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nzo Biochem, Inc.

Annual Report 2005

Enzo Biochem, Inc. is a leading biotechnology company engaged in the research, development, marketing and manufacture of innovative health care products. In business since 1976. Enzo's products and services are sold to and used by scientists and the medical community worldwide. The Company has proprietary technologies and expertise in manipulating and modifying genetic material and other biological molecules. Through three whollyowned subsidiaries, the Company targets its technology toward satisfying specific market needs. Enzo Therapeutics, Inc. is leading the development of medicines based on genetic and immune regulation to combat cancer, viral and other diseases. Enzo Life Sciences, Inc. develops and markets proprietary DNA probe-based products to clinicians and researchers. Enzo Clinical Labs, Inc. provides diagnostic testing services to the New York medical community.

To Our Shareholders:

Fiscal 2005 was an eventful year for Enzo Biochem, and one in which we achieved progress in a number of areas:

- We entered into a settlement and licensing agreement with Digere Corporation, resulting in substantial financial benefits for our Company.
- Enzo Therapeutics presented five papers at the annual meeting of The American Association for the Study of Liver Diseases, including one for EGS21, our immunodulatory agent that shows promise for management of glucose levels and treatment of other immune diseases.
- Our Phase II studies for the treatment of Crohn's disease continued to advance, while a Phase II clinical trial for a compound to treat non-alcoholic steatohepatitis, for which we were awarded a \$1 million grant from the Israel-US Binational Industrial Research and Development Foundation, was begun this year and is moving ahead.
- Enzo Therapeutics has begun studies on two new areas, including a medicine to treat various conditions related to bone growth and development, and a treatment for uveitis, an eye inflammation which we are putting through the regulatory process in Germany for a Phase II trial.
- A second trial site for our proprietary *StealthVector™ HGTV43* transducing vector, Enzo's proprietary gene treatment for HIV, has been set up at the University of California San Francisco, the site of our Phase I trial, where the protocol awaits final review by the university's Institutional Review Board.
- Enzo Clinical Labs had an excellent year of continued gains in both physicians served and number of tests, and strong operating results.
- Enzo Life Sciences introduced two new pivotal products in RNA amplification and array CGH labeling, and continued adding line extensions in the genomics field, while also building a strategically focused sales force.
- The Company's financial position remained strong, with cash and cash equivalents increasing to \$84 million, shareholder's equity exceeding \$108 million and no debt.

Enzo Clinical Labs

Revenues at Enzo Clinical Labs were nearly \$33 million, a 14.6% increase over the \$28.7 million in revenues realized in fiscal 2004, and income before taxes rose to \$2.8

million, as compared to a year-ago loss of \$1.5 million, an improvement of approximately \$4.3 million. These results reflected increased test volume, including a greater number of higher margin tests that previously were referred to other labs and which now are processed in-house. In addition, our wider market coverage in the New York Metropolitan region that now includes northern New Jersey has resulted in more physicians as clients.

Efficiency at Enzo Labs has been enhanced by wider usage of the $EnzoDirect^{\mathsf{TM}}$ system, a physicians' office computer system that provides electronic access to patient information. In addition, a web-based version of the $EnzoDirect^{\mathsf{TM}}$ system enables physicians to view results from any web enabled computer has been introduced.

Our emphasis on improving efficiencies at Enzo Labs has also resulted in upgrades to our billing and collection systems, which, among other benefits, assures greater accuracy in compiling billing information in a timely manner. In addition, a major upgrade to many of our key laboratory instruments was completed to help increase operating efficiencies. In fiscal 2006, we will be looking at further geographic expansion, as well as the possibility of bringing in additional tests to broaden our offerings.

Enzo Life Sciences

During the past year we continued our program to add to Enzo Life Sciences already broad technology base for the labeling, detection, amplification and formatting of nucleic acids for gene analysis. Our new kit for the labeling of array Comparative Genome Hybridization, or CGH, is being marketed among leading institutions as a strategy to establish Enzo's product as a valuable tool in this growing area of research. Our kit contains all the components needed to label these arrays.

Under development are kits to aid researchers in increasing their target RNA more expeditiously, as well as products that could be used in the study of DNA from archived tissue samples, potentially opening a market in retrospective genomic studies. Meanwhile, the Life Sciences website has undergone a major upgrade that now allows orders for our products to be placed on-line, thereby simplifying the ordering process, especially for our overseas customers.

During fiscal 2005, we entered into a settlement and licensing agreement with Digene Corporation relating to one of our patents in the area of the binding of labeled nucleic acids to a solid support. This agreement resulted in a \$14 million payment, as well as a royalty bearing license that will provide a minimum additional \$16.5 million through 2009. In addition, we will receive royalties on sales until the patent expires in 2018.

At Enzo Life Sciences, we continued to build our sales force, as we shift away from the distribution model that we had employed for many years. Building a seasoned sales force takes time, but our efforts in attracting skilled sales people are beginning to

show results. We have identified a number of key geographic areas domestically, and are continuing to fill them as we identify qualified individuals. We are also exploring various opportunities in Europe and the Far East.

Revenues in fiscal 2005 at Enzo Life Sciences reflected certain royalty payments, but revenues nonetheless declined to \$10.5 million, compared with the previous year's approximately \$13 million. The reduction in part stemmed from litigation with two distributors of our products, Roche Molecular Systems, and Perkin Elmer Life Sciences, formerly NEN Life Sciences. However, including the \$14 million gain on the Digene patent litigation settlement, income before taxes for Enzo Life Sciences was \$14.6 million, compared to a year-ago loss of \$1.1 million.

Enzo Therapeutics

At Enzo Therapeutics, we reached several important milestones in fiscal 2005. Having completed in fiscal 2004 the first arm of a Phase II study for Alequel, our treatment for Crohn's disease, we expanded the study this year. Our objective is to enroll additional subjects in order to achieve a critical mass necessary to validate the efficacy of this study drug. We expect to expand the number of trial sites, including some in the United States, in order to enroll a more diverse population. Crohn's Disease represents a major opportunity for Enzo, as estimates suggest that more than one million individuals in the US and Europe are affected by this disease.

In addition, at the Annual Meeting for the Study of Liver Diseases, Enzo Therapeutics presented five papers, including one on EGS21, our immunodulatory agent that may have properties in the management of a number of immune mediate disorders. And our work on a study for the treatment of NASH, or non-alcoholic steatohepatitis, a disease without any current known therapy that afflicts an estimated 6 million Americans, resulted in a \$1 million grant from the Israel-US Binational Industrial Research and Development Foundation. With the improvement of diagnostic and screening procedures, NASH has been identified as a major medically important condition correlated with obesity and can lead impairment of liver function as well as liver cancer and failure. We plan to study this compound for the management of hepatitis C virus associated chronic active hepatitis as well. EGS21 has been shown to be safe in earlier trials.

Our studies involving hepatitis B virus have resulted in the development of a proprietary producing cell line, from which we are seeking to produce a master cell bank under FDA guidelines. Optimization of this cell line is an important criterion for the potential cost of commercialization, because the product, if validated, would be marketed in countries where a low price would be key to effective distribution.

Our HIV-1 clinical trials are awaiting approval by the University of California at San Francisco's Institutional Review Board. UCSF was the site of our Phase I study of HGTV43, and thus has experience in manufacturing the final study drug. The study will focus on a strategy designed to increase the percentage of engineered CD4+ cells. Enzo's

protocol for this phase of the study successfully passed review by the National Institutes of Health Recombinant DNA Advisory Committee, in addition to the Food & Drug Administration.

Beyond these projects, Enzo Therapeutics as part of its strategic goals has sought to increase its pipeline of therapeutic candidates. Thus we initiated in fiscal 2005 two new projects. One involved a study drug for treatment of autoimmune uveitis, an inflammation of a part of the eye known as the uvea. The condition is believed to result from an immune reaction that leads to inflammation in the eye, which can progress to blindness. Enzo Therapeutics acquired the rights and intellectual property to the study drug for this condition. In a physician initiated Phase I clinical trial, nine patients suffering from uveitis were treated with the study drug, and the drug appeared to have an ameliorating effect on the disease activity within the first few weeks of treatment on all of the patients. This amelioration was observed on the follow-up as well. The compound has been granted orphan drug status in Europe, and we are preparing for a Phase II trial which we hope to begin in calendar 2006.

The other area Enzo Therapeutics has added to the pipeline involve bone growth. Preclinical experiments on one small molecule candidate, IIIC3, stimulated increased bone mass in laboratory animals. The compounds appear to work by promoting the differentiation of osteoblasts into bone. Development work continues.

As our therapeutic projects have increased, and we have furthered the clinical activities of many of these programs, we will evaluate the potential for partnering one or more of these programs. These could include joint venture or licensing agreements. We will also look to move each of these key projects through clinical trials as quickly and efficiently as possible.

Financial Results

For all of fiscal 2005, revenues increased to \$43.4 million, compared with \$41.6 million in the previous year, and net income amounted to \$3 million, compared to a year-ago net loss of \$6.2 million. Net income per fully diluted share equaled \$0.09, compared to a net loss per fully diluted share of (\$0.20) a year ago, on 32.8 million and 31.7 million weighted average common shares outstanding, respectively. At year-end, cash and cash equivalents, and marketable securities, amounted to \$83.7 million, with working capital of \$97 million, while shareholders equity increased to a record \$108.3 million. There was no debt.

We are excited about the progress we have made, and the opportunities we see ahead. We remain committed to achieving the greatest value for our shareholders from these efforts.

In a move to reflect our Company's commitment to good shareholder governance, a Lead Director has been elected from among the independent directors on our Board,

who represent five of its eight members. We are appreciative of the contribution and counsel of our Board of Directors, as well as the loyalty and dedication of our employees and the support of our shareholders.

Barry W. Weiner

President

Except for historical information, the matters discussed in this letter may be considered "forward-looking" statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. Such statements include declarations regarding the intent, belief or current expectations of the Company and its management. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve a number of risks and uncertainties that could materially affect actual results. The Company disclaims any obligations to update any forward-looking statement as a result of developments occurring after the date of this correspondence.

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

| (Mark one) | | |
|-------------------------------------|--|--|
| x | ANNUAL REPORT PURS | SUANT TO SECTION 13 or 15(d) OF IANGE ACT OF 1934 |
| For the fiscal y | ear ended July 31, 2005 | |
| | TRANSITION REPORT F | or PURSUANT TO SECTION 13 or 15(d) OF JANGE ACT OF 1934 |
| For the transition | on period from | to |
| | Con | nmission File Number 001-09974 |
| | | IZO BIOCHEM, INC. |
| New | (Exact name of York | registrant as specified in its charter) 13-2866202 |
| | ther jurisdiction | (I.R.S. Employer |
| | on or organization) | Identification No.) |
| 60 Execu | tive Boulevard, | |
| Farmingo | lale, New York | <u>11735</u> |
| (Address of pr | incipal executive offices) | (Zip Code) |
| | | (631) 755-5500 phone number, including area code) |
| | (Negistrant's tele | phone number, including area code) |
| (Title of Each C | istered pursuant to Secti Class) <u>k, \$.01 par value</u> | on 12(b) of the Act: (Name of Each Exchange on Which Registered) The New York Stock Exchange |
| Securities reg | istered pursuant to Secti | on 12(g) of the Act: |
| _ | • | NONE |
| or 15(d) of the | Securities Exchange Act ant was required to file su | he registrant (1) has filed all reports required to be filed by Section 13 of 1934 during the preceding 12 months (or for such shorter period ch reports), and (2) has been subject to such filing requirements for |
| | | Yes ▼ No □ |
| contained here | ein, and will not be conta | ure of delinquent filers pursuant to Item 405 of Regulation S-K is not ained, to the best of registrant's knowledge, in definitive proxy or eference in Part III of this Form 10-K or any amendment to this Form |
| | • | Yes 🗷 No 🗌 |
| Indicat Act). | e by check mark whether | the registrant is an accelerated filer (as defined in Rule 12b-2 of the |
| The accomputed by rebusiness of the | eference to the price at whe registrant's most recently | Yes No Diffusion No handle the voting and non-voting common equity held by non-affiliates ich the common equity was last sold as of January 31, 2005, the last completed second fiscal quarter, was approximately \$462,341,000. If 32,142,400 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 on or about January 20, 2006 are incorporated by reference into Part III.

PART I

Item 1. Business

Overview

Enzo Biochem, Inc. (the "Company" or "Enzo") is a life sciences and biotechnology company focused on harnessing genetic processes to develop research tools, diagnostics and therapeutics and the provision of 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 products marketed to the biomedical and pharmaceutical research markets. We are further using these technologies as platforms in the development of products for the clinical diagnostics market. In addition, our work in gene analysis has led to the development of 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 40 issued U.S. patents, over 167 issued foreign patents, and various pending applications worldwide) around our core technologies.

The business activities of the Company are performed by 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 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, 2005 and 2004, respectively, approximately 24% and 31% of the Company's operating revenues were derived from product sales and approximately 76% and 69% 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 is now more than \$3 billion per year 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

We believe 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 the Company acquired the rights and intellectual property to a candidate drug and technology intended for use in the treatment of autoimmune uveitis. We also entered into a collaboration agreement with scientists at Ludwig-Maximilians University in Munich, Germany to evaluate certain of Enzo's proprietary technology for treating uveitis in an animal model system. In fiscal 2004, 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 if any, emanating from this technology could provide potential therapy for bone disorders, including bone loss, fractures, abnormalities, diseases, and other applications. In fiscal 2004, 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. There can be no assurance that any of these collaborative projects will be successful.

