



***Enzo Biochem, Inc.***

***Annual Report 2006***

**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 wholly-owned 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:

Our Company in fiscal 2006, positioning itself to capitalize on its many opportunities, continued its program of expansion and development, achieving progress in expanding and strengthening our senior management, enhancing our intellectual property estate, and broadening our scientific and technological activities. Among the highlights were:

- The establishment of new positions, President of Life Sciences, President of Therapeutics and Senior Vice President of Finance, expanded our senior management group and represent the establishment of a new organizational structure to support future growth for each of these key areas.
- Enzo was granted two pioneering patents covering fundamental work in the molecular labeling and identification areas, plus obtained an additional patent covering aspects of therapeutic protein and RNA production in living cells.
- Interferences have been declared involving allowed Enzo patent applications for fundamental technology utilized in DNA gel sequencing, and a method of amplification utilizing Enzo technology for diagnostic products. Both involve markets that range in the hundreds of millions of dollars, and Enzo was named the senior party in both actions.
- In two of our litigations, Markman hearing rulings were held in Federal courts in New York City and New Haven, CT, allowing these cases for infringement and contract violations to move forward.
- With four clinical trials underway, and a fifth to be added, Enzo Therapeutics is pursuing novel treatments for Crohn's disease, NASH, HIV-1 and autoimmune uveitis.
- Enzo Clinical Labs won important recognition from leading healthcare insurers as its network was enhanced. In order to meet the anticipated future growth needs of the Company, an additional contiguous facility was acquired to expand the Life Sciences division, thus allowing an enlarged Clinical Labs facility to accommodate the intended diversification of the Laboratory into the molecular diagnostics area.

## *Enzo Life Sciences*

With Dr. Carl Balezentis, an experienced industry executive as its new president, Enzo Life Sciences has mapped out a plan to accelerate products into the market, develop new products, build alliances, expand markets and assist in our program to capitalize more fully on our Intellectual Property base. Specifically, Life Sciences is focused on:

- Increasing efficiency of its global sales and marketing activities.
- Developing new products leveraging our intellectual property and technological expertise, to allow diversification into new market segments.
- Entering into collaborations and agreements with major Life Science companies.
- Acquiring product lines and companies, which also will allow diversification into new markets and integration of existing technologies.

Our approach in the short term is to strengthen the Company's direct selling effort to generate greater revenue, while expanding internationally to enter new markets. We are evaluating these opportunities through their size potential, future growth, and whether we can identify a local partner with whom to establish and develop relationships.

Importantly, as well, while fully utilizing our existing, extensive product lines, we are also reaching out to license technology from others to further expand and complement our present capabilities. This past year we have licensed technology to amplify RNA for gene expression studies, with a new product line utilizing this new technology soon to be released. We also have licensed technology for single copy probes from Mercy Hospital in Kansas City, MO, that provides a novel platform for detecting genetic abnormalities that can have serious developmental consequences. Working closely with key opinion leaders in the field to analyze the commercial potential for these products, we anticipate, upon successful development, that we may be able to produce products that would have superior performance relative to alternative methods now in use.

In the new product category, we have begun to market our Bioscore™ System. This is currently being marketed to enable the amplification of DNA from archived material, such as formalin-fixed paraffin-embedded tissues. Pathologists have established large collections of these materials that form invaluable resources for the study of cancer and other important diseases. Our kit allows researchers to amplify small amounts of starting material from archived sources, rate the quality of the material, and then label and utilize it to determine relevant genetic profiles.

## *Enzo Therapeutics*

Our therapeutics activities have now been placed under the direction of Dr. Gary Cupit, who as President of Enzo Therapeutics, brings to our Company extensive pharmaceutical industry experience. His focus will be on business development, and his experience in the identification, evaluation and due diligence of global business opportunities is expected to be especially helpful as our clinical trials move forward.

Enzo Therapeutics' clinical programs are based primarily on four distinct platforms –immune regulation for managing immune mediated disorders; small molecule treatments that act as both pro and anti inflammatory agents; gene transfer, our pioneering technology that is the foundation for our HIV treatment; and an extensive pre-clinical development program utilizing various metabolic pathways which may have clinical relevance in the treatment of bone disorders and some cancers.

Enzo Therapeutics has underway two separate Phase II trials for the treatment of Crohn's disease, Alequel™, an immune regulation therapy, and EGS21™, a proprietary small molecule immunomodulatory agent. EGS21 is also being evaluated in the treatment of non-alcoholic steatohepatitis (NASH). Nonalcoholic fatty liver disease is one of the most common causes of liver pathology in the United States. It is estimated that approximately 8.6 million obese adult Americans may have NASH and that another 30.1 million may have the milder form of fatty liver.

The Phase I/II trial for HGTV43™, our treatment for HIV-1, is being conducted at the University of California San Francisco. Utilizing 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, the viral RNA.

Our Company also has under development a protocol for a multi-center Phase II clinical trial for uveitis, which we expect to be carried out in both the U.S. and Europe. The study drug has been granted orphan status in Europe, which may have both financial and marketing benefits. There is no known cure for uveitis, which results from inflammation of a part of the eye often leading to severe vision impairment, and is believed to result from an immune reaction against specific antigens in the eye.

Along with these projects, Enzo has a number of compounds in preclinical development that could provide therapy for treating bone disorders, such as osteoporosis and bone loss, as well as other applications.

## ***Enzo Clinical Labs***

Heightened efficiency in the billing and collection areas has enabled Enzo Clinical Labs to reduce the provision for uncollectible accounts receivable for the year by 27%, while the Labs is focusing on providing additional, esoteric testing that enlarges its servicing capabilities. In addition, EnzoDirect™, the Company's proprietary laboratory computer system, now has over 300 physician practices directly connected in the greater New York and New Jersey areas. Besides making test results readily available, given the costs of delivering reports by courier or mail, the electronic delivery also helps to improve our service capabilities.

In addition, a web-based version of EnzoDirect, EnzoDirect.com™, which allows physicians to log on for results from any web-enabled computer, has been installed in over 100 sites. Enzo Clinical Labs also has increased its electronic medical records capabilities, which facilitates the transfer of data into electronic charts and which provides broadened opportunities for service and third party providers. It will help position Enzo Clinical Labs for when paperless record keeping will be the norm.

The newly acquired property in Farmingdale, contiguous to our existing principal facility, is expected to significantly benefit Enzo Clinical Labs by opening up additional space for expanded testing capabilities, particularly of higher margin assays. Tests in the areas of allergy and immunology have recently been added to its capabilities. The naming of Enzo Clinical Labs as a regional testing laboratory by both Aetna and United Healthcare insurance providers is indicative of the increased recognition of the Lab.

## ***Intellectual Property***

One of our Company's major assets is our Intellectual Property estate, and over the past few years we have invested substantially and aggressively to build and protect it. The more than 200 patents issued to Enzo plus nearly an equivalent number for which patent applications have been filed, had their genesis in the early days of our Company's founding and result from the pioneering work we have pursued over the years in recognizing the value and potential of DNA as a source of biological information. This information will facilitate the understanding of biological mechanisms and how variations and mutations result in disease, enabling more rapid and accurate detection of specific diseases and the development of new therapeutics to treat them. We are seeing today a focus on the use of molecular information to drive the development of a new generation of gene-based diagnostics that will benefit the healthcare industry by delivering earlier and predictive diagnostic capabilities. Also, we are seeing the integration of diagnostics that correlate with therapeutic efficacy and thus, will drive the use of more effective medical treatment. Enzo's intellectual property estate has been focused on these areas of technology development for the past twenty-five years, and positions us to participate in the growth of this important sector.

We are pleased that over the past year we have been awarded several significant new patents by the U.S. Patent and Trademarks Office. Included are:

- U.S. Patent No. 6,986,985, a patent covering processes for producing large quantities of therapeutic proteins or RNAs within living target cells, application for which would be to deliver therapeutic proteins to particular target cells in animals and humans.
- U.S. Patent No. 6,992,180, which covers nucleic acid labeling molecules that are attached through the phosphate portion of nucleic acid, either directly or indirectly. The technology can be applied to a range of commercial products, some of which are currently used for both diagnostics and research. The current annual market for gene-based testing ranges from \$500 million to as high as \$1 billion.
- U.S. Patent No. 7,064,197, relating to core nucleic acid array technology with industrial, diagnostic and therapeutic applications where quantifiable and efficient detection of genetic material is desired. According to one industry analysis, the areas of array technology related to this patent are estimated currently at approximately \$825 million and are projected in three years to exceed \$2.4 billion.
- In November, 2006, the U.S. Patent and Trademark Office declared an interference relating to an allowed patent application and a patent held by the California Institute of Technology and licensed exclusively to Applied Biosystems, Inc. The technology involves gel sequencing, which is the primary technique for sequencing DNA, which, in addition to helping to map the human genome, is providing insights in the molecular basis for many genetic diseases, as well as contributing to developments in both diagnostics and therapeutics. Sales of products related to DNA sequencing are estimated at approximately \$5 billion annually. Enzo is named in the senior party in the interference action because its original application filing date predates that of the existing patent.

## ***Financial Results***

Fiscal 2006 total revenues were \$39.8 million, versus \$43.4 million in the previous year, and the net loss amounted to \$15.7 million, or \$0.49 per share, compared to a year-ago income of \$3 million, or \$0.09 per share, which included an after-tax gain of \$8.1 million, or \$0.34 per share, from the settlement with Digene Corp. Excluding the Digene impact, fiscal 2005 would have shown a loss of \$5.1 million, or \$0.18 per share. In fiscal 2006, pre-tax results were impacted by: a decline in Life Sciences research product revenue, the initial year of expensing share-based compensation in accordance with SFAS 123(R) of approximately \$1.6 million, an approximately \$1.0 million increase in research and development expenses, and higher legal fees, which rose \$1.9 million, to \$7.4 million. Our fiscal 2006 net loss was negatively impacted by the limitation of recording a tax benefit on the pre-tax loss, which increased the loss per share by \$0.18.

