 - ACQUISITIONS

In fiscal 2004, the Company purchased the assets of a privately held company for $650,000, of which $350,000 was paid in cash during fiscal 2004 and the remaining $300,000 is to be paid in two $150,000 installments on the 18 and 36 month anniversary date of the acquisition. The Company has allocated the entire purchase price to patents as of July 31, 2004.

NOTE 12 - 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, 2004, 2003 and 2002, the Company has authorized employer contributions of 50% of the employees' contribution up to 10% of the employees' compensation in Enzo Biochem, Inc. common stock. The 401(k) employer contributions expense was $282,300, $257,200, and $247,000 in fiscal years 2004, 2003 and 2002, respectively.

NOTE 13 - QUARTERLY FINANCIAL DATA (UNAUDITED)

The following table contains statement of operations information for each quarter of fiscal 2004 and 2003. The Company believes that the following information reflects all normal recurring adjustments necessary for a fair presentation of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.





Unaudited quarterly financial data (in thousands, except per share amounts) for fiscal 2004 and 2003 is summarized as follows:

<TABLE>
<CAPTION>

| | Three Months Ended | | | |
|---|---|---|---|---|
| October 31, 2003 | January 31, 2004 | April 30, 2004 | July 31, 2004 | |

| | | | | |
|---|---|---|---|---|
| <S> | <C> | <C> | <C> | <C> |
| Revenues | $10,273 | $11,028 | $11,765 | $8,578 |
| Gross profit | 7,567 | 8,099 | 8,705 | 4,167 |
| Loss before benefit for taxes on income | ($816) | ($2,755) | ($891) | ($6,618) |
| Net loss | ($323) | ($1,455) | ($460) | ($3,994) |
| Basic loss per common share | ($.01) | ($0.05) | ($0.02) | ($0.12) |
| Diluted loss per common share | ($.01) | ($0.05) | ($0.02) | ($0.12) |

</TABLE>

<TABLE>
<CAPTION>

| | Three Months Ended | | | |
|---|---|---|---|---|
| | October 31, 2002 | January 31, 2003 | April 30, 2003 | July 31, 2003 |
| <S> | <C> | <C> | <C> | <C> |
| Revenues | $17,356 | $13,112 | $11,640 | $10,659 |
| Gross profit | 13,966 | 10,340 | 8,923 | 6,556 |
| Income (loss) before provision for taxes on income | 6,047 | 2,370 | 2,022 | (4,714) |
| Net income (loss) | $3,688 | $1,446 | $1,233 | ($2,523) |
| Basic income (loss) per common share | $.12 | $.04 | $.04 | ($.08) |
| Diluted income (loss) per common share | $.12 | $.04 | $.04 | ($.08) |

</TABLE>

NOTE 14 - SUBSEQUENT EVENT

On October 13, 2004, the Company, its wholly owned subsidiary Enzo Life Sciences, Inc. ("Enzo Life Sciences") and Digene Corporation ("Digene") entered into a Settlement and License Agreement (the "Agreement") and a Joint Stipulation and Order of Dismissal with Prejudice (the "Stipulation"). The Agreement provides for (i) the full and final settlement of the litigation involving Life Sciences' U.S. Patent No. 6,221,581 (the "581 Patent") which is the subject matter of a lawsuit in the U.S. District Court for the District of Delaware, in a case entitled ENZO LIFE SCIENCES V. DIGENE CORP. (the "Litigation") and (ii) the grant to Digene of a non-exclusive, worldwide, royalty-bearing license with respect to such `581 Patent and the remaining patents in the '581 patents global family. The '581 patent is set to expire on

April 24, 2018. Pursuant to the Agreement Digene is irrevocably required to pay Enzo Life Sciences and aggregate of $30.5 million of which Life Sciences received U.S. $16 million (the "First Payment") from Digene on October 13, 2004. In addition, Digene has irrevocable agreed to pay to Enzo U.S. $16.5 million (subject to the $2 million credit discussed below) ("Additional Irrevocable Payments"); $2.5 million of which shall be paid by November 14, 2005 and $3.5 million per year by November 14 of each of 2006, 2007, 2008 and 2009. Digene will pay to Enzo Life Sciences Running Royalties on Net Sales of Licensed Products. Each Additional Irrevocable Payment is fully creditable by Digene against the Running Royalties that are due under the Agreement. Digene at its discretion may credit $2 million of the First Payment against either the payment required to be paid by Digene by November 14, 2005 or the Running Royalties due Enzo Life Sciences under the Agreement. The Stipulation which will be filed with the Court by October 14, 2004 dismisses with prejudice all claims, counterclaims and defenses brought or raised by any party to the Litigation.





Note 15--Segment Reporting

The Company applies SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information." SFAS No. 131 establishes standards for reporting information regarding operating segments in annual financial statements and requires selected information for those segments to be presented in interim financial reports issued to stockholders. SFAS No. 131 also establishes standards for related disclosures about products and services and geographic areas. The chief operating decision maker, or decision-making group, in making decision how to allocate resources and assess performance, identifies operating segments as components of an enterprise about which separate discrete financial information is available for evaluation.

The 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 (loss) income before (benefit) provision 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 for taxes on income and reported as other consist of corporate general and administrative costs that 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 have not been included in the reportable segments below.

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

<TABLE>
<CAPTION>

| | RESEARCH AND DEVELOPMENT | | | CLINICAL REFERENCE LABORATORIES | |
|---|---|---|---|---|---|
| | FISCAL YEAR ENDED JULY 31, | | | FISCAL YEAR ENDED JULY 31, | |
| | 2004 | 2003 | 2002 | 2004 | 2003 | 2002 |
| <S> | <C> | <C> | <C> | <C> | <C> | <C> |
| Operating revenues: | | | | | | |
| Research product revenues | $12,972 | $23,253 | $25,963 | --- | --- | --- |
| Clinical laboratory services | --- | --- | --- | $28,672 | $29,514 | $28,052 |
| Cost and expenses: | | | | | | |
| Cost of research product revenues | 2,518 | 3,389 | 1,837 | --- | --- | --- |
| Cost of clinical laboratory services | --- | --- | --- | 10,586 | 9,593 | 10,110 |
| Research and development expense | 8,078 | 8,311 | 6,179 | --- | --- | --- |
| Depreciation and amortization | 1,414 | 881 | 923 | 902 | 893 | 1,231 |
| Provision for uncollectible accounts | 1,753 | 616 | --- | 10,234 | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 8,729 | 14,188 | | | | | | |
| Other costs and expenses | | 508 | 609 | 420 | 8,429 | | |
| 7,294 | 6,279 | | | | | | |
| Interest income | | --- | --- | --- | --- | | |
| --- | --- | | | | | | |
| | | ----- | ----- | ----- | ----- | | |
| ----- | ----- | | | | | | |
| (Loss) income before (benefit) provision for income Taxes on income | | $(1,299) | $9,447 | $16,604 | $(1,479) | | |
| $3,005 | $(3,756) | | | | | | |
| | | ======== | ====== | ======= | ======== | | |
| ====== | ======== | | | | | | |