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 fiscal 2004 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 2005, 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, as well as the enhancement of the 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 2005, distribution agreements were in effect with, among others, Roche Diagnostic Systems and Perkin-Elmer Life Sciences. The Company received notice in December 2004 that Perkin-Elmer Life Sciences was terminating its agreement with the Company. See Item 3. Legal Proceedings.

Research product revenue from Affymetrix represented approximately 0%, 0% and 22% of the consolidated revenues in fiscal 2005, 2004 and 2003, respectively, under a non-exclusive distribution and supply agreement. At July 31, 2005 and 2004, of the Company's net accounts receivable no monies were included from this former major distributor. Research product revenue from Perkin-Elmer represented approximately 3%, 8% and 4% of the consolidated revenues in fiscal 2005, 2004 and 2003, respectively, under a non-exclusive distribution and supply agreement. At July 31, 2005 and 2004, approximately 0% and 5%, respectively, of the Company's net accounts receivable relate to amounts due from this distributor. Research product revenue from Amersham represented approximately 0%, 0% and 1% of the consolidated revenues in fiscal 2005, 2004 and 2003, respectively, under a terminated 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 former distributor. Research product revenue from Roche represented approximately 0%, 8% and 6% of the consolidated revenues in fiscal 2005, 2004 and 2003, respectively, under a non-exclusive distribution and supply agreement. At July 31, 2005 and 2004, 0% and 0% respectively of the Company's net accounts receivable relate to amounts due from the this distributor.

The following is a table outlining the above for the respective consolidated fiscal years:

| | % of Revenue | | | % of Accounts Receivable | | |
|--------------|--------------|-------------|-------------|--------------------------|-------------|--|
| | <u>2005</u> | <u>2004</u> | <u>2003</u> | <u>2005</u> | <u>2004</u> | |
| Affymetrix | 0% | 0% | 22% | 0% | 0% | |
| Perkin-Elmer | 3% | 8% | 4% | 0% | 5% | |
| Amersham | 0% | 0% | 1% | 0% | 0% | |
| Roche | 0% | 8% | 6% | 0% | 0% | |

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:

<u>Efficient transduction</u>. 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.

• Immunologically "Quiet." Transduced cells often produce non-essential proteins that trigger an immune response, causing such cells to be cleared from the body before they can produce a therapeutic effect. Cells transduced with our Stealth Vectors™ have not expressed extraneous proteins.

• "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 though there can be no assurance that our vector technology has broad applicability in the field of gene medicine. This can be attributed to the following properties of our construct:

- the viral promoters are inactivated;
- insertional gene activation is prevented a major safety factor;

- chromosomal integration; and
- nuclear localization.

Immune Regulation.

<u>•Oral Immune Regulation.</u> We are exploring a potentially 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. There can be no assurance that we will be able to secure patents or that these programs will be successful. We are applying our expertise in immune regulation to develop proprietary therapeutics for the treatment of a variety of diseases, including chronic active hepatitis caused by HBV and HCV infection, graft versus host disease and inflammatory bowel disease, including Crohn's Disease and ulcerative colitis. During this fiscal year, the Company acquired the rights and intellectual property to a candidate drug and technology intended for use in the treatment of autoimmune uveitis, a chronic inflammation of the eye that can lead to blindness.

•Immune Potentiation. We have developed a new immunomodulator agent, EGS21, a beta-D-glucosylceramide (GC) compound, as a potential therapeutic for treating immune mediated disorders. GC is a glycolipid that has been shown by Enzo scientists and collaborators to act as an anti-inflammatory agent in animal model systems, and therefore is being evaluated as 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 might 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*® 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*® 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*® 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 is marketed under the *BioArray*® brand name. This product line also includes a new kit for amplifying small quantities of genetic material as well as our new *GeneBeam*™ 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 60 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. Over 20 million have died since the first cases of AIDS were identified in 1981. At present, two classes of products have received FDA marketing approval for HIV-1 infection: reverse transcriptase inhibitors and protease inhibitors. 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.

<u>HGTV43™ gene medicine</u>. Enzo's proprietary Stealth Vector™ HGTV43™ gene construct is a 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 long-term safety 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® HGTV43[™] 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 60 months to date.

- all subjects tolerated the procedure;
- anti HIV-1 antisense RNA was detected in the circulation of subjects, the longest at 60 months
- purified CD4+ cells from 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.

The next phase of clinical trials is to be conducted at University of California San Francisco the site of the Phase I study. This study will focus on a strategy designed to increase the percentage of engineered CD4+ cells using a low dose of total body irradiation (TBI). Enzo's protocol for this phase of the study successfully passed review by the National Institutes of Health Recombinant DNA Advisory Committee (RAC) and has been submitted to the UCSF Committee on Human Research (CHR) for approval. We anticipate initiating the study and enrolling subjects as soon as the protocol is successfully reviewed by CHR. The study initiated at New York Presbyterian Hospital-Cornell Medical Center has not enrolled subjects pending completion of manufacturing protocols.

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.

<u>EHT899 immune regulation product</u>. 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; and
- 33% of subjects showed a decrease in inflammation seen on liver biopsy.

Based on these results, the Company is exploring improved manufacturing processes and pharmaceutical partnerships are being explored.

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.

Uveitis. Posterior uveitis, which results from inflammation of a part of the eye known as the uvea, is believed to result from an immune reaction against some of the antigens in the eye, specifically the S antigen protein (Sag) and the interphotoreceptor retinoid-binding protein (IRBP). There is no known cure for uveitis, which in the United States, according to the American Uveitis Society, is diagnosed in approximately 38,000 people every year. While there are steps that can be taken to preserve sight and slow the progress of vision loss, individuals with uveitis are also at increased risk of developing cataracts, glaucoma or retinal detachment.

Enzo recently acquired rights and intellectual property to a candidate drug and technology intended for use in the treatment of uveitis. The drug is the result of a discovery by scientists at the eye clinic of the Ludwig Maximilians University in Munich, Germany, who found a small peptide that when fed to rats with experimental allergic uveitis promoted their recovery. Based on favorable preclinical studies, the developers conducted a small Phase I clinical trial in Germany with encouraging results that indicated a number of the patients treated with the study drug showed a decrease in inflammation and a few showed improved visual acuity.

Using its immune regulation platform and the recently acquired rights to the candidate drug, Enzo is currently composing a protocol to initiate the next phase of clinical trials that will be submitted to the central regulatory agencies in Germany.

Inflammatory bowel diseases. We believe our immune regulation technology may be used 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.

Patients are managed during short-term episodes through the use of anti-inflammatory medications, or immunosuppressants, that provide symptomatic relief over short periods of time, but do 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*™ 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. An expanded study to broaden the diversity of the patient population is ongoing at Hadassah Hospital. Enzo plans to continue the study at additional sites in the United States and is currently conducting a selection review process to determine the appropriate site at which to expand the study.

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 suggest that our immune regulation technology could be effective in treating GvHD. Currently, clinical protocols are in development.

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.

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. A Phase 2 open label study is currently being conducted at Hadassah-Hebrew University Medical Center.

Clinical Laboratory Services

We operate a regional clinical 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 and may be performed less frequently than routine tests. The Company does not perform certain low-volume esoteric tests in-house, generally many of these tests are referred to an esoteric clinical testing laboratory that specializes in performing these more complex 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 full service clinical laboratory in Farmingdale, NY with an infrastructure that includes a comprehensive information technology, logistics, client service and billing departments. Also, we have a network of nineteen patient service centers and a full service phlebotomy department. Patient service centers collect the specimens as requested by physicians. 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 laboratory facilities by our logistics department accompanied by a test requisition form. These forms, which are completed by the ordering physician, indicate the tests to be performed and demographic patient information. Once this information is entered into the laboratory computer system the tests are performed and the results are entered primarily through an interface from the laboratory testing equipment or in some instances, manually into the laboratory computer system. 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 electronically via our EnzoDirectTM system or delivered by the logistic department directly to the ordering physicians' offices. Physicians who request that they be called with a result are so notified.

For fiscal years ended July 31, 2005 and 2004, respectively, 76% and 69% of the Company's revenues were derived from the clinical laboratory. At July 31, 2005 and 2004, respectively, approximately 94% and 89% of the Company's net accounts receivable were derived from its clinical laboratory business. 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 various numbers of third party insurance carriers, the Federal Medicare Program and the numerous individual patient accounts. Revenue, net of contractual allowances, from direct billings under the Federal Medicare program during the years ended July 31, 2005, 2004 and 2003 were approximately 20%, 19%, and 11%, respectively, of the Company's total revenue. The clinical 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 payers 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 and the Federal Medicare Program, all of which have different requirements. In New York State, the law prohibits the Company from billing the ordering physician. Compliance with applicable laws and regulations as well as, internal compliance policies and procedures adds further complexity to the billing process. We depend on the ordering physician to provide timely, accurate billing demographic and diagnostic coding information to us. We believe that most of our bad debt expense is primarily the result of missing or incorrect billing information on requisitions received from the ordering physician rather than credit related issues. We perform the requested tests and report test results regardless of whether the billing or diagnostic coding information is incorrect or missing. We subsequently attempt to contact the ordering physician to obtain any missing information and rectify incorrect billing information. Missing or incorrect information on requisition adds complexity to and slows the billing process, creates backlogs of unbilled requisitions, and generally increases the aging of accounts receivable. When all issues relating to the missing or incorrect information are not resolved in a timely manner, the related receivables are fully reserved to the allowance for doubtful accounts or written off. 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, 2005, 2004 and 2003, the Company incurred costs of approximately \$8,452,000, \$8,078,000, and \$8,311,000, respectively, for research and development activities.

Internal Research Programs

Our professional staff of 45 scientists, including 23 with post doctorate degrees, performs our internal research and development activities. 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 research 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 ordering physicians in the metro New York and New Jersey region 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 market our research products through a direct field sales group and professional sales management team as well as through our interactive e-commerce web site. Our domestic and 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 research products through leading life sciences companies. Through these arrangements, we are able to leverage the established marketing and distribution infrastructure of these companies. During fiscal 2005, we distributed under an agreement with Perkin-Elmer Life Sciences, among other companies. Enzo Life Sciences is focused 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 2005 we owned or licensed 40 U.S. and over 167 foreign patents relating to products, methods and procedures resulting from our internal or sponsored research projects. During this year, several patents relating the BioProbe® nucleic acid probe system have expired, while additional patents 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 thereunder govern, among other things, the testing, licensing, manufacturing, marketing, distributing, safety, and efficacy requirements, labeling, storage, exporting, record keeping, advertising and other promotional practices involving biologics or new drugs, as the case may be. FDA review or approval or other clearances must be obtained before clinical testing, and before 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 postmarketing 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 by 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 payers, 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 payers, 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, Medicare has 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 payers, 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 in February 2003 and went into effect April 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.

Medical Regulated Waste

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, 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 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 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 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 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

Most of the manufacturing and scientific efforts for our research and development segment and clinical laboratory segment take place at our leased 43,000 square feet facility in Farmingdale, New York. We have a completely integrated laboratory and manufacturing facility, with special handling capabilities and clean rooms suitable for our operations.

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, 2005, we employed 292 full-time and 50 part-time employees. Of the full-time employees, 59 were engaged in research, development, manufacturing, administrative support and marketing of research products and 233 at the clinical reference laboratories. Our scientific staff, including 23 individuals with post doctorate degrees, 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 clinical laboratory 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 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 information technology 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 https://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.

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, but are not limited to:

- (a) Heightened competition, including the intensification of price competition.
- (b) Impact of changes in payer mix, including the shift from traditional, fee-for-service medicine to managed-cost health care.
- (C) Adverse actions by governmental or other third-party payers, 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.
- (I) 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 which are 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 approvable or viable products.
- (O) 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:

| <u>Location</u> 60 Executive Blvd Farmingdale, N.Y. | Principal Operations Corporate headquarters, clinical laboratory, research and manufacturing facilities (See note 6 of Notes to Consolidated Financial Statements) | Approximate Area (sq. ft.) 43,000 | <u>Base Rent</u> \$1,161,000 | Lease expiration <u>Date</u> March 31, 2017 |
|---|--|---|---------------------------------|---|
| 527 Madison Ave New York, NY | Executive office | 6,400 | \$367,000 | December 31, 2008 |

In March 2005, the Company amended and extended the lease for its Farmingdale laboratory and headquarters for a period of 12 years. We believe the current facilities are suitable and adequate for the Company's current operating needs for both its clinical laboratories and research and development segments, and that the production capacity in the Farmingdale facility is being substantially utilized.

Item 3. Legal Proceedings

On October 14, 2004, the Company as plaintiff finalized and executed a settlement and license agreement with Digene Corporation to settle a patent litigation lawsuit (the "Digene agreement"). Under the terms of the agreement, the Company received an initial payment of \$16.0 million, would earn in the first "annual period" (October 1, 2004 to September 30, 2005) a minimum royalty payment of \$2.5 million, and receive a minimum royalty of \$3.5 million in each of the next four annual periods. In addition, the agreement provides for the Company to receive quarterly running royalties on the net sales of Digene products subject to the license until the expiration of the patent on April 24, 2018. These quarterly running royalties will be fully creditable against the minimum royalty payments due in the first five years of the agreement. The balance, if any, of the minimum royalty payment will be recognized in the final quarter of the applicable annual royalty period. As a result of the Digene agreement, the Company recorded a gain on patent litigation settlement of \$14.0 million in the first quarter of fiscal 2005, and deferred \$2 million which would be earned from net sales of the Company's licensed products covered by the agreement during the first annual period. As of July 31, 2005, the balance of the deferred revenue from the settlement was \$359,400.