The Company's finances remain strong, with year-end working capital of \$80.2 million and cash and cash equivalents of \$69.9 million. Shareholders equity stood at \$95.6 million. There was no debt.

## ***Outlook***

Our Company is well positioned with three solid operating arms and an exceptional asset in our extensive and valuable Intellectual Property. We view the future as having uncommon opportunities, especially since many of the projects and markets in which we are engaged are on the cusp of where medical diagnosis and treatment are headed. Our resolve is to realize for all shareholders the substantial value embedded in Enzo Biochem, and which we believe makes our Company truly unique in the biotechnology and life sciences industries.

We are appreciative of your support, the commitment and dedication of our employees, and that of the members of our Board of Directors.

Barry Weiner  
President



**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549  
FORM 10-K**

(Mark one)



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

For the fiscal year ended July 31, 2006

or



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

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

Commission File Number 001-09974

**ENZO BIOCHEM, INC.**

(Exact name of registrant as specified in its charter)

New York

(State or other jurisdiction  
of incorporation or organization)

13-2866202

(I.R.S. Employer  
Identification No.)

527 Madison Ave.

New York, New York

(Address of principal executive offices)

10022

(Zip Code)

(212) 583-0100

(Registrant's telephone number, including area code)

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

(Title of Each Class)

Common Stock, \$.01 par value

(Name of Each Exchange on Which Registered)

The New York Stock Exchange

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes  No

The aggregate market value of the registrant's voting stock held by non-affiliates of the registrant was approximately \$355,971,000 as of January 31, 2006.

The number of shares of the Company's common stock, \$.01 par value, outstanding at September 30, 2006 was approximately 32,274,500.

**DOCUMENTS 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 22, 2007 are incorporated by reference into Part III of this annual report.

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## **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 a provider of diagnostic services to the medical community. Since its founding in 1976, Enzo's strategic focus has been on the development, for commercial purposes, of enabling technologies in the life sciences field. Enzo's pioneering work in genomic analysis coupled with its extensive patent estate and enabling platforms have strategically positioned Enzo to play an important role in the rapidly growing life sciences and molecular medicine marketplaces.

In the course of the Company's research and development activities, Enzo has built a substantial portfolio of intellectual property assets, with 211 issued patents worldwide, and more than 185 pending patent applications, along with extensive enabling technologies and platforms.

Enzo is comprised of three interconnected operating companies that have evolved out of Enzo's core competence: the use of nucleic acids as informational molecules and the use of compounds for immune modulation. These wholly owned operating companies conduct their operations through three segments (see Note 13 in the notes to financial statements).

Below are brief descriptions of each of the three operating segments:

**Enzo Life Sciences** is a company that manufactures, develops and markets biomedical research products and tools to research and pharmaceutical customers around the world and has amassed a large patent and technology portfolio. The pioneering platforms developed by Enzo Life Sciences enable the development of a wide range of products in the research products marketplace.

**Enzo Therapeutics** is a biopharmaceutical company that has developed multiple novel approaches in the areas of gastrointestinal, infectious, ophthalmic and metabolic diseases, many of which are derived from the pioneering work of Enzo Life Sciences. The Company has focused its efforts on developing treatment regimens for diseases and conditions in which current treatment options are ineffective, costly, and/or cause unwanted side effects. This focus has generated a clinical and preclinical pipeline, as well as more than 40 patents and patent applications.

**Enzo Clinical Labs** is a regional clinical laboratory to the greater New York and New Jersey medical community. The Company believes having this capability allows us to capitalize firsthand on our extensive advanced molecular and cytogenetic capabilities and the broader trends in predictive diagnostics. We offer a menu of routine and esoteric clinical laboratory tests or procedures used in general patient care by physicians to establish or support a diagnosis, monitor treatment or medication, or search for an otherwise undiagnosed condition. We operate a full-service clinical laboratory in Farmingdale, New York, a network of 19 patient service centers, a stand alone "stat" or rapid response laboratory in New York City, and a full-service phlebotomy department.

The Company's primary sources of revenue have historically been from sales and royalties of Life Sciences' products utilized in life science research and from the clinical laboratory services provided to the healthcare community. For the fiscal years ended July 31, 2006, 2005 and 2004, respectively, approximately 20%, 24% and 31% of the Company's operating revenues were derived from product sales and royalties and approximately 80%, 76% and 69% were derived from clinical laboratory services.

#### **Markets**

##### **Background**

Deoxyribonucleic Acid ("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 well over 30,000 genes, has been identified by genome research, including the Human Genome Project. 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 diagnostics – tools that both facilitate and accelerate the generation of biological information. This demand can be met by gene-based diagnostics and 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 and systems, 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 that have been identified by genome research;
- 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 has currently been reported by industry sources to be greater than \$20 billion annually. 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 months, 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 the 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**

Many diseases result from either the expression of foreign genes, such as those residing in viruses and pathogenic organisms, or from 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. In addition, a number of diseases result from the body's failure to adequately regulate its immune system.

Recent advancements in gene analysis have provided the information and tools necessary to develop drugs that intervene in the disease process at the genetic 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, ribonucleic acid ("RNA") produced by a specific 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 therapy involves the insertion of a gene into a cell. The inserted gene biologically manufactures the therapeutic product within the cell 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, the inserted gene may code for a molecule that would deactivate either an overactive gene or a gene producing an unwanted protein. 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 to enable 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 nucleic acid of the vector not produce proteins or antigens that can trigger an adverse immune response.

Other diseases may be the consequence of an inappropriate reaction of the body's immune system, either to a foreign antigen, such as a bacterium or virus, or, in the case of an autoimmune condition, to the body's own components. In recent years, several new strategies of medication for the treatment of immune-based diseases such as Crohn's disease, uveitis, and rheumatoid arthritis, have been developed. These treatments are all based on a systemic suppression of certain aspects of the immune system and can lead to significant side effects. Thus, there continues to be a need for a therapeutic strategy that is more specific and less global in its effect on the immune system.

## **Strategy**

Our objective is to be a leading developer and provider of the tools and diagnostics used to study and detect disease at the molecular level and provider of therapeutic approaches to various diseases. There can be no assurance that our objective will be met. Key elements of our strategy include:

### **Apply our innovative technology to the infectious and immune mediated disease markets**

We believe our core technologies have broad diagnostic and therapeutic applications. We have initially focused our efforts on the infectious and immune mediated disease markets. 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. Many viral diseases such as hepatitis have an immune component. It is known that the cytopathic effect on the liver in patients infected with hepatitis is caused, not by the virus itself, but by a reaction of the immune system against the virus. Although the cause of disorders such as Crohn's disease, certain forms of uveitis and non-alcoholic steatohepatitis (NASH) remains unknown, various features suggest immune system involvement in their pathogenesis.

We continue to develop 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 continue to capitalize 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 relating to our immune regulation technology and the University of California at San Francisco for the application of our genetic antisense technology against HIV.

During fiscal 2005 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 a privately owned biotechnology company specializing in immune regulation technologies. This acquisition is expected to broaden our capabilities in the area of immune 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 2006, Enzo Life Sciences continued to develop the sales and marketing infrastructure to more directly service its end users, while simultaneously positioning the Company for product line expansion. The program has evolved into strategic initiatives to develop direct key relationships and collaborations with end users, sustaining a marketing campaign, increased attendance at top industry trade meetings, as well as the continued updating and enhancement of the interactive web site. In addition to our direct sales, we distribute our research products through other life sciences companies in foreign markets.

#### **Expand and protect 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. During fiscal 2006 we increased our intellectual property estate with several new patents including two patents covering nucleic acid labeling and another patent covering processes for producing large quantities of therapeutic proteins of RNAs within living target cells as follows:

U.S. Patent No. 6,992,180, "Oligo-or polynucleotides comprising phosphate-moiety labeled nucleotides," among other aspects, covers, nucleic acid labeling molecules that are attached through the phosphate portion of the nucleic acid, either directly or indirectly. Among the labeling elements covered by this patent are fluorescent, chemiluminescent, and chemical molecules, including biotin. These are the labeling components most commonly used in medical research and diagnostic products.

U.S. Patent No. 7,074,197, "System, array and non-porous solid support comprising fixed or immobilized nucleic acids," covers nucleic acids that are fixed or immobilized to non-porous solid supports and includes systems containing such supports and arrays with fixed or immobilized nucleic acids. These compositions are useful for nucleic acid analyses and a host of applications, including, for example, detection, mutational analysis and quantification.

U.S. Patent No. 6,986,985, "Process for producing multiple nucleic acid copies *in vivo* using a protein nucleic acid construct," covers processes for producing large quantities of therapeutic proteins or RNAs within living target cells. An important application of this technology may be to deliver therapeutic proteins to particular target cells in animals and humans. It may also facilitate delivery of regulatory RNA molecules, including antisense RNA molecules for the management of medically important diseases. As such it could represent a potentially safer and a more efficient strategy for gene expression and protein production in mammals, including humans.

## **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 which is supported by our significant proprietary position in these fields.

**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.

**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.

### **Therapeutic Technology Platforms**

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

**Gene Regulation.** 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, in a process called transduction, we have developed proprietary vector technology. Our vector technology has the following strengths:

•Efficient transduction . A principal problem of many 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 or engineered cells (cells containing the gene that was delivered by the vector) often produce non-essential proteins that may 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 are designed to 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 transduces the intended cell type. This may ultimately permit us to develop a genetic antisense product that is administered directly to the patient.

•Safety components . Certain retroviral vectors have been shown to insert within the cell in regions of the cellular DNA that could activate genes that cause cells to grow or multiply. This insertional gene activation may cause uncontrolled cell division resulting in a cancer. Enzo's vector has been designed to prevent insertional gene activation by inactivation of the viral promoters.