<TABLE>
<CAPTION>

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | OTHER | | | | |
| CONSOLIDATED | | | | | | | |
| | | ---------- | ---------- | ---------- | ---------- | | |
| --- | --- | | | | | | |
| | | FISCAL YEAR ENDED JULY 31, | | | FISCAL YEAR | | |
| ENDED JULY 31, | | | | | | | |
| | | ---------- | ---------- | ---------- | ---------- | | |
| --- | --- | | | | | | |
| | | 2004 | 2003 | 2002 | 2004 | | |
| 2003 | 2002 | | | | | | |
| | | ---- | ---- | ---- | ---- | | |
| ---- | ---- | | | | | | |
| <S> | | <C> | <C> | <C> | <C> | | |
| <C> | <C> | | | | | | |
| Operating revenues: | | | | | | | |
| Research product revenues | | --- | --- | --- | $12,972 | | |
| $23,253 | $25,963 | | | | | | |
| Clinical laboratory services | | --- | --- | --- | 28,672 | | |
| 29,514 | 28,052 | | | | | | |
| | | | | | | | |
| Cost and expenses: | | | | | | | |
| Cost of research product revenues | | --- | --- | --- | 2,518 | | |
| 3,389 | 1,837 | | | | | | |
| Cost of clinical laboratory services | | --- | --- | --- | 10,586 | | |
| 9,593 | 10,110 | | | | | | |
| Research and development expense | | --- | --- | --- | 8,078 | | |
| 8,311 | 6,179 | | | | | | |
| Depreciation and amortization | | $45 | $34 | --- | 2,361 | | |
| 1,808 | 2,154 | | | | | | |
| Provision for uncollectible accounts | | --- | --- | --- | 11,987 | | |
| 9,345 | 14,188 | | | | | | |
| Other costs and expenses | | 9,409 | 8,048 | $3,858 | 18,346 | | |
| 15,951 | 10,557 | | | | | | |
| Interest income | | 1,152 | 1,355 | 1,350 | 1,152 | | |
| 1,355 | 1,350 | | | | | | |
| | | ----- | ----- | ----- | ----- | | |
| ----- | ----- | | | | | | |
| (Loss) income before (benefit) provision for income Taxes on income | | $(8,302) | ($6,727) | ($2,508) | $(11,080) | | |
| $5,725 | $10,340 | | | | | | |
| | | ======== | ======== | ======== | ========= | | |
| ====== | ======= | | | | | | |

</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:

| | 2004 | 2003 | 2002 |
|---|---|---|---|
| United States | $8,029 | $19,492 | $21,431 |
| Foreign Countries | 4,943 | 3,761 | 4,532 |
| | $12,972 | $23,253 | $25,963 |



ENZO BIOCHEM, INC
SCHEDULE II - VALUATION
AND QUALIFYING ACCOUNTS
Years ended July 31, 2004, 2003 and 2002

<TABLE>
<CAPTION>

| Description | Balance at Beginning of period | Additions: Charged (credited) to costs and expenses | Additions: Charged to other accounts | Deductions (Additions) | Balance at end of period |
|---|---|---|---|---|---|
| <S> | <C> | <C> | <C> | <C> | <C> |
| 2004 | | | | | |
| Allowance for doubtful accounts receivable | $4,900,000 | $11,986,500 | --- | $11,383,500 (1) | $5,503,000 |
| 2003 | | | | | |
| Allowance for doubtful accounts receivable | $4,445,000 | $9,345,000 | --- | $8,890,000 (1) | $4,900,000 |
| 2002 | | | | | |
| Allowance for doubtful accounts receivable | $6,526,000 | $14,188,000 | --- | $16,269,000 (1) | $4,445,000 |

</TABLE>

(1) Write-off of uncollectible accounts receivable.

EXHIBIT 10(s)

# SETTLEMENT AND LICENSE AGREEMENT

This Settlement and License Agreement (the "Agreement") is entered into as of the Effective Date defined below in paragraph 1.2, by (i) ENZO LIFE SCIENCES, INC. ("LIFE SCIENCES") and ENZO BIOCHEM, INC. ("BIOCHEM" and referred to collectively herein, with LIFE SCIENCES, as "ENZO"), and (ii) DIGENE CORPORATION ("DIGENE").

WHEREAS, LIFE SCIENCES is the owner of all rights in and to United States Patent No. 6,221,581 (hereinafter the "`581 patent");

WHEREAS, LIFE SCIENCES is a wholly owned subsidiary corporation of BIOCHEM;

WHEREAS, ENZO and DIGENE are currently engaged in litigation involving the `581 patent in the United States District Court for the District of Delaware, in a case entitled ENZO LIFE SCIENCES V. DIGENE CORP., Civil Action No. 02-212-JJF (the "Litigation");

WHEREAS, LIFE SCIENCES filed a complaint in the Litigation alleging that DIGENE has willfully infringed the `581 patent by making, selling and/or using certain products, as identified in the complaint and the Litigation;

WHEREAS, DIGENE filed an answer and counterclaims in the Litigation alleging that it does not infringe the `581 patent, and further, that the `581 patent is invalid and unenforceable;

WHEREAS, DIGENE filed counterclaims against BIOCHEM in the Litigation alleging damages from various alleged business torts;

WHEREAS, BIOCHEM filed an answer to DIGENE's counterclaims in the Litigation denying any liability for the business torts alleged by DIGENE;

WHEREAS, ENZO and DIGENE desire to fully and finally settle and resolve the Litigation and all claims, counterclaims, and defenses asserted therein and all issues involved therein, without resort to further litigation, and in accordance with the provisions of this Agreement; and

WHEREAS, DIGENE desires to acquire from ENZO a license under the Licensed Patents, as defined herein below, and clearance under ENZO's patent portfolio, as set forth herein and subject to the limitations herein, to make, have made, use, sell, offer to sell and import Licensed Products, as defined hereinbelow;

NOW, THEREFORE, in consideration of the premises and promises contained herein, ENZO and DIGENE (each a "Party" and collectively, the "Parties") agree as follows:

## ARTICLE I: DEFINITIONS

1.1 "Affiliate" of a Party means any corporation, company, firm, partnership or other entity that directly or indirectly controls, is controlled by or is under common control with the Party in question. For purposes of this definition, "control" shall mean the ownership, directly or indirectly, of fifty percent (50%) or more of the issued share capital or shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interests in the case of any other entity, or the legal power to direct or cause the direction of the general management and policies of the entity in question.

1.2 "Effective Date" of this Agreement shall be as of September 30, 2004 and upon receipt of the First Payment recited in paragraph 3.1 of this Agreement.

1.3 "Licensed Patents" means U.S. Patent No. 6,221,581 and any and all U.S. patents that claim priority to any patent application to which the `581 patent claims the benefit of priority, and any foreign (non-U.S.) counterparts of any of the foregoing U.S. patents.

1.4 "Licensed Products" means all products, including test kits, as well as systems, reagents, accessories, consumables, devices and instruments intended for use with same, their methods or means of making, and their methods or means of use embraced by at least one claim of the Licensed Patents. Licensed Products include all products that absent the license granted herein would infringe (or the use of which would infringe) any claim of the `581 patent. Explicitly included as Licensed Products are the DIGENE Hybrid Capture 1, Hybrid Capture 2, Hybrid Capture 3 and SHARP products identified in Exhibit 1 hereto. DIGENE warrants that the trade name "HYBRID CAPTURE" is a registered trademark of DIGENE, and the Parties agree that (a) the use of that trade name in conjunction with the making, having made, using, selling, offering for sale and/or importation of any product shall not be deemed an admission by DIGENE that such products are Licensed Products and/or share any one or more of the attributes of

Licensed Products; and (b) the products listed on Exhibit 1 to this Agreement as of the Effective Date are the only products offered for sale or sold by DIGENE or its Affiliates as of the Effective Date that are required to be identified as Licensed Products under this Agreement. The term "Licensed Products" shall prospectively include any Future Licensed Products, as that term is used and defined hereinunder.

1.5 "Licensed Territory" means the entire world.