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. The defendants have answered the individual complaints and asserted a variety of affirmative defenses and counterclaims. Fact discovery is ongoing. The Court conducted a claim construction hearing from July 5-11, 2005. Closing arguments on claim construction issues were conducted on September 30, 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. The Company recorded revenue from only Perkin Elmer during the fiscal year ended July 31, 2005.

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 Affymetrix 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. Initial pleadings have been completed and discovery has commenced. The Court conducted a claim construction hearing from July 5 - 11, 2005. Closing arguments on claim construction issues were conducted on September 30, 2005. The Company did not record any revenue from Affymetrix during the fiscal years ended July 31, 2005 and 2004.

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 (the "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. Enzo filed an Answer and Counterclaims on November 3, 2004 alleging multiple breaches of the 1994 Agreement and related infringement of Enzo's 373 patent. Discovery has commenced. The Court conducted a claim construction hearing from July 5-11, 2005. Closing arguments on claim construction issues were conducted on September 30, 2005. The Company did not record any revenue from Roche during the fiscal year ended July 31, 2005.

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 filed an appeal of that judgment. On September 30, 2005, the Court of Appeals affirmed the judgment of invalidity. 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 Glaser v. Hyman Gross, Barry Weiner, Enzo Biochemical Inc., Elazar Rabbani, Shahram Rabbani, John Delucca, Dena Engelhardt, Richard Keating, Doug Yates, and Does I-50, Case No. CA-02-1242-A, in the U.S. District Court for the Eastern District of Virginia. This complaint was filed by an investor in the Company who had filed for bankruptcy protection and his family. The complaint alleged securities fraud, breach of fiduciary duty, conspiracy, and common law fraud and sought 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. Plaintiffs thereafter appealed the decision to the United States Court of Appeals for the Fourth Circuit. On March 21, 2005, the Fourth Circuit affirmed the lower Court's prior dismissal of all claims asserted in the action, with the sole exception of a portion of the claim for common law fraud and remanded that remaining portion of the action to the U.S. District Court for the Eastern District of Virginia. On May 20, 2005, defendants again moved the District Court to dismiss the sole remaining claim before it. On July 14, 2005, the District Court granted defendants' renewed motion to dismiss. On July 29, 2005, Plaintiffs moved to amend their Complaint for reconsideration. On August 19, 2005, the Court denied Plaintiffs' motion to amend and entered final judgment dismissing the complaint. Thereafter, Plaintiffs appealed the order and judgment to the Fourth Circuit. That appeal is presently pending. The Company continues to believe that the complaint has no merit whatsoever and intends to continue to defend the action vigorously.

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. Fact discovery is currently scheduled to close on February 28, 2006. Dispositive motions are currently due on March 27, 2006. The trial date is currently scheduled for October 1, 2006. 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. The Company did not record any revenue from either of the above during the fiscal years July 31, 2005 and 2004.

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, 2005.

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.

| | <u>High</u> | <u>Low</u> |
|---|--|--|
| 2004 Fiscal Year (August 1, 2003 to July 3 | 1, 2004): | |
| 1st Quarter 2nd Quarter 3rd Quarter 4th Quarter | \$22.45 \$20.95 \$19.88 \$15.69 | \$17.35 \$15.85 \$14.20 \$12.57 |
| 2005 Fiscal Year (August 1, 2004 to July 3 | 1, 2005): | |
| 1st Quarter 2nd Quarter 3rd Quarter 4th Quarter | \$17.69 \$20.40 \$19.27 \$18.24 | \$11.15 \$17.27 \$13.62 \$14.08 |

As of October 10, 2005, the Company had approximately 1,164 stockholders of record of its Common Stock.

The Company has not paid a cash dividend on its Common Stock and intends to continue a policy of retaining earnings to finance and build its operations. Accordingly, the Company does not anticipate the payment of cash dividends to holders of Common Stock in the foreseeable future. During fiscal 2005, the Company's board of directors declared a 5% stock dividend on October 5, 2004 payable November 15, 2004 to shareholders of record as of October 25, 2004. The fiscal 2004 per share data was adjusted retroactively to reflect the stock dividend declared on October 5, 2004. In fiscal 2003, the Company's board declared a 5% stock dividend on June 10, 2003 payable July 14, 2003 to shareholders of record as of June 30, 2003. The shares and per share data for fiscal 2003 have been adjusted to retroactively reflect the stock dividend in fiscal 2003. The Company recorded a charge to accumulated deficit and offsetting credits to both common stock and additional paid-in capital of approximately \$23,433,400 and \$37,709,200 in fiscal 2005 and fiscal 2003, respectively, which reflects the fair value of the stock dividends on the dates of declaration.

Item 6. Selected Financial Data

The following table, which is derived from the audited consolidated financial statements of the Company for the fiscal years 2001 through 2005 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.

| Operating Results | For the fiscal year ended July 31, (In 000's, except per share data) | | | | |
|---|--|----------------|----------------|----------------|----------------|
| | 2005 | 2004 | 2003 | 2002 | 2001 |
| Operating revenues | \$43,403 | \$41,644 | \$52,767 | \$54,015 | \$52,266 |
| Gain on patent litigation settlement | 14,000 | | | | |
| Interest income | 1,523 | 1,152 | 1,355 | 1,350 | 3,003 |
| Income (loss) before income taxes | 5,217 | (11,080) | 5,725 | 10,340 | 12,231 |
| (Provision) benefit for income taxes | (2,213) | <u>4,848</u> | (1,881) | (3,417) | (5,418) |
| Net income (loss) | \$3,004 | \$(6,232) | <u>\$3,844</u> | <u>\$6,923</u> | <u>\$6,813</u> |
| Basic net (loss) income per common share: | \$0.09 | <u>\$(.20)</u> | <u>\$0.12</u> | \$0.22 | \$0.22 |
| Diluted net (loss) income per common share: | \$0.09 | \$(.20) | <u>\$0.12</u> | \$0.21 | \$0.21 |
| Denominator for per share calculation: | | | | | |
| Basic | 32,097 | 31,700 | 31,399 | 31,359 | 31,254 |
| Diluted | 32,763 | 31,700 | 32,175 | 32,327 | 32,558 |
| Financial Position: | | | | | |
| Working capital | \$97,011 | \$92,259 | \$97,723 | \$92,772 | \$85,094 |
| Total assets | 116,466 | 110,334 | 115,878 | 109,291 | 102,931 |
| Long term obligations | 150 | 300 | | | |
| Stockholders' equity | \$108,267 | \$104,166 | \$109,380 | \$104,733 | \$97,517 |

No cash dividends have been declared on the Company's common stock.

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 13 of the Notes to Consolidated Financial Statements.

The Company's source of revenue has been from the direct sales of research products consisting 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. Payments for clinical laboratory testing services are made by the Medicare program, healthcare insurers and patients. Fees billed to patients, Medicare, and third party payers are billed on the laboratory's standard gross fee schedule, subject to any limitations on fees negotiated with the third party payers or with the ordering physicians on behalf of their patients.

The Company incurs additional costs as a result of our participation in the Medicare programs, as billing and reimbursement for clinical laboratory testing is subject to considerable and complex federal regulations. Compliance with applicable laws and regulations, as well as internal compliance policies and procedures, adds further complexity and costs to our operations. Government payers such as Medicare, as well as healthcare insurers have taken steps and may continue to take steps to control the costs, utilizations and delivery of healthcare services, including clinical laboratory services. Principally as a result of reimbursement reductions and measures adopted by the Centers for Medicare & Medicaid Services, or CMS, which establishes procedures and continuously evaluates and implements changes in the reimbursement process to control utilization, Despite the added cost and complexity of participating in the Medicare program, we continue to participate because we believe that our other business may depend, in part, on continued participation in Medicare since certain ordering physicians may want a single laboratory capable of performing all of their clinical laboratory testing services, regardless of who pays for such services.

Information systems are used extensively in virtually all aspects of the clinical laboratory operations, including 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 systems. Through maintenance, staffing, and investments in our information technology system, we expect to reduce the risk associated with our heavy reliance on these systems

The clinical laboratory is subject to seasonal fluctuations in operating results and cash flows. Typically, testing volume declines during the summer months, year end holiday periods and other major holidays, reducing net revenues and operating cash flows. Testing volume is also subject to declines in winter months due to inclement weather, which varies in severity from year to year.

For the fiscal years ended July 31, 2005 and 2004, respectively, approximately 24% and 31% percent of the Company's operating revenues were derived from research product sales and approximately 76% and 69% were derived from clinical laboratory services.

Research product revenue from Affymetrix represented approximately 0%, 0% and 22% of the consolidated revenues in fiscal 2005, 2004 and 2003, respectively, under a non-exclusive distribution and supply agreement. At July 31, 2005 and 2004, of the Company's net accounts receivable no monies were included from this former major distributor. Research product revenue from Perkin-Elmer represented approximately 3%, 8% and 4% of the consolidated revenues in fiscal 2005, 2004 and 2003, respectively, under a non-exclusive distribution and supply agreement. At July 31, 2005 and 2004, approximately 0% and 5%, respectively, of the Company's net accounts receivable relate to amounts due from this distributor. Research product revenue from Amersham represented approximately 0%, 0% and 1% of the consolidated revenues in fiscal 2005, 2004 and 2003, respectively, under a terminated 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 former distributor. Research product revenue from Roche represented approximately 0%, 8% and 6% of the consolidated revenues in fiscal 2005, 2004 and 2003, respectively, under a non-exclusive distribution and supply agreement. At July 31, 2005 and 2004, 0% and 0% respectively of the Company's net accounts receivable relate to amounts due from the this distributor.

The following table summarizes research product revenues from non-exclusive distribution agreements for the fiscal years ended July 31, 2005, 2004 and 2003:

| | % of Revenue | | | % of Accounts Receivable | | |
|--------------|--------------|-------------|-------------|--------------------------|-------------|--|
| | <u>2005</u> | <u>2004</u> | <u>2003</u> | 2005 | <u>2004</u> | |
| Affymetrix | 0% | 0% | 22% | 0% | 0% | |
| Perkin-Elmer | 3% | 8% | 4% | 0% | 5% | |
| Amersham | 0% | 0% | 1% | 0% | 0% | |
| Roche | 0% | 8% | 6% | 0% | 0% | |

On October 14, 2004, the Company as plaintiff finalized and executed a settlement and license agreement with Digene Corporation to settle a patent litigation lawsuit (the "Digene agreement"). Under the terms of the agreement, the Company received an initial payment of \$16.0 million, would earn in the first "annual period" (October 1, 2004 to September 30, 2005) a minimum royalty payment of \$2.5 million, and receive a minimum royalty of \$3.5 million in each of the next four annual periods. In addition, the agreement provides for the Company to receive quarterly running royalties on the net sales of Digene products subject to the license until the expiration of the patent on April 24, 2018.

These quarterly running royalties will be fully creditable against the minimum royalty payments due in the first five years of the agreement. The balance, if any, of the minimum royalty payment will be recognized in the final quarter of the applicable annual royalty period.

Liquidity and Capital Resources

At July 31, 2005, our cash and cash equivalents of \$77.0 million and marketable securities of \$6.7 million together totaled \$83.7 million, an increase of \$12.0 million from July 31, 2004. We had working capital of \$97.0 million at July 31, 2005 compared to \$92.3 million at July 31, 2004. As a result of the Digene agreement, the Company recorded a gain on patent litigation settlement of \$14.0 million in the first quarter of fiscal 2005, and deferred \$2 million which would be earned from net sales of the Company's licensed products covered by the agreement during the first annual period. As of July 31, 2005, the balance of the deferred revenue from the settlement was \$359,400. See Legal Proceedings.

Net cash provided by operating activities for the year ended July 31, 2005 was approximately \$12.8 million as compared to net cash used by operating activities of \$5.6 million for the year ended July 31, 2004. The increase in net cash provided by operating activities in fiscal 2005 of \$18.4 million was primarily due to fiscal 2005's net income, which includes the gain from the Digene agreement, and by the net change in operating assets and liabilities compared to the prior year, which includes the receipt of the income tax receivable amount of \$3.9 million. In fiscal 2005, net cash provided by investing activities increased approximately \$13.2 million from fiscal 2004, primarily due to sales of marketable securities. In fiscal 2005, net cash provided by financing activities decreased approximately \$0.4 million from fiscal 2004 primarily as a result of the decrease in proceeds from the exercise of stock options.

Net accounts receivable of \$13.4 million and \$14.8 million represented 119 days and 141 days of operating revenues at July 31, 2005 and 2004, respectively. The change in net accounts receivable is due to a decrease in accounts receivable at the clinical laboratory of approximately \$0.6 million and a decrease of research products accounts receivable of approximately \$0.8 million. The decrease in the clinical laboratory receivable is primarily due to improvements in the collection process. The decrease in the research products accounts receivable is primarily due to the decrease in revenues from distributors of research products. Net accounts receivable from our clinical laboratory operations of \$12.5 million and \$13.1 million represented an average of 143 days and 173 days of clinical laboratory services revenues at July 31, 2005 and 2004, respectively.