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**

Oral Immune Regulation. 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 as 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 platforms 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 therapies for the treatment of a variety of diseases, including chronic active hepatitis autoimmune uveitis, and inflammatory bowel disease, including Crohn's Disease and ulcerative colitis. During fiscal 2005, 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.

### **Small Molecule Development**

EGS21 . 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, 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.

Protein-Protein Interactions . 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 Products**

We are a 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.

**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, *Bioscore*™, for amplifying small quantities of genetic material from pathological samples, as well as providing a quality score for that sample, thus saving the researcher precious time and money that would have otherwise been wasted on continuing to process that sample.

## 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)

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 more than 60 million individuals worldwide living with HIV infection during 2005. There were over 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.

HGTV43™ gene medicine. Enzo's proprietary Stealth Vector™ HGTV43™ gene construct is a vehicle designed to carry and deliver anti-HIV-1 antisense RNA genes. These genes produce antisense RNA 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 showed 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 72 months to date.

- all subjects tolerated the procedure – there were no treatment-related adverse events during the study and no evidence for expansion of the inserted transgenes in any subjects tested, nor was any evidence of leukemia seen by standard hematology;
- anti HIV-1 antisense RNA was detected in the circulation of subjects, the longest at 72 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 have commenced 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 Phase I/II study is being conducted at University of California San Francisco (UCSF) the site of the Phase I study. This 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 (RAC), the UCSF Committee on Human Research (CHR) and the U.S. FDA. We have begun the process of enrolling subjects. A similar 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.

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

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

- the drug was well tolerated in all subjects;
- 46% of subjects showed a decrease in HBV viral load and improvement in liver function tests; 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. A master cell bank for manufacture of the HBV specific protein (EHT899) is under construction.

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.

In fiscal 2005, we 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.

Using its immune regulation platform and the recently acquired rights to the candidate drug, B27PD, Enzo is currently developing a protocol for a multi-center Phase I/II clinical trial to be carried out in the United States and in Germany. The study drug has been granted orphan status in Europe and we will apply for the same in the U.S. Orphan status designation can confer both financial and marketing benefits. B27PD has been manufactured and animal toxicology studies were successfully carried out. The protocol will be submitted for approval to both the U.S. FDA and 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, which 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 has 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 latest 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.

Enzo is also investigating the use of EGS21 in managing Crohn's disease. The compound has been shown by Enzo scientists and collaborators to act as an anti-inflammatory agent in animal model systems. EGS21 was tested for safety 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. A Phase II randomized double blind study is currently being carried out at Hadassah.

#### **Non-alcoholic steatohepatitis (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.

Following the successful safety study of EGS21, an open label pilot study was recently conducted at Hadassah-Hebrew University Medical Center. The results suggested that EGS21 may be efficacious in treating NASH and its associated metabolic syndrome in human subjects. A Phase II double blind study was approved by the regulatory authorities in Israel and is currently being conducted. This study is being partially funded by a \$1.0 million grant from the Israel-U.S. Binational Industrial Research and Development Foundation (BIRD).

#### **Osteoporosis and certain bone disorders.**

Enzo has a number of new compounds in preclinical development that could provide therapy for treating bone disorders including osteoporosis, bone loss, fractures, abnormalities, diseases, and other applications.

## 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.

Our full service clinical laboratory in Farmingdale, NY contains 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 New York City. 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 EnzoDirect™ 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, 2006, 2005, and 2004 respectively, 80%, 76%, and 69% of the Company's revenues were derived from the clinical laboratory. At July 31, 2006 and 2005, respectively, approximately 88% and 94% 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 adjustments, from direct billings under the Federal Medicare program during the years ended July 31, 2006, 2005 and 2004 were approximately 23%, 21%, and 26%, respectively, of the clinical laboratory segment'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. 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 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.

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.

The permitted Medicare reimbursement rate for clinical laboratory services has been reduced by the Federal government in a number of instances over the past several years to a present level equal to 74% of the national median of laboratory charges. Clinical Labs have been subjected to a five-year freeze (ending in 2008) on Laboratory

fee updates, as required by the Medicare Modernization Act of 2003. A number of proposals for legislation or regulation, such as competitive bidding on laboratory services are under discussion which could have the effect of substantially reducing Medicare reimbursements to clinical laboratories through reduction of the present allowable percentage or through other means. In addition, the structure and nature of Medicare reimbursement for laboratory services is also under discussion and we are unable to predict the outcome of these discussions. Depending upon the

nature of congressional and/or regulatory action, if any, which is taken and the content of legislation, if any, which is adopted, we could experience a significant decrease in revenue from Medicare, which could have a material

#### **Research & Development**

adverse effect on us.

Our principal research and development efforts are directed toward expanding our research product lines, as well as developing innovative new therapeutic products to meet unmet market needs. We have developed our core research expertise in the life science field as a result of 30 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, 2006, 2005 and 2004, the Company incurred costs of approximately \$7,896,000, \$8,452,000, and \$8,078,000, respectively, for research and development activities.

#### **Internal Research Programs**

Our professional staff of 31 scientists, including 28 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 life science products through three distinct channels: (i) direct sales to end-users; and (ii) supply agreements with manufacturers and (iii) through distributors in major geographic markets. 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 life science 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.

### **Distribution Arrangements**

We also distribute our life science products internationally through a network of distributors. Through these arrangements, we are able to leverage the established marketing and distribution infrastructure of these companies. Enzo Life Sciences is focused on a strategic initiative to expand its international network of distributors. Prior to fiscal 2005, the Company distributed through leading life science companies and is currently evaluating new relationships. 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. Many of these companies are performing research targeting the same technology, applications and markets. Some of these competitors are significantly larger than we are and have more 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, regional, 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, 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 2006 we owned or licensed 44 U.S. and 167 foreign patents relating to products, methods and procedures resulting from our internal or sponsored research projects. During fiscal 2006, the following key enabling patents were issued to Enzo:

U.S. Patent No. 6,992,180, "Oligo- or polynucleotides comprising phosphate-moiety labeled nucleotides," among other aspects, covers nucleic acid labeling molecules that are attached through the phosphate portion of the nucleic acid, either directly or indirectly. Among the labeling elements covered by this patent are fluorescent, chemiluminescent, and chemical molecules, including biotin. These are the labeling components most commonly used in medical research and diagnostic products.

U.S. Patent No. 7,074,197, "System, array and non-porous solid support comprising fixed or immobilized nucleic acids," covers nucleic acids that are fixed or immobilized to non-porous solid supports and includes systems containing such supports and arrays with fixed or immobilized nucleic acids. These compositions are useful for nucleic acid analyses and a host of applications, including, for example, detection, mutational analysis and quantification.

U.S. Patent No. 6,986,985, "Process for producing multiple nucleic acid copies *in vivo* using a protein nucleic acid construct," covers processes for producing large quantities of therapeutic proteins or RNAs within living target cells. An important application of this technology may be to deliver therapeutic proteins to particular target cells in animals and humans. It may also facilitate delivery of regulatory RNA molecules, including antisense RNA molecules



for the management of medically important diseases. As such it could represent a potentially safer and a more efficient strategy for gene expression and protein production in mammals, including humans.

There can be no assurance 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 August of 2006, Enzo was granted interference against patents held by Princeton University (now licensed to Abbott Labs) and Chiron Diagnostics (now Bayer Diagnostics). In this action, Enzo has been designated as the senior party because the Company's filing of its patent application preceded the others. In addition, the relevant claims for this patent were published in Europe before the Princeton and Chiron applications were even filed. Based on this management believes that that Enzo will prevail, and as such, would have the rights to the technology.

During fiscal 2005, several patents relating to the BioProbe® nucleic acid probe system expired, while additional patents were issued in the U.S. and Europe. During fiscal 2006 we increased our intellectual property estate with several new patents including two patents covering nucleic acid labeling and another patent covering processes for producing large quantities of therapeutic proteins of RNAs within living target cells.

Enzo's intellectual property portfolio can be divided into patents that provide claims in three primary categories, as described below:

### **Nucleic Acid Chemistry**

We currently have broad patent coverage in the area of nucleic acid chemistry. The Company has done extensive work on the labeling of nucleic acids for the purpose of generating a signal that dates back over twenty years. Enzo has multiple issued patents covering the modification of nucleic acids at all three potential modification sites (sugar, base and phosphate). The claims contained in these patents cover any product that incorporates a signaling moiety into a nucleic acid for the purpose of nucleic acid sequence detection or quantification.

### **Signal Delivery**

We also have a long history of innovation in the area of analyte detection using non-radioactive signaling entities. At the signaling entity itself, there are several Enzo patents that cover the formation of this structure. A patent which was allowed in 2006, covers the attachment of signaling molecules through the phosphate moiety of a nucleic acid, which is how the signal-generating enzyme is bound. Additionally, the allowed claims contained in Enzo's signal delivery patents cover any product that incorporates either of the following:

- A first part which comprises a molecular bridging entity comprising of a first portion that hybridizes to an analyte and a second portion comprising of nucleic acid sequences or segments.
- A second part which comprises one or more non-radioactive signaling entities incapable of binding to the aforementioned bridging entity second portion, and or more signaling portions.

### **Nucleic Acid Analysis Format**

We also have patents with issued claims covering the use of arrays of single-stranded nucleic acids fixed or immobilized in hybridizable form to a non-porous solid support. These patents cover any product that uses arrays of nucleic acids for molecular analysis.

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. 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. In fiscal 2006, the Enzo Life Sciences entered into an agreement with the Children's Mercy Hospital and Clinics ("Mercy") in Kansas City, MO whereby Enzo licensed from Mercy two patents in the area of single copy genomic hybridization probes. The Company plans to utilize this technology in its plans to develop a line of products and services designed specifically for the cytogenetics market.