1.6 "Net Sales" means the greater of (1) the gross amount invoiced by DIGENE and its Affiliates for the sale, transfer, use or other disposition of test kits referenced in paragraph 1.4 above or (2) ninety-three percent (93%) of the gross amount invoiced by DIGENE and its Affiliates for the sale, transfer, use or other disposition of all Licensed Products , less for both (1) or (2), respectively: (a) usual and customary trade discounts actually taken for the test kits or all Licensed Products, respectively; (b) forwarding expenses, freight, taxes, fees, duties, postage and other similar items routinely actually paid and invoiced by DIGENE or its Affiliates for the test kits or all Licensed Products, respectively; and (c) credits actually given for the test kits or all Licensed Products, respectively. Net Sales shall be calculated on the price from DIGENE or its Affiliates to distributors, agents and customers, and not on sales between or among DIGENE and



its Affiliates.. The ninety-three percent (93%) calculation shall be made on an annual basis and DIGENE shall make the necessary payments, if any, with the fourth quarter Running Royalties payments as provided in paragraph 3.7.

1.7 "Bankruptcy Event" means the Party in question becomes insolvent, or voluntarily or involuntary proceedings by or against such Party are instituted in bankruptcy or under any insolvency law, or a receiver or custodian is appointed for such Party, or proceedings are instituted by or against such Party for corporate reorganization or the dissolution of such Party, which proceedings, if involuntary, shall not have been dismissed within sixty (60) days after the date of filing, or such Party makes an assignment for the benefit of its creditors, or substantially all of the assets of such Party are seized or attached and not released within sixty (60) days thereafter.

1.8 "Future Licensed Products" means any Licensed Product which, as of the Effective Date of this Agreement, is not commercially made, used, sold, offered for sale or imported by DIGENE.

1.9 "Joint Stipulation and Order of Dismissal with Prejudice" means the stipulation of dismissal of the Litigation, with prejudice, including all claims, counterclaims and defenses asserted therein as between BIOCHEM, LIFE SCIENCES and DIGENE, attached hereto as Exhibit 2 and incorporated herein by reference.

ARTICLE II: LICENSE GRANT

2.1 LICENSE GRANT: ENZO hereby grants DIGENE an irrevocable, non-exclusive, royalty-bearing license under the Licensed Patents to make, have made, use, sell, offer to sell or import Licensed Products in the Licensed Territory.

ARTICLE III: PAYMENTS, ROYALTIES AND DISMISSAL OF THE LITIGATION

3.1 FIRST PAYMENT. As consideration for the execution of this Agreement and the Joint Stipulation and Order of Dismissal with Prejudice, on the date of execution of this Agreement DIGENE shall pay LIFE SCIENCES, on behalf of ENZO and in full satisfaction of the payment owed to ENZO under this paragraph 3.1, a First Payment of U.S. $16,000,000.00 ( sixteen million U.S. dollars) by wire transfer to the following bank account for LIFE SCIENCES: CITIBANK Account No. 020-047478 and ABA Routing No. 21000089. Of the foregoing amount, DIGENE may credit U.S. $2,000,000.00 (two million U.S. dollars) against any payments due to ENZO for either the Running Royalties or the first Additional Guaranteed Payment under paragraph 3.3 of this Agreement until such credit is fully applied. Upon filing of the Joint Stipulation and Order of Dismissal with Prejudice, this First Payment by DIGENE to ENZO shall be irrevocable.

3.2 DISMISSAL OF THE LITIGATION. Upon execution of this Agreement, ENZO and DIGENE shall cause their attorneys to file the Joint Stipulation and Order of Dismissal with Prejudice, in identical form as Exhibit 2 attached hereto, and incorporated herein by reference, which shall be



executed and filed with the Court in the Litigation within three (3) days after payment of the First Payment stated in paragraph 3.1 of this Agreement.

3.3 ADDITIONAL GUARANTEED PAYMENTS. As further consideration for the execution

of this Agreement and the Joint Stipulation and Order of Dismissal with Prejudice, DIGENE shall pay LIFE SCIENCES, on behalf of ENZO, and in full satisfaction of the payments owed to ENZO under this paragraph 3.3, five Additional Guaranteed Payments, the first in the amount of U.S. $2,500,000 (two million five hundred thousand U.S. dollars), and the remaining four each in the amount of U.S. $3,500,000 (three million five hundred thousand U.S. dollars) for the annual periods ending September 30, 2005, 2006, 2007, 2008 and 2009. DIGENE shall pay these five Additional Guaranteed Payments as of September 30 of each of 2005, 2006, 2007, 2008 and 2009 (with payment to be made by November 14 of each such year), less a credit in the amount of Running Royalties due and actually paid to LIFE SCIENCES pursuant to paragraph 3.4 of this Agreement for the preceding one-year period (I.E., October 1, 2004 to September 30, 2005 for the first annual period and, for each of the four subsequent annual periods, October 1 of the preceding year to September 30, 2006, 2007, 2008 and 2009 ) with respect to which such Additional Guaranteed Payment is being made and, solely in the case of the first Additional Guaranteed Payment due by September 30, 2005, also less the remaining credit, if any, of the U.S. $2,000,000 (two million U.S. dollars) credit described in paragraph 3.1 of this Agreement. The application of the foregoing credits (other than the credit specified in paragraph 3.1 of this Agreement) and the actual payment of the Additional Guaranteed Payments shall be carried out in accordance with the provisions of paragraph 3.7 of this Agreement, i.e., the amount, if any, necessary to equal an Additional Guaranteed Payment will be made with the payment of Running Royalties for the fourth quarter of each of the five annual periods. The credit set forth in paragraph 3.1 may be taken by DIGENE as a pre-payment of Running Royalties over the course of the first annual period running from October 1, 2004 to September 30, 2005, until such U.S. $2,000,000 credit has been fully taken, with the understanding that any such pre-payment credits taken by DIGENE against Running Royalties due in that first annual period shall reduce (by the same amount as the credit so taken) the amount of credit that DIGENE may take against the first Additional Guaranteed Payment due as of September 30, 2005. DIGENE shall provide ENZO with a report indicating the portion of the credit taken with each Running Royalties report provided in such first annual period pursuant to paragraph 7.1 of this Agreement. The Additional Guaranteed Payments are each guaranteed and irrevocable. In the event that DIGENE becomes subject to a Bankruptcy Event, LIFE SCIENCES may declare the entire unpaid balance of the Additional Guaranteed Payments immediately due and payable by providing DIGENE with written notice of same. Moreover, DIGENE shall be obligated to pay the full amount of all such unpaid Additional Guaranteed Payments under the schedule set forth in this paragraph, notwithstanding any prior termination of this Agreement for any reason, and DIGENE's obligation to pay same on that schedule shall survive any such termination of the entire Agreement or any part thereof.

3.4 RUNNING ROYALTIES: In consideration for the license and rights granted it by ENZO in Article II of this Agreement, DIGENE shall pay LIFE SCIENCES, on behalf of ENZO and in full satisfaction of the payments owed to ENZO under this paragraph 3.4, running royalties on Net Sales in the Licensed Territory (the "Running Royalties") based on the following Net Sales



levels at the stated rates for each annual period, with the first annual period starting on October 1, 2004:

| | |
|---|---|
| The first $100 million | * |
| The next $50 million | * |
| The next $100 million | * |
| All in excess of $250 million | * |

* The information omitted is confidential and has been filed separately with the Commission pursuant to Rule 24b-2.

In the event the provisions of paragraph 3.6 apply during the term of this Agreement, the Running Royalties will be calculated based upon the Adjusted Royalty Rate rather than the rates set forth above.