The Company has entered into various real estate and equipment leases. The real estate lease for the Company's Farmingdale headquarters is with a related party. See Note 6 to the Consolidated Financial Statements for a further description of these various leases.

The following is a summary of future payments under the Company's contractual obligations as of July 31, 2005:

Payments Due by Period

| | Less than | | | |
|------------------------------------|----------------------------|------------------|------------------|--------------|
| | <u>Total</u> <u>1 year</u> | <u>1-3 years</u> | <u>4-5 γears</u> | Over 5 years |
| Real estate and equipment leases | \$23,637,000 \$2,601,000 | \$5,394,000 | \$4,664,000 | \$10,978,000 |
| Total contractual cash obligations | \$23,637,000 \$2,601,000 | \$5,394,000 | \$4,664,000 | \$10,978,000 |

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

Research product revenues

Revenues from research product sales, exclusive of certain non-exclusive distribution agreements, are recognized when the products are shipped, the sales price is fixed or determinable and collectibility is reasonably assured. 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.

Clinical laboratory services

Revenues from the clinical laboratory are recognized upon completion of the testing process for a specific patient and reported to the ordering physician. The Company's revenue is based on gross amounts billed or billable for services rendered, net of estimated contractual adjustments and other arrangements made with third-party payers to provide services at less than established billing rates. Our accounting system does not record contractual adjustments at the time of billing. Instead, contractual adjustments, and the provision for doubtful accounts, are estimated based on historical collection experience using a retrospective collection analysis and aging models.

The following is a table of the clinical laboratory segment's gross billing percentages by billing category:

| | Fiscal year | Fiscal year |
|----------------------|---------------|---------------|
| Gross | July 31, 2005 | July 31, 2004 |
| Billing Category | % to total | % to total |
| Medicare | 29% | 31% |
| Third party carriers | 40% | 40% |
| Patient self-pay | 13% | 10% |
| HMO's | <u> 18%</u> | <u>19%</u> |
| Total | <u>100%</u> | 100% |

Contractual Allowances

Medicare regulations and the various third party payers and 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 based on our interpretation of the applicable regulations and historical calculations. The Company estimates its contractual allowance based on historical collection experience using a retrospective collection analysis and aging models. 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.

The process the Company uses to determine its estimate of the contractual allowances for its laboratory services segment is based upon a rolling monthly weighted average of historical reimbursement statistics. During the fiscal years ended July 31, 2005, 2004, and 2003, the contractual allowance percentages, determined using the rolling monthly weighted average historical reimbursement statistics, were 72.5%, 70.9%, and 68.0%, respectively. The

Company projects (by using a sensitivity analysis) that each 1% change in the contractual allowance percentage could result in a change in the net accounts receivable of approximately \$531,000 and \$596,000 as of July 31, 2005 and 2004, respectively, and a change in clinical laboratory services revenues of approximately \$1,202,000, \$987,000, and \$922,000 for the fiscal years ended July 31, 2005, 2004, and 2003, respectively

Allowance for Doubtful Accounts

The Company utilizes a historical collection analysis to establish allowances for doubtful accounts for each receivable category, which considers the aging of the receivables and results in an increase in the allowances as the aging of the related receivables increases. The Company believes collection of receivables from self payers is subject to credit risk and the patient's ability to pay.

The allowance for doubtful accounts also includes the uncollectible balances from third party payers for the insufficient diagnosis information received from the ordering physician, which result in denials of payment. In addition, the allowance is increased when a receivable from a third party or HMO remains open due to a denial of coverage based upon the provider relationships. The Company reserved for or wrote off 100% of all accounts receivable (for all payers) over 210 days during fiscal 2005 as it assumed all these accounts are uncollectible. The written off amounts are kept on the aging for patient billing and demographic information. The Company also set up reserves for accounts under 210 days in fiscal 2005. The Company adjusts the estimate for any recoveries on an ongoing basis through the historical collection analysis.

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 payer 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.

Results of Operations

Comparative Financial Data for the Fiscal Years Ended July 31, (in 000's)

| | | Increase | | | Increase | | |
|--|----------------|-----------|----------|-------------------|------------|----------|----------------|
| _ | 2005 | Decrease) | % Change | 2004 | (Decrease) | % Change | 2003 |
| Revenues: | | | | | | | |
| Research product sales and royalties | \$10,546 | \$(2,426) | (19) | \$12,972 | (\$10,281) | (44) | \$23,253 |
| Clinical laboratory services | 32,857 | 4,184 | 15 | 28,672 | (842) | (3) | 29,514 |
| Total revenue | 43,403 | 1,758 | 4 | 41,644 | (11,123) | (21) | 52,767 |
| Costs and expenses and other (income): | | | | | | | |
| Cost of research products | 2,196 | (322) | (13) | 2,518 | (871) | (26) | 3,389 |
| Cost of laboratory services | 12,548 | 1,962 | 19 | 10,586 | 993 | 10 | 9,593 |
| Research & development | 8,452 | 374 | 5 | 8,078 | (233) | (3) | 8,311 |
| Selling, general and administrative | 20,069 | 5,702 | 40 | 14,367 | 2,270 | 19 | 12,097 |
| Provision for uncollectible A/R | 4,967 | (7,020) | (59) | 11,987 | 2,642 | 28 | 9,345 |
| Legal expenses | 5,476 | (864) | (14) | 6,340 | 679 | 12 | 5,661 |
| Interest income | (1,523) | (371) | ` 32 | (1,152) | 203 | (15) | (1,355) |
| Gain on patent litigation settlement | (14,000) | (14,000) | | | | | |
| Costs and expenses | 38,186 | (14,538) | (28) | 52,724 | 5,683 | 12 | 47,041 |
| Operating income (loss) | <u>\$5,217</u> | \$16,297 | - | <u>\$(11,080)</u> | \$(16,806) | - | <u>\$5,726</u> |

Fiscal 2005 Compared to Fiscal 2004

Fiscal 2005 research product revenues and royalty income was \$10.5 million compared to \$13.0 million in fiscal 2004, a decrease of \$2.4 million or 19%. The decrease was primarily due to the Company not recording revenue due to the ongoing dispute with certain distributors on the sales of certain licensed products, partially offset by the increase in direct sales of our research products and royalty income from Digene. The decline in the gross profit margin on research product sales and royalties in fiscal 2005 compared to fiscal 2004 is due to the decline in revenues from distributors with whom we had supply agreements. Revenues from these distributors were net of manufacturing costs. See Legal Proceedings.

Fiscal 2005 clinical laboratory revenues were \$32.9 million compared to \$28.7 million in fiscal 2004, an increase of \$4.2 million or 15%, primarily due to the increase in the number of customer accounts being serviced. This increase in new customer accounts is due to the expansion into the New Jersey and Westchester market that commenced in the fourth quarter of fiscal 2004.

The cost of research products revenues in fiscal 2005 was \$2.2 million compared to \$2.5 million in fiscal 2004, a decrease of \$0.3 million or 13%, primarily due to lower royalty costs because of the expiration of a licensed patent agreement with Yale University.

The cost of clinical laboratory services in fiscal 2005 was \$12.5 million compared to \$10.6 million in fiscal 2004, an increase of \$1.9 million or 19%, primarily due to the increased number of tests performed and higher costs incurred to perform certain esoteric tests. The increase in tests performed is due to the new accounts being serviced through the expansion into New Jersey markets.

Fiscal 2005 research and development expenses were \$8.5 million compared to \$8.1 million in fiscal 2004, an increase of \$0.4 million or 5% primarily due to increases in clinical trial study costs for the development of therapeutic products.

Fiscal 2005 selling, general and administrative expenses were \$20.1 million compared to \$14.4 million in fiscal 2004, an increase of \$5.7 million or 40%. The increase was primarily due to an increase in direct selling expenditures for our clinical reference laboratory and life science divisions, an increase in information technology costs for the expansion of the information technology connectivity system and data center personnel costs including infrastructure expenses and accounting related fees for the compliance with the Sarbanes-Oxley Act of 2002.

Fiscal 2005 provision for uncollectible accounts receivable in the clinical reference laboratory segment was \$5.0 million, compared to \$12.0 million during the same period in 2004, a decrease of \$7.0 million or 59%. The percentage of the provision for uncollectible accounts receivable as a proportion of clinical laboratory services revenues decreased to 15.0% in fiscal 2005 compared to 36% for the 2004 period. This decrease was primarily due to improved collection procedures and due to the change in the mix of the demographics of the patients from the New Jersey new customer accounts.

Fiscal 2005 legal expenses were \$5.5 million compared to \$6.3 million in fiscal 2004, a decrease of \$0.8 million or 14%. The decrease is primarily due to the reduction of legal activities because of the settlement with Digene Corporation during fiscal 2005's first quarter ended October 31, 2004.

Fiscal 2005 interest income increased \$0.4 million or 32% to \$1.5 million compared to \$1.2 million during fiscal 2004, due to the increased amount of cash available for investment and the increase in interest rates offered on debt securities. The Company earns interest on its cash and cash equivalents by investing primarily in short term (90 days or less) diverse financial instruments with high credit ratings.

On October 14, 2004, the Company as plaintiff finalized and executed a settlement and license agreement with Digene Corporation to settle a patent litigation lawsuit (the "Digene agreement"). Under the terms of the agreement, the Company received an initial payment of \$16.0 million, would earn in the first "annual period" (October 1, 2004 to September 30, 2005) a minimum royalty payment of \$2.5 million, and receive a minimum royalty of \$3.5 million in each of the next four annual periods. In addition, the agreement provides for the Company to receive quarterly running royalties on the net sales of Digene products subject to the license until the expiration of the patent on April 24, 2018. These quarterly running royalties will be fully creditable against the minimum royalty payments due in the first five years of the agreement. The balance, if any, of the minimum royalty payment will be recognized in the final quarter of the applicable annual royalty period.

As a result of the above settlement, the Company recorded a gain on patent litigation settlement of \$14.0 million in the first quarter of fiscal 2005, and deferred \$2 million which would be earned from net sales of the Company's licensed products covered by the agreement during the first annual period. As of July 31, 2005, the balance of the revenue deferred from the settlement was \$359,400. See Legal Proceedings.

In fiscal 2005, the Company's provision for income taxes was \$2.2 million which was based on the effective federal, state and local income tax rates applied to the fiscal year's taxable income. The provision for income taxes, at an effective rate of 42%, was different from the U.S. federal statutory rate of 34% due to state income taxes, net of federal tax deduction of approximately 6%, expenses not deductible for income tax return purposes of 2%, a benefit for foreign sales(-1%) and other adjustments of 1%. In fiscal 2004, the Company's benefit for income taxes was \$4.8 million which was based on the effective federal, state and local income tax rates applied to the fiscal year's taxable income. The benefit for income taxes, at an effective rate of 44%, was different from the U.S. federal statutory rate of 34% due to state income tax benefit, net of federal, of approximately 4%, a benefit for foreign sales of 2% and other benefits, net, of 4%.

The research and development segment's fiscal 2005 income before income taxes was \$11.5 million compared to a loss of \$1.3 million in fiscal 2004. The fiscal 2005 increase resulted from the \$14 million gain and related earned royalties from the Digene agreement. The gain was partially offset by a decline in research product revenues due to the ongoing dispute with certain distributors on the sales of certain licensed products. The clinical reference laboratory segment's income before income taxes was \$2.8 million versus a loss of \$1.5 million. The increase is due to higher revenues, due to the increase in the number of customer accounts being serviced, and a lower provision for uncollectible accounts, due to the change in the mix of payers and the expansion into the New Jersey markets. The Other segment's (loss) before income taxes was (\$9.0) million versus (\$8.3) million in fiscal 2004, primarily due to accounting related fees for compliance with the Sarbanes-Oxley Act of 2002 not incurred in the 2004 period.

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 payers and HMO's. Clinical laboratory services are provided to patients covered by various third party payer 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 \$0.9 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 \$0.2 million as a result of a decrease in the expenses related to the clinical trial activities and other research projects.

Selling, general and administrative expenses increased by \$2.2 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, an increase at the clinical lab in the information technology expenditures, and an increase in the in-house legal patent costs

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 payers 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 \$0.6 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.

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 payers. 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.

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

Disclosure Controls and Procedures.

The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") as of July 31, 2005. Based on this evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that, as of July 31, 2005, the Company's disclosure controls and procedures were effective to provide reasonable assurance that information is accumulated and communicated to the Company's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure, and ensure that information required to be disclosed in the reports the Company files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms.

Management's Annual Report on Internal Control over Financial Reporting.

Management of Enzo Biochem, Inc. is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. The Company's internal control over financial reporting is a process designed 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 principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management utilized the criteria set forth in "Internal Control-Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, to conduct an assessment of the effectiveness of the Company's internal control over financial reporting as of July 31, 2005. Based on the assessment, management has concluded that, as of July 31, 2005, the Company's internal control over financial reporting is effective.

Management's assessment of the effectiveness of the Company's internal control over financial reporting as of July 31, 2005, has been audited by Ernst & Young LLP an independent registered public accounting firm. Ernst & Young LLP has issued an attestation report on management's assessment of the Company's internal control over financial reporting, which is included herein.

Changes in Internal Control over Financial Reporting.