## 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 therapeutics products that we develop will require regulatory review before clinical trials, and additional regulatory clearances before commercialization. New human gene medicine products as well as immune regulation products, as therapeutics, are subject to regulation by the FDA and comparable agencies in other countries. 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 therapeutics protocols. In addition, 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 (GLP). 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, Good Clinical Practices (GCP) and the general investigational plan and protocols contained in the IND. Each clinical study is reviewed and approved by an Institutional Review Board (IRB). The IRB will consider, among other things, ethical factors and the safety of human subjects. Clinical trials are normally conducted in three phases, although the phases might overlap. Phase I trials, concerned primarily with the safety and tolerance of the drug, and its pharmacokinetics (or how it behaves in the body including its absorption and distribution) involve fewer than 100 subjects. Phase II trials normally involve a few hundred patients and are designed primarily to demonstrate preliminary effectiveness and the most suitable dose or exposure level for treating or diagnosing the disease or condition for which the drug is intended, although short-term side effects and risks in people whose health is impaired may also be examined. Phase III trials are expanded, adequate and well-controlled clinical trials with larger numbers of patients and are intended to gather the additional information for proper dosage and labeling of the drug. Clinical trials generally take two to five years, but the period may vary. Certain regulations promulgated by the FDA may shorten the time periods and reduce the number of patients required to be tested in the case of certain life-threatening diseases, which lack available alternative treatments.

The FDA receives reports on the progress of each phase of clinical testing, and it may require the modification, suspension or termination of clinical trials if an unwarranted risk is presented to patients. Human gene medicine products are a new category of therapeutics. There can be no assurance regarding the length of the clinical trial period, the number of patients that the FDA will require to be enrolled in the clinical trials in order to establish the safety, purity and potency of human gene medicine products, or that the clinical and other data generated will be acceptable to the FDA to support marketing approval.

After completion of clinical trials of a new product, FDA marketing approval must be obtained before the product can be sold in the United States. If the product is regulated as a new biologic, CBER requires the submission and approval of a Biologics License Application (BLA) before commercial marketing of the biologic product. If the product is classified as a new drug, we must file a New Drug Application ("NDA") with CDER and receive approval before commercial marketing of the drug. The NDA or BLA must include results of product development, pre-clinical studies and clinical trials. The testing and approval processes require substantial time and effort and there can be no assurance that any approval will be granted on a timely basis, if at all. The median time to obtain new product approvals after submission to the FDA is approximately 12 months. If questions arise during the FDA review process, approval can take longer. Before completing its review, the FDA may seek guidance from an Advisory Committee of outside experts at a public or closed meeting. While the advice of these committees is not binding on the FDA, it is often followed. Notwithstanding the submission of relevant data, the FDA might ultimately decide that the NDA or BLA does not satisfy its regulatory criteria for approval and, thus, reject the application, refuse to approve it, or require additional clinical, preclinical or chemistry studies. Even after FDA regulatory approval or licensure, a marketed drug product is subject to continual review by the FDA. In addition, if previously unknown problems are discovered or we fail to comply with the applicable regulatory requirements, we might be restricted from marketing a product, we might be required to withdraw the product from the market, and we might possibly become subject to seizures, injunctions, voluntary recalls, or civil, monetary or criminal sanctions. In addition, the FDA may condition marketing approval on the conduct of specific post-marketing studies to further evaluate safety and effectiveness.

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

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

## **Regulation of Diagnostics**

The diagnostic products that are developed by our collaborators or us are likely to be regulated by the FDA as medical devices. Unless an exemption applies, medical devices must receive either "510(k) clearance" or pre-market approval ("PMA") from the FDA before marketing them in the United States. The FDA's 510(k) clearance process usually takes from four to 12 months, but it can last longer. The process of obtaining PMA approval is much more costly, lengthy and uncertain. It generally takes from one to three years or even longer. We cannot be sure that 510(k) clearance or PMA approval will ever be obtained for any product we propose to market.

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

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

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

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

### **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 deadline for providers to obtain and implement use of the National Provider Identifier is May 23, 2007. The National Provider Identifier is an identifier that will replace all other identifiers that are currently used for healthcare transactions (e.g., UPIN, Medicaid provider numbers; identifiers assigned by commercial insurers). Those providers who do not have their National Provider Number by May 23, 2007 will not be able to conduct common healthcare transactions, such as claims submission and eligibility verification. Even though there is no cost associated with obtaining a National Provider Identifier, there could be a significant financial impact for failure to obtain the National Provider Identifier in a timely fashion. Enzo has submitted the application for its National Provider Identifier and is waiting for it to be assigned. It is anticipated that Enzo will receive its National Provider Identifier well in advance of the deadline.

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.

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.

The implementation of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations impacts electronic billing and the security and privacy of patient identifiable health information by all health providers, including Enzo Clinical Labs. In response to this challenge, we have implemented an approach to identify, assess and plan for changes required by the HIPAA regulations. A HIPAA Oversight Committee ("Oversight Committee"), was formed to coordinate this task. The Oversight Committee consists of members from management and a designated HIPAA Compliance Officer. We have in place a framework for activities in this area.

As the HIPAA rules are released and their impact upon our operations are analyzed, our response to HIPAA is reviewed and revised as necessary.

### **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 three segments 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.

In June 2006, we acquired a 22,000 square foot facility adjacent to our Farmingdale, New York facility that will be utilized, upon completion of renovations for the Life Science and Therapeutics research and manufacturing operations.

## **Employees**

As of July 31, 2006, we employed 285 full-time and 55 part-time employees. Of the full-time employees, 35 were engaged in research, development, manufacturing, and marketing of research products, 10 in therapeutics research, 225 in the clinical laboratories and 15 in finance, legal and administrative functions. Our scientific staff, including 28 individuals with post doctoral 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. Over the past two fiscal years, we have invested heavily in the upgrade of our information and telecommunications systems to improve the quality, efficiency and security of our businesses. In addition, we have developed and currently maintain, a proprietary physician connectivity solution, Enzo Direct TM, which provides the clinical laboratory clients with the ability to electronically laboratory tests and receive patient results.

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 laboratory tests to be of critical importance, and, therefore, we maintain 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.

## 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.

The Company files annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission (the “SEC”). These filings are available to the public via the Internet at the SEC’s website located at <http://www.sec.gov>. You may also read and copy any document the Company files with the SEC at the SEC’s public reference room located at 100 F Street, N.E., Washington, D.C. 20549. For more information, please call the SEC at 1-800-SEC-0330.

The Company’s website is located at [www.enzo.com](http://www.enzo.com). You may request a copy of the Company’s filings with the SEC (excluding exhibits) at no cost by writing or telephoning us at the following address or telephone number:

Enzo Biochem, Inc.  
527 Madison Ave.  
New York, New York 10022  
Tel: (212) 583-0100  
Attn: Investor Relations

### Item 1A – Risk factors

Risks Relating to our Company and our industries

**We have experienced significant losses in our last fiscal year. If such losses continue, the value of your entire investment could decline significantly.**

We incurred a net loss of \$15,667,000 for the fiscal year ended July 31, 2006. We cannot assure you that we will be able to achieve net income on a quarterly or annual basis. If our revenues do not increase, or if our operating expenses exceed expectations or cannot be reduced, we will continue to suffer substantial losses which could have an adverse effect on our business and adversely affect your investment in our Company.

**We face intense competition, which could cause us to decrease the prices for our products or services or render our products uneconomical or obsolete, any of which could reduce our revenues and limit our growth.**

Our competitors in the biotechnology industry in the United States and abroad are numerous and include major pharmaceutical, energy, food and chemical companies, as well as specialized genetic engineering firms. Many of our large competitors in genetic engineering have substantially greater resources than us and have the capability of developing products which compete directly with our products. Many of these companies are performing research in the same areas as we are.

Our clinical laboratory business is highly fragmented and intensely competitive, and we compete with numerous national and local companies. Some of these entities are larger than we are and have greater resources than we do. We compete primarily on the basis of the quality of our testing, reporting and information services, our reputation in the medical community, the pricing of our services and our ability to employ qualified laboratory personnel.

These competitive conditions could, among other things:

- Require us to reduce our prices to retain market share;
- Require us to increase our marketing efforts which could reduce our profit margins;
- Increase our cost of labor to attract qualified laboratory personnel;
- Render our biotechnology products uneconomical or obsolete; or
- Reduce our revenue.

**We are required to expend significant resources for research and development for our products in development and these products may not be developed successfully. Failure to successfully develop these products may prevent us from earning a return on our research and development expenditures.**

The products we are developing are at various stages of development and clinical evaluations and may require further technical development and investment to determine whether commercial application is practicable. There can be no assurance that our efforts will result in products with valuable commercial applications. Our cash requirements may vary materially from current estimates because of results of our research and development programs, competitive and technological advances and other factors. In any event, we will require substantial funds to conduct development activities and pre-clinical and clinical trials, apply for regulatory approvals and commercialize products, if any, that are developed. We do not have any commitments or arrangements to obtain any additional financing and there is no assurance that required financing will be available to us on acceptable terms, if at all. Even if we spend substantial amounts on research and development, our potential products may not be developed successfully. If our product candidates on which we have expended significant amounts for research and development are not commercialized, we will not earn a return on our research and development expenditures, which may harm our business.

**Protecting our proprietary rights is difficult and costly. If we fail to adequately protect or enforce our proprietary rights, we could lose revenue.**

Our success depends in large part on our ability to obtain maintain and enforce our patents. Our ability to commercialize any product successfully will largely depend on our ability to obtain and maintain patents of sufficient scope to prevent third parties from developing similar or competitive products. In the absence of patent protection, competitors may impact our business by developing and marketing substantially equivalent products and technology.

Patent disputes are frequent and can preclude the commercialization of products. We have in the past been, are currently, and may in the future be, involved in material patent litigation, such as the matters discussed under "Part I--Item 3. Legal Proceedings" in this report. Patent litigation is time-consuming and costly in its own right and could subject us to significant liabilities to third parties. In addition, an adverse decision could force us to either obtain third-party licenses at a material cost or cease using the technology or product in dispute.