3.5 All Running Royalties paid by DIGENE for Licensed Products under this Agreement, and DIGENE's obligation to pay them, shall be irrevocable, subject only to the following sentences of this paragraph. DIGENE's obligation to pay Running Royalties for Licensed Products shall extend through and until April 24, 2018, and shall only be relieved prior to that date if all of the claims of the Licensed Patents are determined to be invalid or unenforceable in a final judgment from which no appeal has been or can be taken, provided that neither DIGENE nor any of its Affiliates was involved in any respect with any proceeding that resulted in such an unenforceability of invalidity finding, except as required by Court order or otherwise required by law. However, even if all of the claims of the Licensed Patents are determined to be invalid and/or unenforceable in a final judgment from which no appeal has been or can be taken, DIGENE's obligations and duties to pay the First Payment and the Additional Guaranteed Payments shall survive such a determination, and DIGENE's obligations and duties to pay Running Royalties incurred up to the date of that determination shall likewise survive that determination.

3.6 DIGENE shall be deemed a most favored licensee with respect to the Licensed Patents, with its most favored treatment being limited to the following provisions of this paragraph: if ENZO as of or after the Effective Date enters into a license for one or more of the Licensed Patents with a third party other than DIGENE, at an effective royalty rate (taking into account all consideration received for the rights granted) that is less than the effective Running Royalty rate paid and/or owed by DIGENE under this Agreement at such time, DIGENE shall be entitled to a reduction in the effective rate of its Running Royalties to a rate not to exceed any such other licenses (the "Adjusted Royalty Rate"). In such instances, DIGENE shall be entitled to a credit against any future Running Royalties in the amount of any such Running Royalties already paid by DIGENE on sales occurring after the date ENZO entered into such license with a third party other than DIGENE at the Running Royalty rates set forth in paragraph 3.4, less the amount that would have been due ENZO in such periods for sales in accordance with the Adjusted Royalty Rate; provided, however, that nothing in this paragraph 3.6 or any other part of this Agreement shall impact in any way the obligations and duties of DIGENE to pay the entire amounts of the First Payment and the Additional Guaranteed Payments specified in paragraphs 3.1 and 3.3 above.

3.7 PAYMENT OF RUNNING ROYALTIES AND ADDITIONAL GUARANTEED PAYMENTS. DIGENE shall pay the Running Royalties, at the rates set forth in paragraph 3.4 or at the Adjusted Royalty Rate



described in paragraph 3.6, as the case may be, on a quarterly basis in accordance with the provisions of paragraph 7.1 of this Agreement. In each twelve month period beginning October 1, 2004 and ending as of September 30, 2009 for which an Annual Guaranteed Payment is due, DIGENE shall credit the Running Royalties paid for each of the four quarters in such annual period against the Annual Guaranteed Payment due as of September 30 for such annual period. DIGENE will make the payment, if any, necessary to make the amount of such Running Royalties equal the Annual Guaranteed Payment for such annual period on the date when the fourth quarter Running Royalties are paid for such annual period, which date shall be within 45 days after the end of such fourth quarter as described in paragraph 7.1. In the event that the Running Royalties in any of the five, twelve month periods beginning on October 1, 2004 and ending on September 30, 2009 exceeds the Additional Guaranteed Payment due on September 30 of any of the years falling within that time, the Parties agree that DIGENE is not entitled to a refund of the difference between the Running Royalties for that annual period and the Additional Guaranteed Payment for that annual period, which difference shall instead by kept by LIFE SCIENCES.

3.8 In the event that DIGENE intends in the future to sell or offer for sale any product that DIGENE contends is a Future Licensed Product, DIGENE shall, within no less than thirty (30) days prior to the first such sale or offer for sale of such Future Licensed Product, provide ENZO with notice in writing of such intent. Such Future Licensed Product shall thereafter be included as a Licensed Product under this Agreement, and shall thereafter be subject to all other provisions and limitations of this Agreement, including, without limitation, application of the Running Royalties at the applicable rates as set forth herein to the sales of such Future Licensed Product. Any dispute over whether a given product is a Future Licensed Product shall be resolved in accordance with the provisions of paragraph 12.2 of this Agreement.

ARTICLE IV: WARRANTIES, COVENANTS AND LITIGATION RELEASES

4.1 (a) With regard to the Licensed Products listed on Exhibit 1 of this Agreement, during the term of this Agreement: (1) ENZO covenants that it will not assert any claims against or sue DIGENE (or its Affiliates, contract manufacturers, distributors or customers) with respect to any past matter (i.e., one occurring prior to the Effective Date of this Agreement) relating to those Exhibit 1 Licensed Products, and (2) ENZO covenants that it will not assert any claims against or sue DIGENE (or its Affiliates, contract manufacturers, distributors or customers) for infringement of any patent owned or controlled by ENZO on account of the manufacture (by DIGENE, its Affiliates or its contract manufacturers), use, sale, offer for sale, or importation of any such Licensed Product listed on Exhibit 1; (b) With regard to any Licensed Product not listed on Exhibit 1 of this Agreement (including any Future Licensed Product), during the term of this Agreement, and solely with regard to the Licensed Patents identified herein, ENZO covenants that it will not assert any claims against or sue DIGENE (or its Affiliates, contract manufacturers, distributors or customers) for infringement of the Licensed Patents on account of the manufacture (by DIGENE, its Affiliates or its contract manufacturers), use, sale, offer for sale, or importation of any such Licensed Products that are not listed on Exhibit 1; (c) During the term of this Agreement, solely with regard to any Licensed Product not listed on Exhibit 1 of this Agreement that is covered by one or more of the same claims, either literally or under the doctrine of equivalents, in any existing (as of the Effective Date) ENZO patent or existing (as of

the Effective Date) patent application (or one or more of the same claims in any ENZO patents or applications claiming priority from any such existing patents or existing patent applications) that also cover Licensed Products listed on Exhibit 1, ENZO covenants that it will not assert any claims against or sue DIGENE (or its Affiliates, contract manufacturers, distributors or customers) for patent infringement solely with regard to the foregoing same claims in any existing (as of the Effective Date) ENZO patent or existing (as of the Effective Date) patent application issuing as a patent (or with regard to the foregoing same claims in any ENZO patents claiming priority from any such existing patents or existing patent applications), on account of the manufacture (by DIGENE, its Affiliates or its contract manufacturers), use, sale, offer for sale, or importation of any such Licensed Products not listed on Exhibit 1; (d) During the term of this Agreement, DIGENE covenants that it will not, and its Affiliates will not, initiate or conduct on its own, or assist or participate (except as required by Court order or otherwise required by law) with any third party in initiating, conducting or defending, any court or administrative proceeding relating to the Licensed Patents. DIGENE shall not be obligated to assist ENZO in any such actions taken against any third parties for infringement of the Licensed Patents or taken by third parties against any of the Licensed Patents; and (e) each of the foregoing convenants in this paragraph 4.1 shall survive the expiration on April 24, 2018 or earlier termination of this Agreement pursuant to paragraph 6.1 hereof.

4.2 Upon LIFE SCIENCES' receipt, on behalf of ENZO, of the First Payment required by paragraph 3.1 of this Agreement, (i) ENZO (and its past, present and future subsidiaries, parents, officers, directors, legal representatives, shareholders, predecessors, successors, heirs, Affiliates, assigns, agents, attorneys, representatives and employees) shall release DIGENE (and its contract manufacturers, distributors and customers) and all of DIGENE's past, present and future subsidiaries, parents, officers, directors, legal representatives, shareholders, predecessors, successors, heirs, Affiliates, assigns, agents, attorneys, representatives and employees from all past claims against such released parties for all claims asserted or that could have been asserted with respect to the Licensed Products listed on Exhibit 1, including all claims that the Licensed Products listed on Exhibit 1 infringe the Licensed Patents or any other patents owned or controlled by ENZO, and (ii) DIGENE shall release ENZO and all of ENZO's past, present and future subsidiaries, parents, officers, directors, legal representatives, shareholders, predecessors, successors, heirs, Affiliates, assigns, agents, attorneys, representatives and employees from all claims asserted or that could have been asserted in the Litigation, and from all claims arising from the assertion of the `581 patent and any other patent owned or controlled by ENZO against DIGENE with respect to Licensed Products listed on Exhibit 1.