The Company has expended significant resource in achieving compliance with Section 404 of the Sarbanes-Oxley Act. Through internal resources and the assistance of outside consultants, the Company developed and executed a plan to evaluate, document, test and improve, where necessary, its internal controls over financial reporting. Although, as stated below, the Company has not made any changes during the most recent fiscal quarter that have materially affected internal controls over financial reporting, in the course of achieving compliance with the Section 404 of the Sarbanes-Oxley Act, the Company has made changes designed to improve several areas within its system of internal controls. The nature of these changes included greater segregation of responsibilities, better documentation of work procedures and managerial review, dual approvals, revisions to delegation of authority and tightening access restrictions to systems, data and assets.

There has been no change in the Company's internal control over financial reporting that occurred during the Company's fiscal fourth quarter ended July 31, 2005 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders Enzo Biochem, Inc.

We have audited management's assessment, included in Item 9A, that Enzo Biochem, Inc. (the "Company") maintained effective internal control over financial reporting as of July 31, 2005, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Enzo Biochem, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed 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 principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Enzo Biochem, Inc. maintained effective internal control over financial reporting as of July 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Enzo Biochem, Inc. maintained, in all material respects, effective internal control over financial reporting as of July 31, 2005, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Enzo Biochem, Inc. (the "Company") as of July 31, 2005 and 2004, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended July 31, 2005 and our report dated October 12, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Melville, NY October 12, 2005 ITEM 9B. OTHER INFORMATION

None

PART III

Item 10. 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 78) has been a Director of the Company since 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 62) has been a Director of the Company since 1982. From 2003 to 2004, Mr. Delucca was Executive Vice President and Chief Financial Officer of REL Consulting Group. Mr. Delucca was the Chief Financial Officer & Executive Vice President, Finance & Administration of Coty, Inc., from 1999 to 2002. From 1993 until 1999, he was Senior Vice President and Treasurer of RJR Nabisco, Inc. From 1992 to 1993, he was managing director and Chief Financial Officer of Hascoe Associates, Inc. From 1990 to 1992, he was President of The Lexington Group. From 1989 to 1990, he was Senior Vice President-Finance of the Trump Group. From 1986 until 1989, he was senior Vice President-Finance at International Controls Corp. From 1985 to 1986, he was a Vice President and Treasurer of Textron, Inc. Prior to that, he was a Vice President and Treasurer of the Avco Corporation, which was acquired by Textron.

IRWIN C. GERSON (age 75) has been a Director of the Company since May 2001. From 1995 until December 1998, Mr. Gerson served as Chairman of Lowe McAdams Healthcare and prior thereto had been, since 1986, Chairman and Chief Executive Officer of William Douglas McAdams, Inc., one of the largest advertising agencies in the U.S. specializing in pharmaceutical marketing and communications to healthcare professionals. In February 2000, he was inducted into the Medical Advertising Hall of Fame. Mr. Gerson has a 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 66) has been a Director of the Company since August 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 holds a Bachelor of Business Administration degree from The City College of New York (Baruch College).

MARCUS A. CONANT, M.D. (age 69) was appointed to the board in July 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:

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

Position
Chief Executive Officer, Chairman of the Board of Directors
Chief Operating Officer, Secretary, Treasurer
President, Chief Financial Officer
Executive Vice President
Senior Vice President
Vice President of Finance
Vice President, Corporate Development
Vice President, Business Development

DR. ELAZAR RABBANI (age 61) 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 53) 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 55) 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 65) 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 66) 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 57) 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 65) 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 numerous 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 48) 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.

Item 11. <u>Executive Compensation</u>

The information required under this item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission on or before November 28, 2005 and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The information required under this item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission on or before November 28, 2005 and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions

The information required under this item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission on or before November 28, 2005 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 expected to be filed with the Securities and Exchange Commission on or before November 28, 2005 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, 2005 and 2004

Consolidated Statements of Operations- Years ended July 31, 2005, 2004 and 2003

Consolidated Statements of Stockholders' Equity - Years ended July 31, 2005, 2004 and 2003

Consolidated Statements of Cash Flows - Years ended July 31, 2005, 2004 and 2003

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

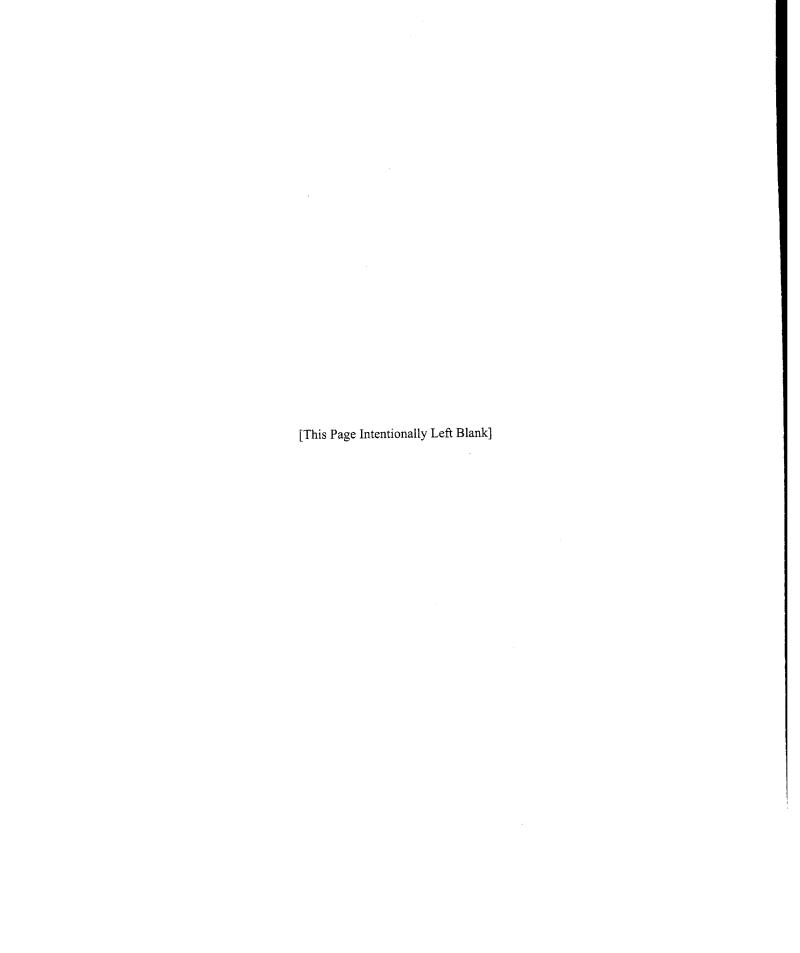
The following documents are filed as Exhibits to this Annual Report on Form 10-K:

| Exhibit <u>No.</u> | 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. (3) |
| 3(d) | Bylaws. (1) |
| 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(I) | 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 (r) | Code of Ethics (10) |
| 10 (s) | Settlement and License Agreement with Digene Corporation effective as of September 30, 2004 (10) (12) |
| 10 (t) | Joint Stipulation and Order of Dismissal with Prejudice dated October 14, 2004 (10) (12). |
| 10 (u) | 2005 Equity Compensation Incentive Plan (11) |
| 10 (v) | Lease agreement with Pari Management (filed herewith) |
| 14 (a) | Code of Ethics (10) |

- 21 Subsidiaries of the registrant:
 - Enzo Clinical Labs, Inc., a New York corporation.
 - Enzo Life Sciences, Inc., a New York corporation.
 - 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.

Notes to exhibits

- (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.
- (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) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 2004 and is incorporated herein by reference.
- (11) This exhibit was filed as an exhibit to the Company's Proxy Statement of Schedule 14A filed on January 19, 2005 and is incorporated herein by reference.
- (12) These exhibits are subject to a confidential treatment request pursuant to securities exchange act rules.
- (b) See Item 15(a) (3), above.
- (c) See Item 15(a) (2), above.



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):

| Report of Independent Registered Public Accounting Firm | F-2 |
|---|-----|
| Consolidated Balance Sheets July 31, 2005 and 2004 | F-3 |
| Consolidated Statements of Operations Fiscal years ended July 31, 2005, 2004 and 2003 | F-4 |
| Consolidated Statements of Stockholders' Equity Years ended July 31, 2005, 2004 and 2003 | F-5 |
| Consolidated Statements of Cash Flows Years ended July 31, 2005, 2004 and 2003 | F-6 |
| Notes to Consolidated Financial Statements | F-7 |
| Schedule II - Valuation and Qualifying Accounts Years ended July 31, 2005, 2004 and 2003 | S-1 |

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 Independent Registered Public Accounting Firm

The 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, 2005, and 2004, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended July 31, 2005. Our audits also included the financial statement schedules listed in the Index at Item 15(a). These financial statements and schedules are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedules based on our audits.

We conducted our audits in accordance with the 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 financial statements referred to above present fairly, in all material respects, the consolidated financial position of Enzo Biochem, Inc. at July 31, 2005 and 2004, and the consolidated results of their operations and their cash flows for each of the three years in the period ended July 31, 2005, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedules, when considered in relation to the basic financial statements taken as a whole, present fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of July 31, 2005, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated October 12, 2005, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Melville, NY October 12, 2005

ENZO BIOCHEM, INC. CONSOLIDATED BALANCE SHEETS

ASSETS

| ASSETS | July | 31. |
|--|----------------------------|---------------------------|
| Current assets: | 2005 | 2004 |
| Cash and cash equivalents | \$76,980,900 | \$54,499,100 |
| Marketable securities | 6,713,600 | 17,241,500 |
| Accounts receivable, net of allowance for doubtful accounts of \$2,291,700 | | |
| in 2005 and \$2,770,300 in 2004 | 13,420,500 | 14,794,400 |
| Income tax receivable | | 3,906,900 |
| Inventories | 2,876,100 | 3,434,300 |
| Prepaid expenses | 2,579,900 | 1,832,500 |
| Prepaid taxes | 1,329,200 | |
| Deferred taxes | <u>899,700</u> | <u>1,974,800</u> |
| Total current assets | 104,799,900 | 97,683,500 |
| | | |
| Property and equipment, net of accumulated depreciation | | |
| and amortization of \$7,278,700 in 2005 and \$7,681,000 in 2004 | 2,669,500 | 2,414,600 |
| Goodwill | 7,452,000 | 7,452,000 |
| Patent costs, net of accumulated amortization of \$9,695,300 in 2005 | | |
| and \$8,383,600 in 2004 | 1,332,800 | 2,624,500 |
| Other | <u>211,600</u> | <u>159,600</u> |
| | <u>\$116,465,800</u> | <u>\$110,334,200</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accrued legal fees | \$2,716,800 | \$2,050,500 |
| Trade accounts payable | 2,413,600 | 2,092,300 |
| Other accrued expenses. | 1,347,900 | 494,300 |
| Accrued payroll | 515,100 | 475,400 |
| Deferred revenue | 359,400 | |
| Accrued research and development expenses | 286,300 | 225,000 |
| Installment payable | 150,000 | |
| Deferred rent | | 86,700 |
| Total current liabilities | 7,789,100 | 5,424,200 |
| | , , , , , | . , |
| Deferred taxes | 260,000 | 444,200 |
| Long term installment payable | 150,000 | 300,000 |
| Commitments | | |
| 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: 32,526,800 in 2005 and 30,864,800 in 2004 | 325,300 | 308,600 |
| Additional paid-in capital | 230,643,800 | 205,920,000 |
| Less treasury stock at cost: 384,400 shares in 2005 | 200,040,000 | 200,020,000 |
| and 349,900 shares in 2004 | (5,994,400) | (5,668,900) |
| Accumulated deficit | (116,577,400) | (96,148,000) |
| Accumulated deficit | (110,377,400) (130,600) | (90,145,000) (245,900) |
| Total stockholders' equity | 108,266,700 | 104,165,800 |
| Total Stockholders Squity | \$116,465,800 | \$110,334,200 |
| | * LIN' AND OND | ALIA'OOT'EOO |

ENZO BIOCHEM, INC. CONSOLIDATED STATEMENTS OF OPERATIONS

| | Fisca | al years ended Jul | y 31, |
|---|--------------------|--------------------|--------------------|
| _ | <u> 2005</u> | <u>2004</u> | 2003 |
| Revenues: | | | |
| Research product revenues and royalty income | \$10,546,000 | \$12,972,200 | \$23,253,100 |
| Clinical laboratory services | <u>32,856,600</u> | <u> 28,672,200</u> | 29,513,900 |
| | 43,402,600 | 41,644,400 | 52,767,000 |
| Costs and expenses and other (income): | | | |
| Cost of research product revenues | 2,196,400 | 2,517,800 | 3,388,900 |
| Cost of clinical laboratory services | 12,547,600 | 10,586,200 | 9,592,900 |
| Research and development expense | 8,452,400 | 8,078,300 | 8,311,200 |
| Selling, general, and administrative expense | 20,069,200 | 14,367,200 | 12,097,400 |
| Provision for uncollectible accounts receivable | 4,967,100 | 11,986,500 | 9,345,300 |
| Legal expense | 5,475,500 | 6,339,900 | 5,661,000 |
| Interest income | (1,522,900) | (1,151,800) | (1,355,000) |
| Gain on patent litigation settlement | (14,000,000) | | |
| | 38,185,300 | 52,724,100 | 47,041,700 |
| Income (loss) before income taxes | 5,217,300 | (11,079,700) | 5,725,300 |
| (Provision) benefit for income taxes | (2,213,300) | <u>4,848,100</u> | (1,881,300) |
| Net income (loss) | <u>\$3,004,000</u> | (\$6,231,600) | <u>\$3,844,000</u> |
| Net income (loss) per common share: | | | |
| Basic | \$0.09 | (\$0.20) | <u>\$0.12</u> |
| Diluted | <u>\$0.09</u> | (\$0.20) | \$0.12 |
| Weighted average common shares outstanding: | | | |
| Basic | <u>32,097,000</u> | 31,700,000 | <u>31,399,000</u> |
| Diluted | 32,763,000 | 31,700,000 | 32,175,000 |