We have filed applications for United States and foreign patents covering certain aspects of our technology, but there is no assurance that pending patents will issue or as to the degree of protection which any issued patent might afford. We also utilize certain unpatented proprietary technology.

**Lawsuits in the biotechnology industry are not uncommon. If we become involved in any significant litigation, we would suffer as a result of the diversion of our management's attention, the expense of litigation and any judgments against us.**

In addition to intellectual property litigation, other substantial, complex or extended litigation could result in large expenditures by us and distraction of our management. For example, lawsuits by employees, stockholders, collaborators or distributors could be very costly and substantially disrupt our business. Disputes from time to time with companies or individuals are not uncommon in the biotechnology industry, and we cannot assure you that we will always be able to resolve them out of court.

**We may be unable to obtain or maintain regulatory approvals for our products, which could reduce our revenue or prevent us from earning a return on our research and development expenditures.**

Our research, preclinical development, clinical trials, product manufacturing and marketing are subject to regulation by the FDA and similar health authorities in foreign countries. FDA approval is required for our products, as well as the manufacturing processes and facilities, if any, used to produce our products that may be sold in the United States. The process of obtaining approvals from the FDA is costly, time consuming and often subject to unanticipated delays. Even if regulatory approval is granted, such approval may include significant limitations on indicated uses for which any products could be marketed. Further, even if such regulatory approvals are obtained, a marketed product and its manufacturer are subject to continued review, and later discovery of previously unknown problems may result in restrictions on such product or manufacturer, including withdrawal of the product from the market.

New government regulations in the United States or foreign countries also may be established that could delay or prevent regulatory approval of our products under development. Further, because gene therapy is a relatively new technology and has not been extensively tested in humans, the regulatory requirements governing gene therapy products are uncertain and may be subject to substantial further review by various regulatory authorities in the United States and abroad. This uncertainty may result in extensive delays in initiating clinical trials and in the regulatory approval process. Our failure to obtain regulatory approval of their proposed products, processes or facilities could have a material adverse effect on our business, financial condition and results of operations. The proposed products under development may also be subject to certain other federal, state and local government regulations, including, but not limited to, the Federal Food, Drug and Cosmetic Act, the Environmental Protection Act, and Occupational Safety and Health Act, and state, local and foreign counterparts to certain of such acts.

We cannot be sure that we can obtain necessary regulatory approvals on a timely basis, if at all, for any of the products we are developing or manufacturing or that we can maintain necessary regulatory approvals for our existing products, and all of the following could have a material adverse effect on our business:

- Significant delays in obtaining or failing to obtain required approvals;
- Loss of, or changes to, previously obtained approvals;
- Failure to comply with existing or future regulatory requirements; and
- Changes to manufacturing processes, manufacturing process standards or Good Manufacturing Practices following approval or changing interpretations of these factors.

**Our clinical laboratory business is subject to extensive government regulation and our loss of any required certifications or licenses could require us to cease operating this part of our business, which would reduce our revenue and injure our reputation.**

The clinical laboratory industry is subject to significant governmental regulation at the Federal, state and local levels. Under the Clinical Laboratory Improvement Act of 1967 and the Clinical Laboratory Improvement Amendments of 1988 (collectively, as amended, "CLIA") virtually all clinical laboratories, including ours, must be certified by the Federal government. Many clinical laboratories also must meet governmental standards, undergo proficiency testing and are subject to inspection. Certifications or licenses are also required by various state and local laws. The failure of our clinical laboratory to obtain or maintain such certifications or licenses under these laws could interrupt our ability to operate our clinical laboratory business and injure our reputation.

**Regulations requiring the use of "standard transactions" for healthcare services issued under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, may negatively impact our profitability and cash flows.**

Pursuant to the Health Insurance Portability and Accountability Act of 1996, or HIPAA, the Secretary of the Department of Health and Human Services, or HHS, has issued final regulations designed to improve the efficiency and effectiveness of the healthcare system by facilitating the electronic exchange of information in certain financial and administrative transactions while protecting the privacy and security of the information exchanged. Three principal regulations have been issued in final form: standards for electronic transactions, security regulations and privacy regulations.

The HIPAA transaction standards are complex, and subject to differences in interpretation by payers. For instance, some payers may interpret the standards to require us to provide certain types of information, including demographic information not usually provided to us by physicians. While most of our transactions are submitted and / or received in ANSI standard format, inconsistent application of transaction standards by some remaining payers or our inability to obtain certain billing information not usually provided to us by physicians could increase our costs and the complexity of billing. In addition, new requirements for additional standard transactions, such as claims attachments, could prove technically difficult, time-consuming or expensive to implement. We are working closely with our payers to establish acceptable protocols for claims submissions and with our industry trade association and an industry coalition to present issues and problems as they arise to the appropriate regulators and standards setting organizations.

**Compliance with the HIPAA security regulations and privacy regulations may increase our costs.**

The HIPAA privacy and security regulations, which became fully effective in April 2003 and April 2005, respectively, establish comprehensive federal standards with respect to the uses and disclosures of protected health information by health plans, healthcare providers and healthcare clearinghouses, in addition to setting standards to protect the confidentiality, integrity and availability of protected health information. The regulations establish a complex regulatory framework on a variety of subjects, including:

- the circumstances under which uses and disclosures of protected health information are permitted or required without a specific authorization by the patient, including but not limited to treatment purposes, activities to obtain payments for our services, and our healthcare operations activities;
- a patient's rights to access, amend and receive an accounting of certain disclosures of protected health information;
- the content of notices of privacy practices for protected health information; and
- administrative, technical and physical safeguards required of entities that use or receive protected health information.

We have implemented practices to meet the requirements of the HIPAA privacy and security regulations, as required by law. The privacy regulations establish a "floor" and do not supersede state laws that are more stringent. Therefore, we are required to comply with both federal privacy regulations and varying state privacy laws. In addition, for healthcare data transfers from other countries relating to citizens of those countries, we must comply with the laws of those other countries. The federal privacy regulations restrict our ability to use or disclose patient-identifiable laboratory data, without patient authorization, for purposes other than payment, treatment or healthcare operations (as defined by HIPAA), except for disclosures for various public policy purposes and other permitted purposes outlined in the privacy regulations. The privacy and security regulations provide for significant fines and other penalties for wrongful use or disclosure of protected health information, including potential civil and criminal fines and penalties. Although the HIPAA statute and regulations do not expressly provide for a private right of damages, we also could incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information.

Compliance with all of the HIPAA regulations, including new standard transactions, requires ongoing resources from all healthcare organizations, not just clinical laboratories. While we believe our total costs to comply with HIPAA will not be material to our operations or cash flows, new standard transactions and additional customer requirements resulting from different interpretations of the current regulations could impose additional costs on us.

**Reimbursements from third-party payers, upon which our clinical laboratory business is dependent, are subject to inconsistent rates and coverage and legislative reform that are beyond our control. This inconsistency and any reform that decreases coverage and rates could reduce our earnings and harm our business.**

Our clinical laboratory business is primarily dependent upon reimbursement from third-party payers, such as Medicare (which principally serves patients 65 and older) and insurers. We are subject to variances in reimbursement rates among different third-party payers, as well as constant renegotiation of reimbursement rates. We also are subject to audit by Medicare which can result in the return of payments made to us under these programs. These variances, rates and audit results could reduce our margins and thus our earnings.

The health care industry continues to undergo significant change as third-party payers' increase their efforts to control the cost, utilization and delivery of health care services. In an effort 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. Some of the proposals include managed competition, global budgeting and price controls. Changes that decrease reimbursement rates or coverage, or increase administrative burdens on billing third-party payers could reduce our revenues and increase our expenses.

**FDA regulation of laboratory-developed tests, analyte specific reagents, or genetic testing could lead to increased costs and delays in introducing new genetic tests.**

The FDA has regulatory responsibility over instruments, test kits, reagents and other devices used to perform diagnostic testing by clinical laboratories. In the past, the FDA has claimed regulatory authority over laboratory-developed tests, but has exercised enforcement discretion in not regulating tests performed by high complexity CLIA-certified laboratories. In December 2000, the HHS Secretary's Advisory Committee on Genetic Testing recommended that the FDA be the lead federal agency to regulate genetic testing. In late 2002, a new HHS Secretary's Advisory Committee on Genetics, Health and Society, or SACGHS, was appointed to replace the prior Advisory Committee. Ultimately, SACGHS decided that it would continue to monitor the progress of the federal agencies in the oversight of genetic technologies, but it did not believe that further action was warranted. In the meantime, the FDA is considering revising its regulations on analyte specific reagents, which are used in laboratory-developed tests, including laboratory-developed genetic testing. FDA interest in or actual regulation of laboratory-developed tests or increased regulation of the various medical devices used in laboratory-developed testing could lead to periodic inquiry letters from the FDA and increased costs and delays in introducing new tests, including genetic tests.

**The continued growth of managed care may reduce our revenues and increase our loss or reduce our net earnings.**

The number of individuals covered under managed care contracts or other similar arrangements has grown over the past several years and may continue to grow in the future. In addition, Medicare and other government healthcare programs may continue to shift to managed care. Entities providing managed care coverage have reduced payments for medical services, including clinical laboratory services, in numerous ways such as entering into arrangements under which payments to a service provider are capitated, limiting testing to specified procedures, denying payment for services performed without prior authorization and refusing to increase fees for specified services. These trends reduce our revenues and limit our ability to pass cost increases to our customers. Also, if these or other managed care organizations do not select us as a participating provider, we may lose some or all of that business, which could have an adverse effect on our business, financial condition and results of operations.

**Compliance with Medicare administrative policies, including those pertaining to certain automated blood chemistry profiles, may reduce the reimbursements we receive.**

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. 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, or 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.