4.3 ENZO represents and warrants to DIGENE as follows:

(a) ENZO has the full and unencumbered right, power and authority to enter into this Agreement, ENZO has the full and unencumbered right to grant the license rights granted by ENZO to DIGENE hereunder, and otherwise to carry out its obligations hereunder and that, upon execution, this Agreement shall constitute a legal, valid and binding agreement of ENZO, enforceable in accordance with its terms.



(b) ENZO owns all right, title, and interest in and to the Licensed Patents free of any claims of third parties. No third party has made any claim of ownership of, or interest in, the Licensed Patents and no basis for such a claim is known to ENZO.

(c) ENZO is the only person with the power to enforce the Licensed Patents.

(d) ENZO has not licensed or granted to any third party, and shall not license or grant to any third party during the term of this Agreement, any rights in or to the Licensed Patents that are inconsistent with any rights granted by ENZO to DIGENE hereunder. If ENZO licenses or grants rights under the Licensed Patents to any other party, ENZO will provide DIGENE with written notice identifying the name of the party licensed. DIGENE shall be permitted to review any such license under appropriate confidentiality terms, to enable it to ensure compliance with the provisions of this Agreement, including but not limited to the requirements of paragraph 3.6.

(e) ENZO has not received any written notice or claim, and is not otherwise aware that any Licensed Product infringes or misappropriates the proprietary rights of any third party.

(f) There is no action or proceeding pending or, in so far as ENZO knows, threatened against ENZO before any court, administrative agency or other tribunal which could impact upon ENZO's right, power and

authority to enter into this Agreement, to grant the license rights granted by ENZO to DIGENE hereunder, or to otherwise carry out its obligations hereunder.

(g) In the event that ENZO has knowledge or is informed by DIGENE or a third party that any person is or may be infringing the Licensed Patents, ENZO shall use its best efforts to cause such person to cease and desist from any and all infringing activities, including without limitation filing suit for patent infringement (including contributory infringement or inducement to infringe) against such person at ENZO's sole cost and expense. In the event that ENZO does not promptly take such action, ENZO hereby assigns to DIGENE the right to take such action at DIGENE's sole cost and expense, with DIGENE retaining any and all recovery including but not limited to any and all monetary damages, costs and attorneys' fees recovered. Nothing contained herein shall obligate DIGENE to take such action.

4.4 DIGENE represents and warrants to ENZO as follows:

(a) DIGENE has the full and unencumbered right, power and authority to enter into this Agreement and otherwise to carry out its obligations hereunder and that, upon execution, this Agreement shall constitute a legal, valid and binding agreement of DIGENE, enforceable in accordance with its terms.



(b) There is no action or proceeding pending or, in so far as DIGENE knows, threatened against DIGENE before any court, administrative agency or other tribunal which could impact upon DIGENE's right, power and authority to enter into this Agreement or to otherwise carry out its obligations hereunder.

(c) DIGENE shall not bind or purport to bind ENZO to any affirmation, representation or warranty with respect to the Licensed Patents or the Licensed Products to any third party.

4.6 EXCEPT FOR THE EXPRESS WARRANTIES CONTAINED IN THIS AGREEMENT, THE LICENSED PATENTS ARE LICENSED TO DIGENE "AS IS." NEITHER ENZO NOR DIGENE MAKES ANY OTHER WARRANTIES OR REPRESENTATIONS, EXPRESS OR IMPLIED, IN FACT OR IN LAW, CONCERNING THE LICENSED PATENTS OR ANY OTHER MATTER COVERED BY THIS AGREEMENT, INCLUDING, WITHOUT LIMITATION, ANY WARRANTIES OF TITLE, NON-INFRINGEMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND INCLUDING, WITHOUT LIMITATION, ANY WARRANTIES ARISING BY STATUTE OR OTHERWISE AT LAW OR FROM A COURSE OF DEALING, USAGE OR TRADE.

4.7 EXCEPT FOR THE INDEMNIFICATION OBLIGATIONS OF DIGENE UNDER ARTICLE V, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY HERETO FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING LOST PROFITS, LOST SAVINGS AND PRICE EROSION) SUFFERED OR INCURRED BY SUCH OTHER PARTY IN CONNECTION WITH THE LICENSED PATENTS, THE LICENSED PRODUCTS, OR ANY OTHER MATTER COVERED BY THIS AGREEMENT, EVEN IF SUCH OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

4.8 NO IMPLIED OR EXPRESS LICENSE IS BEING GRANTED TO DIGENE (or its Affiliates, contract manufacturers, distributors or customers) UNDER THIS AGREEMENT UNDER ANY ENZO PATENT OTHER THAN AS PROVIDED FOR IN THIS AGREEMENT, INCLUDING, BUT NOT LIMITED TO, PARAGRAPHS 2.1 AND 4.1, SUBJECT TO ALL OF THE LIMITATIONS OF THIS AGREEMENT, AND NO IMPLIED OR EXPRESS COVENANT NOT TO SUE IS BEING GRANTED TO DIGENE (or its Affiliates, contract manufacturers, distributors or customers) FOR ANY ENZO PATENT UNDER THIS AGREEMENT EXCEPT FOR THE EXPRESS CONVENANT NOT TO SUE DIGENE (or its Affiliates, contract manufacturers, distributors or customers) WITH RESPECT TO THE LICENSED PRODUCTS LISTED ON EXHIBIT 1 UNDER ANY ENZO PATENT, INCLUDING THE LICENSED PATENTS, AND THE EXPRESS CONVENANT NOT TO SUE DIGENE (or its Affiliates, contract manufacturers, distributors or customers) WITH RESPECT TO ANY LICENSED PRODUCT (INCLUDING THOSE NOT LISTED ON EXHIBIT 1) UNDER THE LICENSED PATENTS, BOTH SUBJECT TO ALL OF THE LIMITATIONS OF THIS AGREEMENT.



4.9 THE PARTIES HERETO ACKNOWLEDGE AND AGREE THAT THE FOREGOING DISCLAIMERS AND LIMITATIONS OF LIABILITY REPRESENT BARGAINED FOR ALLOCATIONS OF RISK, AND THAT THE ECONOMICS, TERMS AND CONDITIONS OF THIS AGREEMENT REFLECT SUCH ALLOCATIONS.

ARTICLE V: INDEMNIFICATION

5.1 DIGENE hereby fully indemnifies ENZO and all of its past, present and future Affiliates, subsidiaries, parents, officers, directors, legal representatives, shareholders, predecessors, successors, heirs, assigns, agents, attorneys, representatives and employees (collectively, "ENZO Indemnitees") from any past, present or future action or claim for damages of any sort against any of them, that stems from or relates in any way to DIGENE's or any of its Affiliates' sale

or other disposition of any Licensed Product. In the event that any such action or claim is brought against any of the ENZO Indemnitees, DIGENE shall assume control of such action or claim and agrees to fully defend any of them against that action or claim, including, but not limited to, paying for all attorneys' fees (of the attorneys of DIGENE's choosing, after consultation with ENZO) and costs necessary to fully defend that action or claim and fully satisfying any monetary award entered against any of them relating to that action or claim. No ENZO Indemnitee shall be entitled to settle or defend any such action or claim. DIGENE is not obligated to indemnify the ENZO Indemnitees except as expressly provided for in this paragraph.