ENZO BIOCHEM, INC CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

Years ended July 31, 2005, 2004 and 2003

| Total Stockholders' <u>Equity</u> \$104,733,200 3,844,000 | (85,000) | 630,800 257,200 109,380,200 | (6,231,600) | (6,392,500) (5,668,900) | 6,564,800 282,200 104,165,800 | 3,004,000 | 115,300 | 3,119,300 (325,500) 124,300 | 831,200 351,600 \$108,266,700 |
|---|------------------------|---|--|----------------------------|-------------------------------------|---|--------------------------------------|---------------------------------------|---|
| Accumulated Other Comprehensive Loss | (\$85,000) | (85,000) | | | (245,900) | | 122,000 (49,800) | 1 1 | (\$130,600) |
| Accumulated (\$56,051,200) 3,844,000 | (37,709,200) | (89,916,400) | (6,231,600) | I | (96,148,000) | \$3,004,000 | 1 | (23,433,400) | (\$116,577,400) |
| Treasury Stock <u>Amount</u> | 1 1 | | | (\$5,668,900) | (5,668,900) | 1 1 | 1 | (325,500) | (\$5,994,400) |
| Additional Paid-in <u>Capital</u> \$160,499,800 | 37,694,900 | 630,100 257,000 199,081,800 | [] | 1 | 6,556,100 282,100 205,920,000 | i i | I | 23,417,900 | 830,200 351,400 \$230,643,800 |
| Common Stock Amount \$284,600 | | 700 200 299,800 | | 1 | 8,700 100 308,600 | | 1 | 15,500 | 1,000 200 \$325,300 |
| Freasury Stock <u>Shares</u> | | 1 | | 349,900 | 349,900 | | 1 | 17,500 17,000 | 384,400 |
| Common Treasury Stock Stock Shares Shares 28,459,800 | 1,423,600 | 73,300 18,400 29,975,100 | | (| 873,900 15,800 30,864,800 | 1 1 | l | 1,543,600 | 100,300 18,100 32,526,800 |
| Balance at July 31, 2002 | Securities, net of tax | Increase in common stock and paid-in capital due to exercise of stock options | Net loss for the year ended July 31, 2004Unrealized loss on available for-sale | Comprehensive loss | due to exercise of stock options | Net income for the year ended July 31, 2005 | realized and reported in net income. | Comprehensive loss | due to exercise of stock options. Issuance of stock for employee 401(k) plan match Balance at July 31, 2005 |

ENZO BIOCHEM, INC CONSOLIDATED STATEMENTS OF CASH FLOWS

| _ | Fis | cal years ended | July 31, |
|---|------------------|-----------------|---------------------|
| | <u>2005</u> | 2004 | 2003 |
| Operating activities | | | |
| Net income (loss) | \$3,004,000 | (\$6,231,600) | \$3,844,000 |
| Adjustments to reconcile net income (loss) to net cash | | | |
| provided by (used in) operating activities: | | | |
| Depreciation and amortization of property and equipment | 1,020,400 | 1,076,000 | 1,058,000 |
| Amortization of patent costs | 1,311,700 | 1,285,500 | 750,000 |
| Provision for uncollectible accounts receivable | 4,967,100 | 11,986,500 | 9,345,300 |
| Deferred taxes | 890,900 | (1,650,700) | (128,100) |
| Issuance of stock for 401 K plan employer match | 351,600 | 282,200 | 257,200 |
| Deferred rent | (86,700) | (232,600) | (195,400) |
| Loss on sales of marketable securities | 200,200 | | |
| Tax benefit on stock option exercise | 124,300 | | |
| Other | (51,900) | 1,400 | (14,800) |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable before provision for | | | |
| uncollectible amounts | (3,593,200) | (9,514,500) | (6,344,200) |
| Inventories | 558,200 | (12,500) | 768,400 |
| Income taxes receivable | 3,906,900 | (3,364,600) | 1,426,300 |
| Prepaid expenses | (747,400) | 400,400 | (741,900) |
| Prepaid taxes | (1,329,200) | | |
| Trade accounts payable and other accrued expenses | 1,174,900 | 714,600 | (374,700) |
| Accrued research and development expenses | 61,300 | (228,400) | 453,400 |
| Deferred revenue | 359,400 | | |
| Accrued legal fees | 666,300 | 135,300 | 1,775,200 |
| Accrued payroll | <u>39,700</u> | (227,600) | <u>227,100</u> |
| Total adjustments | 9,824,500 | <u>651,000</u> | <u>8,261,800</u> |
| Net cash provided by (used in) operating activities | 12,828,500 | (5,580,600) | 12,105,800 |
| Investing activities | | | |
| Capital expenditures | (1,275,700) | (1,303,800) | (956,700) |
| Patent costs deferred | (19,700) | (443,800) | (353,900) |
| Sales (purchases) of marketable securities, net | 10,442,800 | (2,349,000) | (15,293,400) |
| Net cash provided by (used in) investing activities | <u>9,147,400</u> | (4,096,600) | <u>(16,604,000)</u> |
| Financing activities | | | |
| Proceeds from the exercise of stock options, net | 505,900 | 895,700 | 630,800 |
| Proceeds from insurance loss | | <u>13,000</u> | |
| Net cash provided by financing activities | 505,900 | <u>908,700</u> | <u>630,800</u> |
| Net increase (decrease) in cash and cash equivalents | 22,481,800 | (8,768,500) | (3,867,400) |
| Cash and cash equivalents at the beginning of the year | 54,499,100 | 63,267,600 | 67,135,000 |
| Cash and cash equivalents at the end of the year | \$76,980,900 | \$54,499,100 | \$63,267,600 |

See Note 2 for supplemental disclosure for statement of cash flows - non cash transactions

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

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.

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 its investments in highly liquid corporate debt instruments with maturities of three months or less at the date of purchase to be cash equivalents. The Company limits concentration of credit risk by diversifying its investments among a variety of high credit quality issuers.

Marketable securities

Investments with a maturity greater than three months at the date of purchase are designated as marketable securities. At July 31, 2005 and 2004, management designated marketable securities held by the Company as available-for-sale securities, for purposes of Statement of Financial Accounting Standards No. 115 "Accounting for Certain Investments in Debt and Equity Securities". Securities available-for-sale are carried at fair value with the unrealized losses reported in stockholders' equity under the caption "Accumulated other comprehensive loss".

The Company periodically reviews its investment portfolio to determine if there is an impairment that is other than temporary. In testing for impairment, the Company considers, among other factors, the length of time and the extent of a security's unrealized loss, the financial condition and near term prospects of the issuer, economic forecasts and market or industry trends. The cost of marketable securities sold is based on the original cost basis plus any reinvested dividends.

Fair Value of Financial Instruments

Financial instruments that subject the Company to significant concentrations of credit risk primarily consist of cash and cash equivalents, marketable securities, net accounts receivable, accounts payable and accrued liabilities, which are carried at cost, which management believes approximates fair value. The Company's cash equivalents and marketable securities are invested in financial instruments with high credit ratings.

Concentration of credit risk

At July 31, 2005 and 2004, approximately 94% and 89%, respectively, 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, the number of insurance carriers it deals with, and its 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. The Company also provides services to certain patients covered by various third-party payers, including the Federal Medicare program. Revenue, net of contractual allowances, from direct billings under the Federal Medicare program during the years ended July 31, 2005, 2004 and 2003 were approximately 20%, 19% and 11%, respectively, of the Company's total revenue. The clinical reference laboratory industry is characterized by a significant amount of uncollectible accounts receivable resulting from the inability to receive accurate and timely billing information in order to forward it to the third party payers for reimbursement, and the inaccurate information received from the covered individual patients for unreimbursed unpaid amounts.

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 or the life of the patent, whichever is shorter, 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.

Comprehensive Income

Statement of Financial Accounting Standards No. 130, "Reporting Comprehensive Income" (SFAS 130"), requires reporting and displaying of comprehensive loss and its components. In accordance with SFAS 130, the accumulated balance of other comprehensive loss, which is comprised of net unrealized losses on marketable securities, is disclosed as a separate component of stockholders' equity.

Revenue Recognition

Revenues from the clinical laboratory are recognized 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 payers to provide services at less than established billing rates. The Company's contractual adjustments, and the provision for doubtful accounts, are estimated based on historical collection experience using a retrospective collection analysis and aging models. Should circumstances change (e.g. shift in payer mix, decline in economic conditions, or deterioration in aging of patient receivables), our estimates of the net realizable value of patient receivables could be reduced by a material amount.

Revenues from research product sales, exclusive of certain non-exclusive distribution agreements, are recognized when the products are shipped, the sales price is fixed or determinable and collectibility is reasonably assured. 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. During the fiscal years ended July 31, 2005, 2004, and 2003, the manufacturing and processing cost of these products sold was \$0.7 million, \$7.4 million, and \$7.0 million, respectively. The revenue from these non-exclusive distribution agreements are recognized when shipments are made to their respective customers and reported to the Company.

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 \$299,000, \$384,000, and \$414,000 for fiscal years ended July 31, 2005, 2004, and 2003, respectively.

Research and Development Expenses

Research and development costs are charged to research and development expenses as incurred. Such costs include costs of scientific personnel, supplies, consultants, allocated facility costs, costs related to pre-clinical and clinical trials, and amortization of patent expense.

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 during the fourth quarter of its fiscal year. Based on this testing, there is no impairment to the goodwill recorded on the accompanying balance sheet as of July 31, 2005 and 2004.

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.

The Company periodically evaluates the recoverability of the net carrying value of its property, and intangible assets. An impairment loss is recognized when the carrying value of the long-lived asset exceeds its undiscounted future cash flows and its fair value. A loss on impairment would be recognized through a charge to earnings. No impairment charges were required in fiscal 2005, 2004, or 2003.

Segment Reporting

The FASB issued Statement of Financial Accounting Standards No. 131, "Disclosures About Segments of an Enterprise and Related Information" which establishes standards for reporting information on operating segments in interim and annual financial statements. An enterprise is required to separately report information about each operating segment that engages in business activities from which the segment may earn revenues and incur expenses, whose separate operating results are regularly reviewed by the chief operating decision maker regarding allocation of resources and performance assessment and which exceed specific quantitative thresholds related to revenue and profit or loss. During all fiscal periods presented, the Company met these requirements, and accordingly has two reportable segments (see Note 13).

Stock Dividends

During fiscal 2005, the Company's board of directors declared a 5% stock dividend on October 5, 2004 payable November 15, 2004 to shareholders of record as of October 25, 2004. The fiscal 2004 per share data was adjusted retroactively to reflect the stock dividend declared on October 5, 2004. In fiscal 2003, the Company's board declared a 5% stock dividend on June 10, 2003 payable July 14, 2003 to shareholders of record as of June 30, 2003. The shares and per share data for fiscal 2003 have been adjusted to retroactively reflect the stock dividend in fiscal 2003. The Company recorded a charge to accumulated deficit and offsetting credits to both common stock and additional paid-in capital of \$23,433,400 and \$37,709,200 in fiscal 2005 and fiscal 2003, respectively, which reflects the fair value of the stock dividends on the dates of declaration

Net income (loss) 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 income (loss) per share represents net income (loss) 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 income (loss) per share pursuant to SFAS No. 128.

| Fiscal years ended July 31, Numerator: | <u>2005</u> | <u>2004</u> | <u>2003</u> |
|---|--------------|----------------|----------------|
| Net income (loss) for numerator for basic and diluted net income per common share | \$3,004,000 | \$(6,231,600) | \$3,844,000 |
| Denominator: | | | |
| Denominator for basic net income (loss) per common share-weighted-average shares | 32,097,000 | 31,700,000 | 31,399,000 |
| Effect of dilutive employee and director stock options | | | |
| | 666,000 | | <u>776,000</u> |
| Denominator for diluted net income (loss) per share- | | | |
| adjusted weighted-average shares | 32,763,000 | 31,700,000 | 32,175,000 |
| Basic net income (loss) per share | <u>\$.09</u> | <u>\$(.20)</u> | <u>\$.12</u> |
| Diluted net income (loss) per share | <u>\$.09</u> | <u>\$(.20)</u> | <u>\$.12</u> |
| | | | |

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.

For the fiscal years ended July 31, 2005, 2004 and 2003, the effect of approximately 818,300, 554,500, and 79,900 respectively, of outstanding options to purchase common shares were excluded from the calculation of diluted net income (loss) per share because their effect would be anti-dilutive.

Stock Compensation Plans

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123 "Share-Based Payment" ("SFAS 123(R)"). The statement requires that the compensation cost relating to share-based payment transactions be recognized in financial statements. That cost will be measured based on the fair value of the equity or liability instrument issued. The statement covers a wide range of share-based compensation arrangements including share options, restricted share plans, performance-based awards, share appreciation rights, and employee share purchase plans. The Company was required to adopt SFAS 123(R) as of August 1, 2005, the first day of its fiscal year ending July 31, 2006. The adoption of SFAS 123(R) will have a material impact on the consolidated financial statements of the Company.