**We depend on key employees in a competitive market for skilled personnel, and the loss of the services of any of our key employees, including our senior management, could delay our research and development programs and would adversely affect our ability to develop our business.**

The specialized scientific nature of our business requires us to attract and retain personnel with a wide variety of scientific capabilities. There is intense competition in the biotechnology industry for qualified scientific and technical personnel. To a large extent, our success in developing proprietary technological products has been the result of the effective efforts of our internal scientific staff and our experience and talent. Since our inception an insignificant number of key employees have left us. We have key man life insurance on Dr. Elazar Rabbani, our Chief Executive Officer, in the amount of \$3,000,000. There can be no assurance that we will continue to attract and retain personnel of high scientific caliber. If we lose the services of our management and scientific personnel and fail to recruit other scientific and technical personnel, our research and development programs could be materially and adversely delayed.

**Negative publicity and news coverage about us or the clinical laboratory industry may harm our business and operating results.**

In the past, the clinical laboratory industry has received negative publicity. This publicity has led to increased legislation, regulation, and review of industry practices. These factors may adversely affect our ability to market our services, require us to change our services and increase the regulatory burdens under which we operate, further increasing the costs of doing business and adversely affecting our operating results.

**Adverse perception and increased regulatory scrutiny of gene medicine and genetic research might limit our ability to conduct our business.**

Ethical, social and legal concerns about gene medicine, genetic testing and genetic research could result in additional regulations restricting or prohibiting the technologies we or our collaborators may use. Recently, gene medicine studies have come under increasing scrutiny, which has delayed ongoing and could delay future clinical trials and regulatory approvals. Federal and state agencies, congressional committees and foreign governments have expressed interest in further regulating biotechnology. More restrictive regulations or claims that our products are unsafe or pose a hazard could prevent us from commercializing any products.

**Our future success will depend in part upon our ability to enhance existing products and to develop and introduce new products.**

The market for our products is characterized by rapidly changing technology, evolving industry standards and new product introductions, which may make our existing products obsolete. Our future success will depend in part upon our ability to enhance existing products and to develop and introduce new products.

The development of new or enhanced products is a complex and uncertain process requiring the accurate anticipation of technological and market trends as well as precise technological execution. In addition, the successful development of new products will depend on the development of new technologies. We will be required to undertake time-consuming and costly development activities and to seek regulatory approval for these new products. We may experience difficulties that could delay or prevent the successful development, introduction and marketing of these new products. Regulatory clearance or approval of any new products may not be granted by the FDA or foreign regulatory authorities on a timely basis, or at all, and the new products may not be successfully commercialized.

**Our inability to carry out our certain of our marketing and sales plans may make it difficult for us to grow or maintain our business.**

During fiscal 2006, Enzo Life Sciences continued to implement an aggressive marketing program designed to more directly service its end users, while simultaneously positioning us for product line expansion. The program involves continuing to expand the reach of companies by the direct field sales force, develop a focused advertising campaign, continued attendance at top industry trade meetings, and publications in leading scientific journals, as well as the on-going enhancement of our interactive web site. In addition to our direct sales, we distribute our products through our international distribution network. If we are unable to successfully implement these programs, we may be unable to grow and our business could suffer.

**Because of competitive pressures and the complexity and expense of the billing process in our clinical laboratory business, we must obtain new customers while maintaining existing customers to grow our business.**

Intense competition in the clinical laboratory business, increasing administrative burdens upon the reimbursement process and reduced coverage and payments by insurers make it necessary for us to increase our volume of laboratory services. To do so, we must obtain new customers while retaining existing customers. Our failure to attract new customers or the loss of existing customers or a reduction in business from those customers could significantly reduce our revenues and impede our ability to grow.

**We depend on suppliers for materials that could impair our ability to manufacture our products.**

Outside vendors provide key components and raw materials used in the manufacture of our products. Although we believe that alternative sources for these components and raw materials are available, any supply interruption in a limited or sole source component or raw material would harm our ability to manufacture our products until a new source of supply is identified and qualified. In addition, an uncorrected defect or supplier's variation in a component or raw material, either unknown to us or incompatible with our manufacturing process, could harm our ability to manufacture products. We might not be able to find a sufficient alternative supplier in a reasonable time period, or on commercially reasonable terms, if at all. If we fail to obtain a supplier for the components of our products, our operations could be disrupted.

**We use hazardous materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be costly and time-consuming.**

Our manufacturing, clinical laboratory and research and development processes involve the storage, use and disposal of hazardous substances, including hazardous chemicals, biological hazardous materials and radioactive compounds. We are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. Although we believe that our safety and environmental management practices and procedures for handling and disposing of these hazardous materials are in accordance with good industry practice and comply with applicable laws, permits, licenses and regulations, the risk of accidental environmental or human contamination or injury from the release or exposure of hazardous materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result, including environmental clean-up or decontamination costs, and any such liability could exceed the limits of, or fall outside the coverage of, our insurance. We may not be able to maintain insurance on acceptable terms, or at all. We could be required to incur significant costs to comply with current or future environmental and public and workplace safety and health laws and regulations.

**We purchase insurance to cover our potential business risk.**

Although we believe that our present insurance coverage is sufficient to cover our current estimated exposures, we cannot assure that we will not incur liabilities in excess of our policy limits. In addition, although we believe that we will be able to continue to obtain adequate coverage, we cannot assure that we will be able to do so at acceptable costs.

**Risks Relating to our Common Stock**

**Our stock price has been volatile, which could result in substantial losses for investors.**

Our common stock is quoted on the New York Stock Exchange, and there has been historical volatility in the market price of our common stock. The trading price of our common stock has been, and is likely to continue to be, subject to significant fluctuations due to a variety of factors, including:

- fluctuations in our quarterly operating and earnings per share results;
- the gain or loss of significant contracts;
- loss of key personnel;
- announcements of technological innovations or new products by us or our competitors;
- delays in the development and introduction of new products;
- legislative or regulatory changes;



- general trends in the industry;
- recommendations and/or changes in estimates by equity and market research analysts;
- biological or medical discoveries;
- disputes and/or developments concerning intellectual property, including patents and litigation matters;
- public concern as to the safety of new technologies;
- sales of common stock of existing holders;
- securities class action or other litigation;
- developments in our relationships with current or future customers and suppliers; and
- general economic conditions, both in the United States and abroad.

In addition, the stock market in general has experienced extreme price and volume fluctuations that have affected the market price of our common stock, as well as the stock of many companies in our industries. Often, price fluctuations are unrelated to operating performance of the specific companies whose stock is affected.

In the past, following periods of volatility in the market price of a company's stock, securities class action litigation has occurred against the issuing company. If we were subject to this type of litigation in the future, we could incur substantial costs and a diversion of our management's attention and resources, each of which could have a material adverse effect on our revenue and earnings. Any adverse determination in this type of litigation could also subject us to significant liabilities.

**Because we do not intend to pay cash dividends on our common stock, an investor in our common stock will benefit only if it appreciates in value.**

We currently intend to retain our retained earnings and future earnings, if any, to finance the expansion of our business and do not expect to pay any cash dividends on our common stock in the foreseeable future. As a result, the success of an investment in our common stock will depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which an investor purchased her shares.

**It may be difficult for a third party to acquire us, which could inhibit stockholders from realizing a premium on their stock price.**

We are subject to the New York anti-takeover laws regulating corporate takeovers. These anti-takeover laws prohibit certain business combinations between a New York corporation and any "interested shareholder" (generally, the beneficial owner of 20% or more of the corporation's voting shares) for five years following the time that the shareholder became an interested shareholder, unless the corporation's board of directors approved the transaction prior to the interested shareholder becoming interested.

Our certificate of incorporation, as amended, and by-laws contain provisions that could have the effect of delaying, deferring or preventing a change in control of us that stockholders may consider favorable or beneficial. These provisions could discourage proxy contests and make it more difficult for stockholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock. These provisions include:

- a staggered board of directors, so that it would take three successive annual meetings to replace all directors; and
- advance notice requirements for the submission by stockholders of nominations for election to the board of directors and for proposing matters that can be acted upon by stockholders at a meeting.

**Future sales of shares of our common stock or the issuance of securities senior to our common stock could adversely affect the trading price of our common stock and our ability to raise funds in new equity offerings.**

We are not restricted from issuing additional common stock, preferred stock or securities convertible into or exchangeable for common stock. Future sales of a substantial number of our shares of common stock or equity-related securities in the public market or privately, or the perception that such sales could occur, could adversely affect prevailing trading prices of our common stock, and could impair our ability to raise capital through future offerings of equity or equity-related securities. No prediction can be made as to the effect, if any, that future sales of shares of common stock or the availability of shares of common stock for future sale, will have on the trading price of our common stock.

**There is no assurance that we will remain listed on an active trading market.**

Although our common stock is quoted on the New York Stock Exchange, there can be no assurance that we will, in the future, be able to meet all the requirements for continued quotation on that exchange. In the absence of an active trading market or if our common stock cannot be traded on the New York Stock Exchange, our common stock could instead be traded on the OTC Bulletin Board or in the Pink Sheets. In such event, the liquidity and stock price in the secondary market may be adversely affected. In addition, in the event our common stock was de-listed; broker-dealers have certain regulatory burdens imposed upon them which may discourage them from effecting transactions in our common stock and hence, could further limit the liquidity of our common stock.

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 1B – Unresolved Staff Comments

None.

Item 2. Properties

The following are the principal facilities of the Company:

<u>Location</u>	<u>Principal Operations</u>	<u>Approximate Area (sq. ft.)</u>	<u>Base Rent</u>	<u>Lease expiration Date</u>
60 Executive Blvd Farmingdale, NY	Clinical laboratory, research and manufacturing facilities (See Note 11 of Notes to Consolidated Financial Statements)	43,000	\$1,193,000	March 31, 2017
10 Executive Blvd Farmingdale, NY	Note 1 below	22,000	Owned	N/A
527 Madison Ave New York, NY	Corporate headquarters	6,400	\$367,000	December 31, 2013

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

Note 1 - In June 2006, we acquired a 22,000 square foot facility adjacent to our Farmingdale, New York facility that will be utilized, upon completion of renovations, for the Life Science and Therapeutics research and manufacturing operations. The new facility will be used to manage the additional space required for anticipated growth.