5.2 If any action, claim, suit, proceeding or investigation arises as to which a right of indemnification provided in this Article V applies, the ENZO Indemnitee in question shall promptly notify DIGENE thereof in writing, and allow DIGENE, its insurers and any other entity that DIGENE reasonably deems necessary or appropriate under the circumstances to assume direction and control of the defense against such action, claim, suit, proceeding or investigation, at DIGENE's sole expense, including the settlement thereof at the sole option of DIGENE or its insurers. Failure by the ENZO Indemnitee to so notify DIGENE within a reasonable period of time shall relieve DIGENE from the obligation to indemnify the ENZO Indemnitee only to the extent that DIGENE suffers actual prejudice as a result of such failure. Each ENZO Indemnitee shall fully cooperate with DIGENE and its insurer in the disposition of any such action, claim, suit, proceeding or investigation with regard to all reasonable requests for such cooperation.

5.3 DIGENE and ENZO agree to negotiate in good faith a potential agreement to add ENZO as an additional insured on DIGENE's product liability insurance policy.

ARTICLE VI: TERM AND TERMINATION

6.1 The term of this Agreement shall begin as of the Effective Date and extend through and until the earlier of April 24, 2018 or the date by which all of the claims of the Licensed Patents are determined to be invalid or unenforceable in a final judgment from which no appeal has been or can be taken, provided that neither DIGENE nor any of its Affiliates was involved in any respect with any proceeding that resulted in such an unenforceability of invalidity finding, except as required by Court order or otherwise required by law. DIGENE shall be obligated to pay the Additional Guaranteed Payments set forth in paragraph 3.3 of this Agreement, notwithstanding any prior termination of this Agreement.



6.2 This Agreement is irrevocable with respect to the duties, obligations and rights of each Party as to the Licensed Products, with the express understanding that (except as set forth in paragraph 4.1 of this Agreement) nothing in this Agreement, including the irrevocability provisions of this paragraph, shall preclude ENZO from asserting against DIGENE in the future a patent that is not a Licensed Patent with regard to a Licensed Product that is not listed on Exhibit 1 of this Agreement.

ARTICLE VII: RECORD KEEPING, PAYMENT AND REPORTS

7.1 DIGENE shall within forty-five (45) days after the end of each calendar quarter, time being of the essence, send to ENZO a written statement, certified by DIGENE, showing for such calendar quarter the Net Sales and quantities of Licensed Products sold during the quarter and the calculation of and amount of Running Royalties due. Such statements shall be accompanied by a payment of the total amount of Running Royalties due, subject to the provisions of Article III of this Agreement. Payment shall be made by wire transfer to an account designated by ENZO in advance of the payment. Any late payment shall accrue interest at the lower of one and one-half percent (1.5%) per month or the highest rate permitted by law. If no Running Royalties are due, DIGENE shall nevertheless render a statement to reflect such fact, along with a detailed written explanation of why it contends that no Running Royalties are due.

7.2 Receipt or acceptance by ENZO of any report furnished pursuant to this Agreement or any sums paid hereunder, shall not preclude ENZO from questioning the correctness thereof at a later date, subject to the time limitations set forth below in paragraph 7.4.

7.3 DIGENE shall maintain, and cause to be maintained by its Affiliates, complete and accurate books and records with respect to Net Sales and all Running Royalties paid or payable by DIGENE under this Agreement, along with such other reconciliation and other information as may be necessary or desirable to calculate or verify all Net Sales and the consideration paid or payable by DIGENE under this Agreement. DIGENE and such Affiliates shall maintain such books and records in accordance with generally accepted accounting principles consistently applied and for a period of three (3) years after the submission of each report required to be submitted by DIGENE to ENZO under this Agreement; provided, however, that if there is a good faith dispute between the Parties continuing at the end of any such three (3) year period with respect to such books or records, then the time period hereunder to maintain such books and

records under dispute shall be extended until such time as the dispute is finally resolved.

7.4 ENZO shall have the right, through an independent accountant selected by it and acceptable to and approved by DIGENE (which approval shall not be unreasonably withheld or delayed), to have access to the relevant books and records of DIGENE and its Affiliates during reasonable business hours, subject to the records maintenance requirements set forth in paragraph 7.3, on thirty (30) days prior written notice, for the purpose of verifying, inspecting or auditing, at the sole expense of ENZO (except as provided for in paragraph 7.5 below), the Net Sales and the Running Royalties provided for pursuant to this Agreement for any of the preceding two (2) years, but this right may not be exercised more than once in any calendar year, and once exercised with respect to any period, the books and records for such period cannot be



reviewed again except upon written request made by ENZO to DIGENE setting forth a reasonable business basis for requiring such a subsequent review, as to which request DIGENE shall not unreasonably withhold its consent. Said independent representatives shall solicit or receive only information relating to or necessary or desirable to verify or audit the accuracy of the information reported and the payments made or due under this Agreement. DIGENE shall be entitled to withhold approval of an accountant which ENZO nominates unless the accountant agrees to sign a confidentiality agreement with DIGENE which shall obligate such accountant to hold the information he or she receives from DIGENE in confidence, except for disclosure to ENZO of information necessary to establish the accuracy of the reports and amounts paid or payable to ENZO. Such audit rights shall survive for three (3) years after the expiration or termination of this Agreement.

7.5 Any underpayment determined pursuant to paragraph 7.4 above shall be paid within thirty (30) days after the delivery of a detailed written accountants' report to DIGENE and ENZO if neither DIGENE nor ENZO disputes the report. If the Parties cannot agree with the accountants' report following a good faith attempt to reach such agreement within thirty (30) days, then any such disputed matter shall be submitted to and determined by an independent accounting firm acceptable to the Parties, which determination shall be final and binding, absent manifest error. The fees and expenses of any such independent accounting firm incurred in resolving such disputed matter shall be shared equally by DIGENE and ENZO. In the event of any such underpayment by seven percent (7%) or more, DIGENE shall also at the same time reimburse ENZO for the out-of-pocket costs of the verification, inspection or audit conducted, plus interest at the lower of one and one-half percent (1.5%) per month or the highest rate permitted by law. Any overpayment shall be credited to the next payment due from DIGENE. If no further payments from DIGENE will be due then a refund of any such overpayment will be made within thirty (30) days after the delivery of a detailed written accountants' report to DIGENE and ENZO.

7.6 The provisions of this Article VII shall survive the expiration or sooner termination of this Agreement.

ARTICLE VIII: NOTICES

8.1 All notices or other communications required or permitted hereunder shall be in writing and shall be delivered personally, by facsimile, with delivery confirmed electronically, or sent by certified, registered or express air mail, postage prepaid, or by reputable overnight courier, and shall be deemed given when so delivered personally, or by facsimile, or by overnight courier, or if mailed, three days after the date of mailing, to the address of the Party set forth below or to such other address as any Party hereto shall notify the other Party hereto from time to time. However, the Parties further agree that each Party shall provide the other Party with notice of execution of this Agreement (along with a copy of the executed Agreement) by facsimile or same-day hand delivery, with confirmation to follow by any of the other foregoing methods.



Notice to ENZO:
c/o Enzo Biochem, Inc.
Enzo Biochem, Inc.
527 Madison Avenue, 9th Floor
New York, New York 10012-4304
Attention: Dr. Elazar Rabbani
Fax: (212) 583-0150

Notice to DIGENE:
Digene Corporation
1201 Clopper Road
Gaithersburg, Maryland 20878
Attention: Chief Executive Officer
Fax: (301) 944-7017

ARTICLE IX: MISCELLANEOUS

9.1 This Agreement is made under and shall be governed by, and construed and interpreted in accordance with, the laws of the State of Delaware.