For the fiscal year ending July 31, 2005, the Company continued to account 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 income (loss) 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, 2005, 2004, and 2003: 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 0.71, 0.74, and 0.77, respectively, for all grants.

During the fiscal years ended July 31, 2005 and 2004, the Company followed 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 did not amend SFAS No. 123 to require companies to account for employee stock options using the fair value method, as SFAS No. 123(R) did, 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 the disclosure provisions of SFAS No. 148 effective January 31, 2004.

On June 3, 2005, the Board of Directors approved the acceleration of vesting of unvested "out of the money" stock options held by employees, including executive officers, and directors. The stock options considered as out of the money were those with an exercise price that was \$1.50 or greater than \$14.82, the closing price of the Company's common stock on June 3, 2005. All other terms and conditions of these "out of the money" options remain unchanged. As a result of the acceleration, options to purchase approximately 666,000 shares of the Company's common stock (which represents approximately 21% of the Company's currently outstanding stock options) became exercisable immediately. The accelerated options range in exercise prices from \$16.39 to \$19.02 and the weighted average exercise price of the accelerated options was \$17.55 per share. The total number of options subject to acceleration include options to purchase 575,000 shares held by executive officers and directors of the Company. This action was taken to avoid expense recognition in future financial statements upon adoption of SFAS 123(R). The accelerated vesting of these "out of the money" options does not result in a charge in the Company's statement of operations for the fiscal year ended July 31, 2005 based on U.S. generally accepted accounting principles. The Company reported approximately \$10.1 million of pro forma compensation expense for the fiscal year ended July 31, 2005 in the pro forma SFAS footnote disclosure below, of which \$6.0 million is applicable to these "out of the money" options.

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

| Fiscal years ended July 31, | <u>2005</u> | <u>2004</u> | <u>2003</u> |
|---|---------------|---------------|------------------|
| Reported net income (loss) | \$3,004,000 | (\$6,231,600) | \$3,844,000 |
| Pro forma compensation expense | (10,128,600) | (3,239,800) | (3,010,900) |
| Pro forma net income (loss) | (\$7,124,600) | (\$9,471,400) | <u>\$833,100</u> |
| Pro forma net income (loss) per share: Basic | (\$.22) | (\$.30) | \$.03 |
| Diluted | (\$.22) | (\$.30) | \$.03 |

Note 2 - Supplemental disclosure for statement of cash flows

In the years ended July 31, 2005, 2004 and 2003, the Company paid cash for income taxes of approximately \$3,566,000, \$219,000 and \$583,000 respectively.

In fiscal 2005, a director exercised 31,660 shares of incentive stock options. The director surrendered 17,000 previously owned shares of the Company's common stock to be utilized to exercise the stock options. The Company recorded the market value of surrendered shares as treasury stock of approximately \$325,500 as a non cash transaction.

In fiscal 2004, certain officers exercised 769,300 shares of incentive stock options. The officers surrendered 349,900 of previously owned shares of the Company's common stock to be utilized to exercise the stock options. The Company recorded the 349,900 of surrendered shares as treasury stock of approximately \$5.7 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.

Note 3 - Marketable securities

Marketable securities are recorded at fair value. The following is a summary of available-for-sale securities:

| | Fair Va | | Unrealized ho | olding (loss) |
|--|---|---|------------------------|---------------|
| Fiscal Years Ended July 31, | <u>2005</u> | <u>2004</u> | <u>2005</u> | <u>2004</u> |
| Income bond mutual fund | \$5,638,600 | \$15,401,300 | \$(125,900) | \$(271,600) |
| Marketable debt securities: U.S. Government and agency securities Corporate debt securities (Average of remaining maturity of debt securities was approximately four months at July 31, 2005 and 2004) | 449,100 <u>625,900</u> <u>\$6,713,600</u> | 1,063,100 <u>777,100</u> \$17,241,500 | (4,700) \$(130,600) | |

During fiscal 2005, the Company realized proceeds of approximately \$10.7 million from maturities and sales of marketable securities, on which it realized a loss of approximately \$200,000, based on the average cost. There were no realized gains or losses on marketable security transactions during fiscal 2004 or fiscal 2003. The Company's cost basis in these marketable securities as of July 31, 2005 and 2004 was \$6,844,200 and \$17,642,500, respectively.

The following is a summary of other comprehensive (loss), which relates to the Company's investments in marketable securities:

| | | Tax (Expense) | Net-of-Tax |
|-------------------------------------|-------------------|---------------|---------------|
| | Before-Tax Amount | or Benefit | <u>Amount</u> |
| Fiscal 2003 unrealized (loss) | \$(139,300) | \$54,300 | \$(85,000) |
| Fiscal 2004 unrealized (loss) | (261,700) | 100,800 | (160,900) |
| Fiscal 2005 realized loss | 200,000 | (78,000) | 122,000 |
| Fiscal 2005 unrealized gain | <u>70,400</u> | (27,300) | <u>43,100</u> |
| · | (130,600) | 49,800 | (80,800) |
| Valuation reserve | · <u>-</u> | (49,800) | (49,800) |
| Cumulative balance at July 31, 2005 | (\$130,600) | <u>\$0</u> | (\$130,600) |

Note 4 - Inventories

| At July 31, 2005 and 200 | 04 inventories consist of: |
|--------------------------|----------------------------|
|--------------------------|----------------------------|

| | <u>2005</u> | <u>2004</u> |
|-------------------|------------------|------------------|
| Raw materials | \$51,700 | \$124,900 |
| Work in process | 1,767,200 | 2,188,000 |
| Finished products | <u>1,057,200</u> | <u>1,121,400</u> |
| · | \$2,876,100 | \$3,434,300 |

Note 5 - Property and equipment

At July 31, 2005 and 2004 property and equipment consist of:

| | <u>2005</u> | <u>2004</u> |
|---|------------------|------------------|
| Laboratory machinery and equipment | \$2,098,100 | \$1,901,900 |
| Leasehold improvements | 2,771,100 | 2,543,400 |
| Office furniture and equipment | <u>5,079,000</u> | <u>5,650,300</u> |
| · | 9,948,200 | 10,095,600 |
| Accumulated depreciation and amortization | (7,278,700) | (7,681,000) |
| · | \$2,669,500 | \$2,414,600 |

The Company's fixed assets have been assigned useful lives of between three and five years. In fiscal 2005, the Company removed the cost basis and accumulated depreciation and amortization of fixed assets that were fully depreciated and disposed.

Note 6 - Lease obligations

The Company leases office and laboratory space under several leases that expire between December 31, 2005 and March 2017. An entity owned by certain executive officers/directors of the Company owns the building that the Company leases as its main facility for laboratories and research and manufacturing operations, and corporate headquarters. In March 2005, the Company amended and extended the lease for another 12 years. In addition to the minimum annual rentals of space, the lease is subject to annual increases, based on the consumer price index. Annual increases are limited to 3% per year. Rent expense under this renewed lease and the prior lease approximated \$1,289,000, \$1,370,000 and \$1,302,000 in fiscal years 2005, 2004 and 2003, respectively.

Total consolidated rent expense incurred by the Company during fiscal 2005, 2004 and 2003 was approximately \$2,140,000, \$1,801,000 and \$1,742,000 respectively. Minimum annual rentals under operating lease commitments for fiscal years ending July 31, are as follows:

| Fiscal year ended July 31, | Minimum Annual Rents |
|----------------------------|----------------------|
| 2006 | \$2,601,000 |
| 2007 | 2,750,000 |
| 2008 | 2,644,000 |
| 2009 | 2,464,000 |
| 2010 | 2,200,000 |
| Thereafter | <u> 10,978,000</u> |
| | \$23,637,000 |

Note 7 - Litigation

On October 14, 2004, the Company as plaintiff finalized and executed a settlement and license agreement with Digene Corporation to settle a patent litigation lawsuit (the "Digene agreement"). Under the terms of the agreement, the Company received an initial payment of \$16.0 million, would earn in the first "annual period" (October 1, 2004 to September 30, 2005) a minimum royalty payment of \$2.5 million, and receive a minimum royalty of \$3.5 million in each of the next four annual periods. In addition, the agreement provides for the Company to receive quarterly running royalties on the net sales of Digene products subject to the license until the expiration of the patent on April 24, 2018. These quarterly running royalties will be fully creditable against the minimum royalty payments due in the first five years of the agreement. The balance, if any, of the minimum royalty payment will be recognized in the final quarter of the applicable annual royalty period. As a result of the Digene agreement, the Company recorded a gain on patent litigation settlement of \$14.0 million in the first quarter of fiscal 2005, and deferred \$2 million which would be earned from net sales of the Company's licensed products covered by the agreement during the first annual period. As of July 31, 2005, the balance of the deferred revenue from the settlement was \$359,400.

In October 2002, the Company filed suit in the United States District Court of the Southern District of New York against Amersham pic, 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. The defendants have answered the individual complaints and asserted a variety of affirmative defenses and counterclaims. Fact discovery is ongoing. The Court conducted a claim construction hearing from July 5-11, 2005. Closing arguments on claim construction issues were conducted on September 30, 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. The Company recorded revenue from only Perkin Elmer during the fiscal year ended July 31, 2005.

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 Affymetrix 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. Initial pleadings have been completed and discovery has commenced. The Court conducted a claim construction hearing from July 5 - 11, 2005.

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

| Fiscal year ended July 31, | <u>2005</u> | <u>2004</u> | 2003 |
|---|---------------|-------------|---------------|
| Federal statutory rate Expenses not deductible for income tax return purposes | (34%) (2%) | 34% (3%) | (34%) (2%) |
| State income taxes, net of (benefit) of federal tax deduction. | (6%) | `4% | (3%) |
| Benefit of foreign sales | 1% | 2% | 4% |
| Fixed asset basis difference | - | 8% | - |
| Other | <u>(1%)</u> | <u>(1%)</u> | <u>2%</u> |
| | (42%) | 44% | (33%) |

Note 9 - Stockholders' equity

Treasury stock

In fiscal 2005, a director exercised 31,660 shares of incentive stock options. The director surrendered 17,000 previously owned shares of the Company's common stock to be utilized to exercise the stock options. The Company recorded the market value of surrendered shares as treasury stock of approximately \$325,500, and is a non cash transaction.

In fiscal 2004, certain officers exercised 769,300 shares of incentive stock options. The officers surrendered 349,900 of previously owned shares of the Company's common stock to be utilized to exercise the stock options. The Company recorded the market value of surrendered shares as treasury stock of approximately \$5.7 million, and is a non cash transaction.

Incentive stock option plans

The Company has incentive stock option plans ("1994 plan" and "1999 plan") under which the Company may grant options for up to 1,336,745 shares (1994 plan) and up to 2,312,356 shares (1999 plan) of common stock. No additional options may be granted under the 1994 plan. In fiscal 2005, the Company set up a new incentive stock options plan ("2005 plan") under which the Company may grant up to 1,000,000 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 non statutory options. Incentive stock options generally become exercisable at 25% per year after one year and expire ten years after the date of grant. 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, 2005, 2004 and 2003 under SFAS No. 123 is as follows:

| | | 2005 | | 2004 | | 2003 |
|--|------------------|----------------|------------------|----------------|------------------|----------------|
| | | Weighted - | | Weighted - | | Weighted - |
| | | Average | | Average | | Average |
| | <u>Options</u> | Exercise Price | <u>Options</u> | Exercise Price | <u>Options</u> | Exercise Price |
| Outstanding at | | | | • | | |
| beginning of year | 2,856,801 | \$11.86 | 3,397,087 | \$9.88 | 2,841,401 | \$9.38 |
| Granted | 431,975 | \$16.57 | 428,925 | \$17.02 | 661,225 | \$11.76 |
| Exercised | (100,332) | | (917,539) | \$7.16 | (79,838) | \$6.85 |
| Cancelled | (34,319) | \$11.64 | <u>(51,672)</u> | \$10.13 | (25,701) | \$12.51 |
| Outstanding at | | | | | | |
| end of year | <u>3,154,125</u> | \$12.61 | <u>2,856,801</u> | \$11.86 | <u>3,397,087</u> | \$9.88 |
| | | | | | | |
| Exercisable at | | | | | | |
| end of year | <u>2,126,442</u> | \$11.28 | <u>1,770,492</u> | \$10.54 | 2,490,003 | \$8.98 |
| Weighted average fair value of options | | | | | | |
| granted during year | | <u>\$11.76</u> | | <u>\$12.40</u> | | <u>\$8.49</u> |

The following table summarizes information for stock options outstanding at July 31, 2005:

| | | Options outstanding | 1 | <u>Option</u> | ns exercisable |
|-------------------|----------------|---------------------|------------------|------------------|------------------|
| | | Weighted-Average | Weighted- | | Weighted- |
| Range of Exercise | | Remaining | Average Exercise | | Average Exercise |
| prices | <u>Shares</u> | Contractual Life | <u>Price</u> | <u>Shares</u> | <u>Price</u> |
| \$5.45-8.08 | 291,451 | 3.2 years | \$5.64 | 291,451 | \$5.64 |
| \$8.33-12.25 | 1,830,092 | 4.7 years | \$11.06 | 1,540,066 | \$10.91 |
| \$12.93-19.02 | 952,706 | 8.3 years | \$16.72 | 215,050 | \$16.60 |
| \$20.20-24.42 | 61,644 | 6.0 years | \$21.42 | 61,644 | \$21.42 |
| \$36.05 | <u> 18,233</u> | 4.4 years | \$36.05 | <u>18,233</u> | \$36.05 |
| | 3,154,125 | | | <u>2,126,444</u> | |

As of July 31, 2005, there were approximately 806,800 shares available for grant under the arrangements described above.