### Item 3. Legal Proceedings

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 issued a claim construction opinion on July 10, 2006. The Company and Sigma Aldrich ("Sigma") entered into a Settlement Agreement and Release effective September 15, 2006 (the "Agreement"). Pursuant to the Agreement, the Company's litigation with Sigma was dismissed and the Company will recognize \$2 million on settlement in the first quarter ending October 31, 2006. There can be no assurance that the Company will be successful with the remaining outstanding 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 has not recorded revenue under these agreements in fiscal 2006. The Company recorded revenue from only Perkin Elmer in fiscal 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 tortious interference, as well as certain injunction relief to prevent alleged unfair competition and tortious 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 issued a Marksman (claim construction) opinion on July 10, 2006. The Company did not record any revenue from Affymetrix during the fiscal years ended July 31, 2006, 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 issued a Markman opinion on July 10, 2006. The Company did not record any revenue from Roche during the fiscal year ended July 31, 2006.

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, Dean Engelhardt, Richard Keating, Doug Yates, and Does 1-50, Case No. CA-02-1242-A (the "Glaser Action"), 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. On September 16, 2006, the United States Court of Appeals for the Fourth Circuit affirmed the dismissal of the Complaint relating to the Glaser Action. Although the Glaser plaintiffs still have the option of pursuing the complaint and its wholly-owned subsidiary, Enzo Life Sciences, and from the United States District Court for the District of Connecticut against Applera Corporation and its wholly-owned subsidiary Supreme C. The complaint alleges infringement of six patents relating to DNA sequencing systems labeled as the "Diaseq and other technology" in 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, estoppels and laches and asserts counterclaims of non-infringement and invalidity. Fact discovery is ongoing. A one-day Markman hearing was held on May 25, 2006 and the parties are currently waiting for a Markman ruling. Dispositive motions due dates are based on the Markman ruling date. The trial date is currently scheduled for December 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.

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, 2006.

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.

2005 Fiscal Year (August 1, 2004 to July 31, 2005):

		<u>High</u>	<u>Low</u>
1st Quarter	\$17.69		\$11.15
2nd Quarter	\$20.40		\$17.27
3rd Quarter	\$19.27		\$13.62
4th Quarter	\$18.24		\$14.08



## 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.

The Company is a life sciences and biotechnology company focused on harnessing genetic processes to develop research tools and therapeutics and the provision of diagnostic services to the medical community. Since its founding in 1976, Enzo's strategic focus has been on the development, for commercial purposes, of enabling technologies in the life sciences field. Enzo's pioneering work in genomic analysis coupled with its extensive patent estate and enabling platforms have strategically positioned Enzo to play a crucially important role in the rapidly growing life sciences and molecular medicine marketplaces

The Company is comprised of three interconnected operating companies that have evolved out of Enzo's core competence: the use of nucleic acids as informational molecules and the use of compounds for immune modulation. These wholly owned operating companies conduct their operations through three segments. Below are brief descriptions of each of the three operating segments (see Note 13 in the notes to consolidated financial statements):

**Enzo Life Sciences** is a company that manufactures, develops and markets biomedical research products and tools to research and pharmaceutical customers around the world and has amassed a large patent and technology portfolio. The pioneering platforms developed by Enzo Life Sciences enable the development of a wide range of products in the research products marketplace.

**Enzo Therapeutics** is a biopharmaceutical company that has developed multiple novel approaches in the areas of gastrointestinal, infectious, ophthalmic and metabolic diseases, many of which are derived from the pioneering work of Enzo Life Sciences. The Company has focused its efforts on developing treatment regimens for diseases and conditions in which current treatment options are ineffective, costly, and/or cause unwanted side effects. This focus has generated a clinical and preclinical pipeline, as well as more than 40 patents and patent applications.

**Enzo Clinical Labs** is a regional clinical laboratory to the greater New York and New Jersey medical community. The Company believes having this capability allows us to capitalize firsthand on our extensive advanced molecular and cytogenetic capabilities and the broader trends in predictive diagnostics. We offer a menu of routine and esoteric clinical laboratory tests or procedures used in general patient care by physicians to establish or support a diagnosis, monitor treatment or medication, or search for an otherwise undiagnosed condition. We operate a full-service clinical laboratory in Farmingdale, New York, a network of 19 patient service centers, a stand alone "stat" or rapid response laboratory in New York City, and a full-service phlebotomy department.

The Company's sources of revenue from the Life Sciences segment have been from the direct sales of products consisting of labeling and detection reagents for the genomics and sequencing markets, as well as through non-exclusive distribution agreements with other companies and royalty income. 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 limit 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, 2006, 2005, and 2004 respectively, approximately 20%, 24%, and 31% of the Company's operating revenues were derived from product sales and royalty income and approximately 80%, 76%, and 69% were derived from clinical laboratory services.

## Results of Operations

(in	<u>Comparative Financial Data for the Fiscal Years Ended July 31,</u>						
	000's)						
	2006	Increase (Decrease)	% Change	2005	Increase (Decrease)	% Change	2004
Revenues:							
Product sales and royalties	\$ 7,900	(\$2,646)	(25)	\$10,546	(\$2,426)	(19)	\$12,972
Clinical laboratory services	<u>31,926</u>	<u>(931)</u>	(3)	<u>32,857</u>	<u>4,185</u>	15	<u>28,672</u>
Total revenue	39,826	(3,577)	(8)	43,403	1,759	4	41,644
Costs and expenses and other (income):							
Cost of products	2,174	(23)	(1)	2,197	(321)	(13)	2,518
Cost of laboratory services	13,917	1,369	11	12,548	1,962	19	10,586
Research & development	7,896	(556)	(7)	8,452	374	5	8,078
Selling, general and administrative	24,971	4,902	24	20,069	5,702	40	14,367
Provision for uncollectible A/R	3,633	(1,334)	(27)	4,967	(7,020)	(59)	11,987
Legal expenses	7,388	1,912	35	5,476	(864)	(14)	6,340
Interest income	(3,144)	(1,621)	106	(1,523)	(371)	32	(1,152)
Gain on patent litigation settlement	-	14,000	(100)	(14,000)	(14,000)	-	--
Costs and expenses	<u>56,835</u>	<u>18,649</u>		<u>38,186</u>	<u>(14,538)</u>		<u>52,724</u>
Operating (loss) income	<u>(\$17,009)</u>	<u>(\$22,226)</u>		<u>\$5,217</u>	<u>\$16,297</u>		<u>(\$11,080)</u>

*Fiscal 2006 Compared to Fiscal 2005*

## Consolidated Results

Fiscal 2006 product revenues and royalty income was \$7.9 million compared to \$10.5 million in fiscal 2005, a decrease of \$2.6 million or 25%. The decrease in product revenue and royalty income was primarily due to the decrease in the volume of shipments of research products of \$2.6 million and a decrease in revenue from a former distributor of \$1.5 million (see Item 3. Legal Proceedings). This decrease was partially offset by an increase in royalty income of \$1.5 million.

Fiscal 2006 clinical laboratory revenues were \$31.9 million compared to \$32.9 million in fiscal 2005, a decrease of approximately \$0.9 million or 3%. The contractual adjustment expense, which reduces gross billings, increased to 75.2% of gross billing as compared to 72.5% in the prior period, due to competitive pricing throughout the industry. In addition, the Company experienced a decrease in gross billing due to decreased reimbursement rates on certain tests.

The cost of products during both fiscal 2006 and fiscal 2005 was \$2.2 million. The cost of product revenues was negatively impacted in fiscal 2006 by the write-off or reserve of approximately \$0.4 million for excess or obsolete inventory due to an evaluation made of the current and estimated demand for such product offerings.

The cost of clinical laboratory services during fiscal 2006 was \$13.9 million compared to \$12.5 million in fiscal 2005, an increase of \$1.4 million or 11%. The increase is primarily due to an increase in the overall cost of performing testing services, including increased reagent costs of \$0.8 million and outside testing costs for certain esoteric tests of \$0.1 million, and an increase of hiring additional phlebotomists for the New Jersey market of approximately \$0.3 million.

Research and development expenses were \$7.9 million in fiscal 2006 compared to \$8.5 million in fiscal 2005, a decrease of \$0.6 million or 7%. The decrease was primarily due to a reduction of \$1.4 million in patent expense and the amortization of patent costs and a decrease in compensation expense for executive officers due to the realignment of responsibilities to other expense categories of \$0.6 million. The decrease was partially offset by an increase in clinical trial study activities of \$1.0 million and the recognition of share-based compensation charges required by the adoption of SFAS 123(R) of \$0.2 million during the 2006 period. Research and development expenses include costs of scientific personnel, supplies, consultants, allocated facility costs, costs related to pre-clinical and clinical trials, amortization of patent expense, and other patent related costs.

Selling, general and administrative expenses were \$25.0 million during fiscal 2006, compared to \$20.1 million in fiscal 2005, an increase of \$4.9 million or 24%. The increase in the 2006 period was primarily due to the recognition of share-based compensation charges required by the adoption of SFAS 123(R) of \$1.5 million, increases in expenditures for corporate governance, consulting, accounting and other professional fees of \$1.2 million, an increase in compensation expense of executive officers previously included in research and development due to the realignment of responsibilities, of \$0.7 million, increases in compensation of \$0.5 million and other increased costs.

The provision for uncollectible accounts receivable relating to the clinical laboratory segment during fiscal 2006 was \$3.6 million, compared to \$5.0 million during fiscal 2005, a decrease of \$1.3 million or 27%. The provision declined due to improved billing and collection procedures and an overall increase in collections.

Legal expense was \$7.4 million during fiscal 2006 compared to \$5.5 million in fiscal 2005, an increase of \$1.9 million or 35%, due to an increase in ongoing patent litigation activities.