9.2 The paragraph headings contained herein are for reference only; such headings are not a part of this Agreement, nor shall they in any way affect the interpretation thereof.

9.3 The express or implied waiver by any Party of any right or breach of any provision of this Agreement shall not constitute a continuing waiver of the same or other provisions of this Agreement.

9.4 The Parties to this Agreement agree that it is the intention of none of them to violate any public policy, statutes, or common laws. However, if any sentence, paragraph, clause or combination of the same is held to be in violation of any state or federal law or otherwise unenforceable by a court from which no appeal is or can be taken, such sentences, paragraphs, clauses, or combinations of the same shall be deleted and the remainder of this Agreement shall remain binding. Promptly following the making of any such deletion, the Parties shall meet and use their best efforts to mutually agree on acceptable language to be added to this Agreement in replacement of the deleted language, which replacement language shall be crafted to come as close as possible to having the same economic effect as the deleted language which it replaces.

9.5 Subject to the terms and conditions herein provided, each of the Parties hereto shall use its best efforts to take, or cause to be taken, all action, and to do, or cause to be done, all things reasonably necessary, proper or advisable under applicable laws and regulations to consummate and make effective the transactions contemplated hereby. In the event that at any time after this Agreement has become effective, any further action is necessary to carry out its purposes, ENZO and DIGENE or the proper directors or officers of either, as the case may be, shall take all such action without any further consideration therefor.

9.6 This Agreement and the Joint Stipulation and Order of Dismissal with Prejudice are the final and complete understanding of the Parties with respect to the subject matter hereof, superseding all prior agreements, understandings and discussions relating thereto. Any modifications or renewal of this Agreement shall be in writing signed by the Parties hereto.



9.7 The Parties to this Agreement may not assign this Agreement in whole or in part without the other Party's prior written consent, except that without such consent either Party may assign this Agreement to an entity under common control with, controlled by or which comes into the control of either Party, or to a third party which succeeds to all or substantially all of its business to which this Agreement relates. Any and all other assignments or attempted assignments by either party shall be null and void AB INITIO and shall be without any legal effect.

9.8 This Agreement may be signed by the Parties in separate counterparts, each of which (including a facsimile copy thereof) when so executed shall be deemed an original, and all of which when taken together shall constitute the original Agreement.

9.9 No Party shall originate any publicity, news release or other public announcement, written or oral, relating to this Agreement (including, without limitation, the terms hereof), without the prior written approval of the other Party, which shall not be unreasonably withheld, except (after prior written notice to the other Party) as otherwise required by law or regulation, including, without limitation, the Securities Act of 1933, as amended ( the "Securities Act"), and the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the rules and regulations of the Securities and Exchange Commission (the "SEC") thereunder, but only to the extent necessary to meet the Party's disclosure obligations thereunder. Neither Party shall object if the other Party makes disclosures in its filings with the SEC regarding this Agreement to satisfy such SEC disclosure obligations, pursuant to the disclosing Party's good faith belief that it has an obligation to do so. Moreover, nothing in this paragraph or any other part of the Agreement shall preclude either Party from making a public statement (without obtaining prior written consent of the other Party), including a press or news release, limited to the statement that the Litigation has been settled and a license under the patent-in-suit was granted by ENZO to DIGENE under that settlement or which otherwise becomes publicly available as a consequence of the aforementioned required SEC filings. After the initial publication of such publicity, news release or other public announcement, each of the Parties shall be entitled to redisclose such approved information in subsequent publicity, news releases, other public announcements or filings made with the SEC under the Securities Act or the Exchange Act without first obtaining the written approval of the other Party. Should any dispute, controversy or disagreement arise concerning any content of any such publicity, the disputed language shall not be included in any such publicity or otherwise publicly disclosed in any manner unless otherwise required by law or regulation.

9.10 This Agreement shall not constitute an agreement on the part of DIGENE to permit ENZO or any of its Affiliates to use any trademarks, service marks, or trade names of DIGENE. This Agreement shall not constitute an agreement on the part of ENZO to permit DIGENE or any of its Affiliates to use any trademarks, service marks, or trade names of ENZO, except as required to comply with Article X hereof.

ARTICLE X: MARKING

10.1 DIGENE shall mark all Licensed Products in a manner sufficient to satisfy the marking requirements of 35 U.S.C. ss. 287(a) or any other provisions of U.S. or foreign law. The Parties



will work in good faith to negotiate a reasonable period of time for DIGENE to exhaust existing inventories and modify its Licensed Products' labeling, which shall be no less than six months and only upon approval of the United States Food and Drug Administration to the extent such approval is required.

ARTICLE XI: CONFIDENTIALITY

11.1 The Parties agree that each of them shall employ its best efforts to keep the material terms of this Agreement, including, but not limited to, the Running Royalty rates set forth in Article III of this Agreement confidential and not disclose them to any third party, including by each seeking from the SEC permission to maintain such royalty rates as confidential.

ARTICLE XII: DISPUTE RESOLUTION

12.1 Except as otherwise indicated in paragraph 7.4 and paragraph 12.2 hereof, if any dispute, controversy or difference arises between the Parties out of, or in connection with, this Agreement, or for the breach thereof, the Parties shall promptly meet and attempt in good faith to resolve such dispute on a mutually agreeable basis. If such dispute, controversy or difference is not resolved or otherwise settled by the Parties within sixty (60) days after one Party has given the other Party written notice of said dispute, controversy or difference, it shall be resolved by litigation in the U.S. District Court for the District of Delaware, which Court the Parties shall stipulate and seek to have retain jurisdiction over the enforcement of this Agreement through provision in the Joint Stipulation of and Order of Dismissal with Prejudice referenced in this Agreement.

12.2 In the event that any dispute, controversy or difference arises between the Parties out of, or in connection with, this Agreement with respect to whether a product offered for sale by DIGENE as of the Effective Date, or not presently offered for sale by DIGENE as of the Effective Date, but which DIGENE offers for sale for the first time at any date subsequent to the Effective Date of this Agreement, is subject to the terms of this Agreement, the Parties shall promptly meet and attempt in good faith to resolve such dispute on a mutually agreeable basis. If such dispute, controversy or difference is not resolved or otherwise settled by the Parties within sixty (60) days after one Party has given the other Party written notice of said dispute, controversy or difference, it shall be resolved by binding arbitration before a panel of three independent arbitrators in accordance with the procedures of the rules governing patent disputes of the American Arbitration Association. The venue for any such arbitration proceeding shall be Wilmington, Delaware. Within sixty (60) days after the Effective Date, the Parties will mutually agree to procedures governing any such arbitration proceeding and include such procedures as an amendment to this Agreement.



IN WITNESS WHEREOF, the Parties hereto have caused this Settlement and License Agreement to be executed on October 13, 2004.

ENZO LIFE SCIENCES, INC.
ENZO BIOCHEM, INC.

By: /s/ Elazar Rabbani
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Name: Elazar Rabbani
Title: CEO

DIGENE CORPORATION

By: /s/ Evan Jones

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Name: Evan Jones
Title: CEO

Exhibit 10(t)

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

| | | |
|---|---|---|
| ENZO LIFE SCIENCES, INC.,<br><br>Plaintiff/<br>Counterclaim Defendant,<br><br>v.<br><br>DIGENE CORPORATION,<br><br>Defendant/<br>Counterclaim-Plaintiff,<br><br>v.<br><br>ENZO BIOCHEM, INC.,<br><br>Counterclaim Defendant. | : | Civil Action<br>No. 02-212-JJF |

JOINT STIPULATION AND ORDER OF DISMISSAL WITH PREJUDICE

Plaintiff/Counterclaim Defendant Enzo Life Sciences, Inc., Defendant/Counterclaim-Plaintiff Digene Corporation and Additional Counterclaim Defendant Enzo Biochem, Inc. have agreed to settle all claims arising out of the pleadings in this action on terms including entry of the following Joint Stipulation and Order of Dismissal with Prejudice and a combined Settlement and License Agreement. Therefore, it is hereby stipulated by the parties and

Ordered, Adjudged and Decreed that:

1. This Court has jurisdiction over the subject matter of this action and over the parties. Venue is proper in this district.