Note 10 - Commitments

The Company had an exclusive licensing agreement to an invention covered by licensed patents. Under this agreement, the Company was required to make certain minimum royalty payments of \$200,000 per year through the life of the patents. The patent expired in December, 2004.

Note 11 - 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, 2005, 2004 and 2003, the Company authorized employer matched contributions of 50% of the employees' contribution up to 10% of the employees' compensation, payable in Enzo Biochem, Inc. common stock. The 401(k) employer matched contributions expense was \$351,600, \$282,200, and \$257,200 in fiscal years 2005, 2004 and 2003, respectively.

Note 12 - Summary of Selected Quarterly Financial Data (unaudited)

The following table contains statement of operations information for each quarter of the fiscal years ended July 31, 2005 and 2004. 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 2005 and 2004 is summarized as follows:

| | | Quarter E | Ended | |
|--|-------------|----------------|-------------------|-------------|
| Fiscal 2005 | October 31, | <u>January</u> | <u> April 30,</u> | July 31, |
| | <u>2004</u> | <u>31.</u> | <u> 2005</u> | <u>2005</u> |
| | | <u> 2005</u> | | |
| Total revenues | \$10,301 | \$11,235 | \$11,000 | \$10,867 |
| Gross profit | 6,812 | 7,821 | 7,035 | 6,991 |
| Income (loss) before income taxes | 12,173 | (944) | (2,553) | (3,459) |
| Net income (loss) | 7,021 | (528) | (1,497) | (1,992) |
| Basic income (loss) per common share | \$0.22 | (\$0.02) | (\$0.05) | (\$0.06) |
| Diluted income (loss) per common share | \$0.22 | (\$0.02) | (\$0.05) | (\$0.06) |

| | | Quarter E | Ended | |
|-------------------------------|-------------|----------------|-------------|-------------|
| Fiscal 2004 | October 31, | <u>January</u> | April 30, | July 31, |
| | <u>2003</u> | <u>31,</u> | <u>2004</u> | <u>2004</u> |
| | | <u>2004</u> | | |
| Total revenues | \$10,273 | \$11,028 | \$11,765 | \$8,578 |
| Gross profit | 7,567 | 8,099 | 8,705 | 4,167 |
| Loss before income taxes | (816) | (2,755) | (891) | (6,618) |
| Net loss | (323) | (1,455) | (460) | (3,994) |
| Basic loss per common share | (\$0.01) | (\$0.05) | (\$0.02) | (\$0.12) |
| Diluted loss per common share | (\$0.01) | (\$0.05) | (\$0.02) | (\$0.12) |

Note 13—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.

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

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

| | Research and Deve | Research and Developmen Fiscal Year Ended July 31, | ţ1 | Clinical Re | Clinical Reference Laboratories Fiscal Year Ended July 31, | oratories Ily 31, | Fiscal Y | Other ear Ended | July 31, | Co Fiscal Ye | Consolidated Fiscal Year Ended July 31 | ly 31, |
|--|-------------------|---|----------|-------------|---|----------------------|-----------|--------------------|-----------|-----------------|---|-------------------|
| | 2005 | 2004 | 2003 | 2005 | 2004 | 2003 | 2005 | 2005 2004 200 | 2003 | 2005 | 2004 | 2003 |
| Operating revenues: Research product and royalty income | \$10,546 | \$12,972 | \$23,253 | 1 | I | 1 | 1 | 1 | İ | \$10,546 | \$12,972 | \$12,972 \$23,253 |
| Clinical laboratory services | I | ł | 1 | \$32,857 | \$28,672 | \$29,514 | i | 1 | ł | 32,857 | 28,672 | 29,514 |
| Expenses and (other income): | | | | | | | | | | | | |
| Cost of research product | 2,196 | 2,518 | 3,389 | 1 | 1 | - | | ł | 1 | 2,196 | 2,518 | 3,389 |
| Cost of clinical laboratory | 1 | j | 1 | 12,548 | 10,586 | 9,593 | 1 | ; | } | 12,548 | 10,586 | 9,593 |
| Research and development | 8,452 | 8,078 | 8,311 | 1 | 1 | 1 | i | ł | 1 | 8,452 | | 8,311 |
| Depreciation and amortization | 1,396 | 1,414 | 881 | 887 | 905 | 893 | \$50 | \$45 | \$34 | 2,333 | 2,361 | 1,808 |
| Provision for uncollectible | 1 | 1,753 | 616 | 4,967 | 10,234 | 8,729 | - | ; | 1 | 4,967 | | 9,345 |
| Other expenses | 1,009 | 508 | 609 | 11,618 | 8,429 | 7,294 | 10,586 | 9,409 | 8,048 | 23,213 | 18,346 | 15,951 |
| Interest | 1 | 1 | } | † 1 | 1 | } | (1,523) | (1,152) | (1,355) | (1,523) | (1,152) | (1,355) |
| Gain on patent litigation settlement | (14,000) | | | 1 | ! | | : | 1 | 1 | (14,000) | 1 | 1 |
| Income (loss) before income taxes | \$11,493 | \$(1,299) | \$9,447 | \$2,837 | \$(1,479) | \$3,005 | \$(9,112) | \$(8,302) | (\$6.727) | \$5,217 | \$(11,080) | \$5,725 |

The Company's clinical 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 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. States and foreign countries:

| United States | \$7,985 | \$8,029 | \$ |
|-------------------|----------|----------|----|
| Foreign countries | 2,561 | 4,943 | |
| | \$10,546 | \$12,972 | 8 |

2003 19,492 3,761 23,253

ENZO BIOCHEM, INC SCHEDULE II - VALUATION AND QUALIFYING ACCOUNTS Years ended July 31, 2005, 2004 and 2003

Additions

| <u>Description</u> | Balance at Beginning of period | Charged (credited) to costs and expenses | Charged to other accounts | (Additions) <u>Deductions</u> | | Balance at end of period |
|--|--------------------------------------|--|---------------------------|-------------------------------|-------|--------------------------|
| 2005 Allowance for doubtful accounts receivable | \$2,770,300 | \$4,967,100 | 1 | \$5,445,700 | (3) | \$2,291,700 |
| 2004 Allowance for doubtful accounts receivable | \$2,257,400 | \$11,986,500 | i | \$11,473,600 | Ξ | \$2,770,300 |
| 2003 Allowance for doubtful accounts receivable | \$2,862,600 | \$9,345,000 | l | \$9,950,200 | Ξ | \$2,257,400 |

(1) Write-off of uncollectible accounts receivable.

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, 333-89308 and 333-123712) of Enzo Biochem, Inc. and in the related Prospectus of our report dated October 12, 2005, with respect to the consolidated financial statements and schedule of Enzo Biochem, Inc., Enzo Biochem, Inc.'s management's assessment of the effectiveness of internal control over financial reporting, and the effectiveness of internal control over financial reporting of Enzo Biochem, Inc. included in this Annual Report (Form 10-K) for the fiscal year ended July 31, 2005.

/s/ Ernst & Young LLP

Melville, New York October 12, 2005

CERTIFICATIONS

In connection with the Annual Report on Form 10-K of Enzo Biochem, Inc. ("the Company") for the fiscal year ended July 31, 2005 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. § 1350, as adopted pursuant to § 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, 2005

By: <u>/s/ Barry Weiner</u>

Barry Weiner

Chief Financial Officer

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

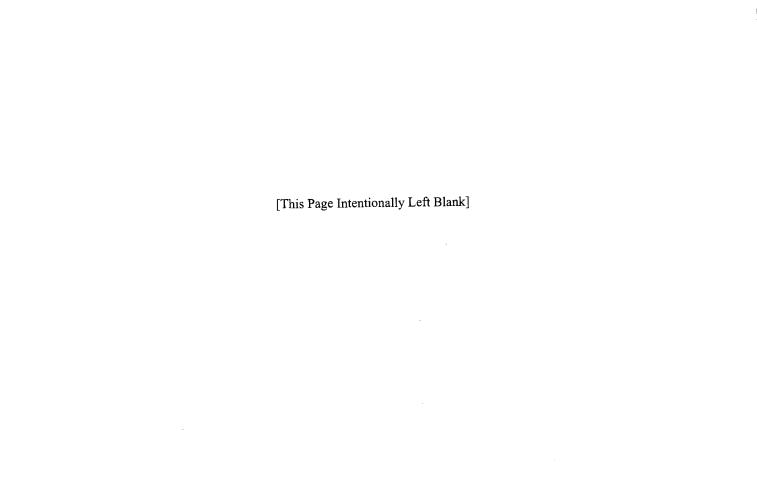
In connection with the Annual Report of Enzo Biochem, Inc., and Subsidiaries ("the Company") on Form 10-K for the fiscal year ended July 31, 2005 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Elazar Rabbani, Ph.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 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, 2005 By: /s/ Elazar Rabbani, Ph.D.

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.



Corporate Information

Board of Directors

Marcus A. Conant, M.D. Clinical Professor, University of California San Francisco

John J. Delucca Former Chief Financial Officer and Executive Vice President Coty, Inc.

Irwin C. Gerson Chairman Emeritus, Lowe McAdams Healthcare Division of the Interpublic Group

Melvin F. Lazar, CPA Founding Partner Lazar, Levine & Felix, LLP

Elazar Rabbani, Ph.D. Chairman of the Board Chief Executive Officer

Shahram K. Rabbani Chief Operating Officer, Treasurer and Secretary

John B. Sias Former President and Chief Executive Officer Chronicle Publishing Co.

Barry W. Weiner President and Chief Financial Officer

Officers and Management

Elazar Rabbani, Ph.D. Chairman of the Board Chief Executive Officer

Shahram K. Rabbani Chief Operating Officer, Treasurer and Secretary

Barry W. Weiner
President and Chief Financial Officer

Dean L. Engelhardt, Ph.D. Executive Vice President

Norman E. Kelker, Ph.D. Senior Vice President

Herbert B. Bass Vice President, Finance

Barbara E. Thalenfeld, Ph.D. Vice President, Corporate Development

David C. Goldberg Vice President, Business Development

Natalie Bogdanos General and Patent Counsel

Ronald Fedus Patent Counsel

Enzo Biochem, Inc.

60 Executive Boulevard Farmingdale, NY 11735 (631) 755-5500

Corporate Offices

527 Madison Avenue New York, NY 10022 (212) 583-0100

Corporate Subsidiaries

Enzo Therapeutics, Inc. 60 Executive Boulevard Farmingdale, NY 11735 (631) 755-5500

Enzo Life Sciences, Inc. 60 Executive Boulevard Farmingdale, NY 11735 (631) 694-7070

Enzo Clinical Labs, Inc. 60 Executive Boulevard Farmingdale, NY 11735

(631) 755-5500

General Counsel Greenberg Traurig, LLP 200 Park Avenue New York, NY 10166

Independent Auditors

Ernst & Young LLP 395 North Service Road Melville, NY 11747

Transfer Agent and Registrar

American Stock Transfer & Trust Company 59 Maiden Lane New York, NY 10038

Common Stock

Listed on NYSE (Symbol:ENZ)

A copy of the Company's annual report on Form 10-K, as filed with the Securities and Exchange Commission, will be furnished without charge to any shareholder upon written request to: Enzo Biochem, Inc. Attention: Investor Relations 527 Madison Avenue, New York, NY 10022.

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 sale price of the Company's Common Stock for the periods indicated as reported on the New York Stock Exchange.

| 2004 Fiscal Year (August 1, 2003 to July 31, 2004): | <u>High</u> | <u>Low</u> |
|--|-------------|------------|
| 1 st Quarter | \$22.45 | \$17.35 |
| 2 nd Quarter | \$20.95 | \$15.85 |
| 3 rd Quarter | \$19.88 | \$14.20 |
| 4 th Quarter | \$15.69 | \$12.57 |
| 2005 Fiscal Year (August 1, 2004 to July 31, 2005): | | |
| 1 st Quarter | \$17.69 | \$11.15 |
| 2 rd Quarter | \$20.40 | \$17.27 |
| 3 rd Quarter | \$19.27 | \$13.62 |
| 4 th Quarter | \$18.24 | \$14.08 |

As of October 10, 2005, the Company had approximately 1,164 stockholders of record of its Common Stock.

The Company has not paid a cash dividend on its Common Stock and intends to continue a policy of retaining earnings to finance and build its operations. Accordingly, the Company does not anticipate the payment of cash dividends to holders of Common Stock in the foreseeable future. During fiscal 2005, the Company's board of directors declared a 5% stock dividend on October 5, 2004 payable November 15, 2004 to shareholders of record as of October 25, 2004. The fiscal 2004 per share data was adjusted retroactively to reflect the stock dividend declared on October 5, 2004. In fiscal 2003, the Company's board declared a 5% stock dividend on June 10, 2003 payable July 14, 2003 to shareholders of record as of June 30, 2003. The shares and per share data have been adjusted to retroactively reflect the stock dividend in fiscal 2003. The Company recorded a charge to accumulated deficit and offsetting credits to both common stock and additional paid-in capital of approximately \$23,433,400 and \$37,709,200 in fiscal 2005 and fiscal 2003, respectively which reflect the fair value of the stock dividends on the dates of declaration.



Enzo Biochem, Inc. 60 Executive Boulevard Farmingdale, NY 11735 (631) 755-5500