2. All claims, counterclaims and defenses brought or raised by any party in this action are dismissed, with prejudice.

3. Each party shall bear its own costs and attorney fees for this action.

4. This Court retains jurisdiction over the subject matter of this action and the parties hereto for the purpose of any proceedings to enforce this Joint Stipulation and Order of Dismissal with Prejudice and the Settlement and License Agreement referenced herein.

5. The parties hereto waive all right to appeal from, or obtain review of, this Joint Stipulation and Order of Dismissal with Prejudice.

IT IS SO ORDERED:

Date:
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United States District Judge

STIPULATED AND AGREED TO:

Dated: October 14, 2004

YOUNG, CONAWAY, STARGATT & TAYLOR, LLP

/s/ Josy W. Ingersoll

Josy W. Ingersoll (No. 1088)
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Attorneys for:
Plaintiff/Counterclaim Defendant Enzo Life Sciences, Inc., and Additional

Dated: October 14, 2004

MORRIS, JAMES, HITCHENS & WILLIAMS LLP

/s/ Richard D. Kirk

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Attorneys for Defendant/
Counterclaim
Plaintiff Digene Corporation

Counterclaim Defendant, Enzo Biochem, Inc.

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EXHIBIT 1

Licensed Products under this Exhibit 1 to the Agreement are the DIGENE Hybrid Capture 1, Hybrid Capture 2, Hybrid Capture 3 and SHARP products that were accused of infringement in the Litigation (as that term is defined in the Agreement) and all products that DIGENE or its Affiliates have, as of the Effective Date of the Agreement, offered for sale or sold, including test kits, as well as systems, reagents, accessories, consumables, devices and instruments intended for use with same, their methods or means of making, and their methods or means of use embraced by at least one claim of the Licensed Patents.

EXHIBIT 14 (a)

# CODE OF ETHICS FOR CEO AND SENIOR FINANCIAL OFFICERS

## EFFECTIVE JANUARY 1, 2003

The Company has a Code of Business Conduct and Ethics applicable to the CEO and all senior financial officers. The CEO and all senor financial officers, including the CFO and principal accounting officer, are bound by the provisions set forth therein relating to ethical conduct, conflicts of interest and compliance with law. In addition to the Code of Business Conduct and Ethics, the CEO and senior financial officers are subject to the following additional specific policies:

The CEO and all senior financial officers are responsible for full, fair, accurate, timely and understandable disclosure in the periodic reports required to be filed with or submitted to the SEC by the Company and in other public communications made by the Company. Accordingly, it is the responsibility of the CEO and each senior financial officer promptly to bring to the attention of the Disclosure Committee any material information of which he or she may become aware that affects the disclosures made by the Company in its public filings or otherwise assist the Disclosure Committee in fulfilling its responsibilities.

The CEO and each senior financial officer shall promptly bring to the attention of the Disclosure Committee and the Audit Committee any information he or she may have concerning (a) significant deficiencies in the design or operation of internal controls which could adversely affect the Company's ability to record, process, summarize and report financial data or (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's financial reporting, disclosures or internal controls.

The CEO and each senior financial officer shall promptly bring to the attention of the CEO and to the Audit Committee any information he or she may have concerning any violation of the Company's Code of Business Conduct and Ethics, including any actual or apparent conflicts of interest between personal and professional relationships, involving any management or other employees who have a significant role in the Company's financial reporting, disclosures or internal controls.

The CEO and each senior financial officer shall promptly bring to the attention of the CEO and to the Audit Committee any information he or she may have concerning evidence of a material violation of the securities or other laws, rules or regulations applicable to the Company and the operation of its business, by the Company or any agent thereof, or of violation of the Code of Business Conduct and Ethics or of these additional procedures.

The Board of Directors shall determine, or designate appropriate persons to determine, appropriate actions to be taken in the event of violations of the Code of Business Conduct and Ethics or of these additional procedures by the CEO and the Company's senior financial officers. Such actions shall be reasonably designed to deter wrongdoing and to promote accountability for adherence to the Code of Business Conduct and Ethics and to these additional procedures, and shall include written notices to the individual involved that the Board has determined that there has been a violation, censure by the Board, demotion or re-assignment of the individual involved, suspension with or without pay or benefits (as determined by the Board) and termination of the individual's employment. In determining what action is appropriate in a particular case, the Board of Directors or such designee shall take into account all relevant information, including the nature and severity of the violation, whether the violation was a single occurrence or repeated occurrences, whether the violation appears to have been intentional or inadvertent, whether the individual in question had been advised prior to the violation as to the proper course of action and whether or not the individual in question had committed other violations in the past.

EXHIBIT 23

Consent of Independent Registered Public Accounting Firm

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, 333-87153 and 333-89308) of Enzo Biochem, Inc. and in the related Prospectus of our report dated October 7, 2004, except for Note 14 and the third paragraph of Note 7, as to which the date is October 14, 2004 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, 2004.

/s/ Ernst & Young LLP

Melville, New York
October 14, 2004

EXHIBIT 31(a)

CERTIFICATIONS

In connection with the Annual Report on Form 10-K of Enzo Biochem, Inc. ("the Company") for the fiscal year ended July 31, 2004 as filed with the Securities and Exchange Commission on the date hereof, I, Elazar Rabbani, Ph.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 302 of the Sarbanes-Oxley Act of 2002, that:

1. I have reviewed this Annual Report on Form 10-K of Enzo Biochem, Inc.

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

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

4. The Company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a - 15(e) and 15d - 15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principals;

   (c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the Company's most recent fiscal quarter (the Company's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: October 14, 2004

By: /s/ Elazar Rabbani, Ph.D.
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Elazar Rabbani, Ph.D.
Chief Executive Officer

EXHIBIT 31(b)

CERTIFICATIONS

In connection with the Annual Report on Form 10-K of Enzo Biochem, Inc. ("the Company") for the fiscal year ended July 31, 2004 as filed with the Securities and Exchange Commission on the date hereof, I, Barry Weiner, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 302 of the Sarbanes-Oxley Act of 2002, that:

1. I have reviewed this Annual Report on Form 10-K of Enzo Biochem, Inc.

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

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

4. The Company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a - 15(e) and 15d - 15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principals;

   (c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the Company's most recent fiscal quarter (the Company's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: October 14, 2004

By: /s/ Barry Weiner
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Barry Weiner
Chief Financial Officer

EXHIBIT 32(a)

CERTIFICATE PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Enzo Biochem, Inc., and Subsidiaries ("the Company") on Form 10-K for the fiscal year ended July 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Elazar Rabbani, Ph.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Dated: October 14, 2004

By: /s/ Elazar Rabbani, PH.D.
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Elazar Rabbani, Ph.D.
Chief Executive Officer

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Act Commission or its staff upon request.xtxt

EXHIBIT 32(b)

CERTIFICATE PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Enzo Biochem, Inc., and Subsidiaries ("the Company") on Form 10-K for the fiscal year ended July 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Barry Weiner., Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: October 14, 2004

By: /s/ Barry Weiner
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Barry Weiner
Chief Financial Officer

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Act Commission or its staff upon request.