Interest income increased \$1.6 million or 106% to \$3.2 million during fiscal 2006 compared to \$1.5 million during fiscal 2005, due to higher interest rates earned offset by lower investments. The Company earns interest by investing primarily in short term (30 – 90 days) commercial paper and money market funds with high credit ratings.

For the year ended July 31, 2006, the Company's net benefit for income taxes was \$1.3 million or an effective rate of 8%, comprised of a federal tax carryback benefit of \$2.0 million for taxes paid in the fiscal year ended July 31, 2005 and other adjustments, offset by a valuation allowance charge of \$0.6 million equal to net deferred tax assets as of July 31, 2005, and by state and local taxes of \$0.1 million, based on capital. Pursuant to SFAS 109 "Accounting for Income Taxes", the Company recorded a valuation allowance charge during the year ended July 31, 2006 equal to its net deferred tax assets at July 31, 2005 and has applied a full valuation allowance against increases in its net deferred tax assets generated during the 2006 period. The benefit for income taxes, at an effective rate of 8% was different from the U.S. statutory rate of 34% due to state and local taxes, net of federal tax benefit, of 5%, expenses not deductible for income taxes of 4%, and the effect of the increase in the valuation allowance of 28%. The Company believes that the valuation allowance is necessary as it is not more likely than not that net deferred tax assets will be realized in the foreseeable future based on positive and negative evidence available at this time. This conclusion was reached because of uncertainties relating to future taxable income, in terms of both its timing and its sufficiency, which would enable the Company to realize the net deferred tax assets. For the year ended July 31, 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 2005 period's taxable income, which was primarily comprised of the \$14 million gain from the Digene agreement. 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 of (1%) and other of 1%.



Fiscal 2006 net loss was \$15.7 million as compared to net income of \$3.0 million in fiscal 2005. Fiscal 2005 results included the gain from the patent litigation settlement from Digene Corp. of \$14 million. Fiscal 2006's net loss was impacted by decreased revenues and increased expenses as discussed above.

### **Segment Results**

The life sciences segment's loss before income taxes was approximately \$0.2 million for the year ended July 31, 2006, compared to income before income taxes of approximately \$14.6 million in the fiscal 2005 period. Fiscal 2006 product revenues and royalty income was \$7.9 million compared to \$10.5 million in fiscal 2005, a decrease of \$2.6 million or 25%. The decrease in product revenue and royalty income was primarily due to the decrease in the volume of shipments of research products of \$2.6 million and a decrease in revenue from a former distributor of \$1.5 million (see Item 3. Legal Proceedings). This decrease was partially offset by an increase in royalty income of \$1.5 million. The 2005 period's income included the \$14 million gain from a settlement and license agreement with Digene Corp. The decline in the gross profit margin on product sales and royalties in fiscal 2006 compared to fiscal 2005 was partially due to the write-off or reserve of approximately \$0.4 million of excess or obsolete inventory due to an evaluation made of the current and estimated demand for such product offerings, decline in sales volumes and pricing competitiveness. Segment operating expenses (research and development and selling, general and administrative) decreased in the 2006 period by approximately \$1.8 million primarily due to a decrease in the amortization of deferred patent expenses of approximately \$1.2 million, and a decrease in compensation expense for executive officers due to the realignment of responsibilities of \$0.6 million.

The therapeutics segment's loss before income taxes was approximately \$4.2 million for the year ended July 31, 2006 as compared to \$3.1 million in the year ago period. The increase in the net loss was due to an increase of \$1.0 million in clinical trial studies expenditures.

The clinical laboratory segment's income before income taxes was \$0.1 million for the year ended July 31, 2006 period versus income of \$2.8 million in fiscal 2005. The 2006 period was impacted by lower revenue of \$0.9 million, an increase in cost of laboratory services of \$1.4 million, as previously explained, and a net increase in operating expenses (provision for uncollectible accounts and selling, general and administrative) of \$0.5 million primarily due to recognition of share-based compensation charges required by the adoption of SFAS 123(R) of \$0.5 million, the inclusion of compensation expense for executive officers of \$0.6 million previously included in the other segment due to the realignment of responsibilities, and compensation and related costs of \$0.4 million relating to increased personnel, offset by a decrease in the provision for uncollectible accounts of \$1.3 million.

The other segment's loss before income taxes was \$12.6 million for the year ended July 31, 2006 versus \$9.1 million in fiscal 2005. The increased loss in fiscal 2006 of approximately \$3.5 million was primarily due to the recognition of share-based compensation charges required by the adoption of SFAS 123(R) of \$0.9 million, increases in expenditures for corporate governance, consulting, accounting and other professional fees of \$1.3 million, an increase in legal fees of \$1.9 million due to ongoing patent litigation, and an increase in compensation expense for executive officers previously included in life sciences and therapeutics segments due to the realignment of responsibilities, of \$0.7 million. These increases were partially offset by higher interest income earned of \$1.6 million.

#### *Fiscal 2005 Compared to Fiscal 2004*

### **Consolidated results**

Fiscal 2005 Product Revenue 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 products and royalty income from Digene Corp. The decline in the gross profit margin on 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 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 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.

The fiscal 2005 provision for uncollectible accounts in the life sciences division was \$0 versus \$1.8 million in the 2004 period, due to the write off of a receivable from a former distributor. The fiscal 2005 provision for uncollectible accounts receivable in the clinical reference segment was \$5.0 million, compared to \$10.2 million in the 2004 period, a decrease of \$5.2 million or 51%. 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 approximately \$359,000.

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%.

## Segment Results

The life science segment's income before income taxes was \$14.6 million in fiscal 2005 compared to \$1.1 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 product revenues due to the ongoing dispute with certain distributors on the sales of certain licensed products.

The therapeutics segment's loss before income taxes was approximately \$3.1 million for the year ended July 31, 2005 as compared to \$2.4 million in the year ago period. The increase in the net loss was due to an increase of \$0.7 million in clinical trial studies expenditures.

The clinical laboratory segment's income before income taxes was \$2.8 million versus a loss of \$1.5 million in fiscal 2004. 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 \$9.1 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.

## Liquidity and Capital Resources

At July 31, 2006, our cash and cash equivalents were \$69.9 million, a decrease of \$13.8 million from cash and cash equivalents and marketable securities at July 31, 2005. We had working capital of \$80.2 million at July 31, 2006 compared to \$96.3 million at July 31, 2005. The decrease was the result of the use of cash to fund operations arising from the net loss in fiscal 2006. In fiscal 2005, 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.

Net cash used in operating activities for the year ended July 31, 2006 was approximately \$10.1 million as compared to net cash provided by operating activities of \$13.0 million for the year ended July 31, 2005. The decrease in net cash provided by operating activities in fiscal 2006 of \$23.1 million was primarily due to the fiscal 2006 net loss of \$15.7 million as compared to net income in fiscal 2005 of \$3.0 million and by the net change in operating assets and liabilities compared to the prior year and the impact of non cash items. In fiscal 2006, net cash provided by investing activities decreased approximately \$6.6 million from fiscal 2005, primarily due to an increase in capital expenditures of approximately \$3.0 million, and a decline in the sales of marketable securities of approximately \$3.8 million. During fiscal 2006, all investments in marketable securities were sold and reinvested in cash equivalents. In fiscal 2006, the Company used cash of approximately \$3.2 million for the purchase of land and building which will be primarily utilized as the Life Sciences and Therapeutics research and development and manufacturing facility. In fiscal 2006, net cash provided by financing activities increased approximately \$0.1 million from fiscal 2005 primarily as a result of the increase in proceeds from the exercise of stock options.

Accounts receivable, net of \$10.4 million and \$13.4 million represented 109 days and 119 days of operating revenues at July 31, 2006 and 2005, respectively. The change in net accounts receivable is due to a decrease in accounts receivable at the clinical laboratory of approximately \$3.4 million and an increase of life science accounts receivable of approximately \$0.4 million. The decrease in the clinical laboratory receivable is primarily due to improvements in the collection process. The increase in the life sciences accounts receivable is primarily due to the increase in royalty income partially offset by a decrease in product revenues. Net accounts receivable from our clinical laboratory operations of \$9.2 million and \$12.5 million represented an average of 124 days and 147 days of clinical laboratory services revenues at July 31, 2006 and 2005, respectively.

We believe that our current cash position is sufficient for our foreseeable liquidity and capital resource needs over the next 12 months, although there can be no assurance that future events will not alter such view.

### **Effect of New Pronouncements**

In June 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections, a replacement of APB Opinion No. 20, Accounting Changes, and FASB Statement No. 3, Reporting Accounting Changes in Interim Financial Statements." SFAS No. 154 changes the requirements for the accounting for and reporting of a change in accounting principle. Previously, most voluntary changes in accounting principles required recognition via a cumulative effect adjustment within net income for the period of the change. SFAS No. 154 requires retrospective application to prior periods' financial statements, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. SFAS No. 154 is effective for accounting changes made in fiscal years beginning after December 15, 2005; however, SFAS No. 154 does not change the transition provisions of any existing accounting pronouncements. The adoption of SFAS No. 154 is not expected to have a material impact on the Company's financial condition or results of operations.

In June 2006, the FASB issued FASB Interpretation No. 48 ("FIN 48"), "Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109 ("FAS 109")", to clarify the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FAS 109, "Accounting for Income Taxes". This Interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This Interpretation also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. The provisions of FIN 48 are effective for fiscal years beginning after December 15, 2006. The Company has not evaluated the impact of FIN 48 on its financial statements at this time.

### **Contractual Obligations**

The Company has entered into various real estate and equipment operating leases and has employment agreements with certain executive officers. The real estate lease for the Company's Farmingdale headquarters is with a related party. See Note 11 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, 2006:

In 000's	Total	Payments Due by Period			
		Less than 1 year	1-3 years	4-5 years	Over 5 years
Real estate and equipment leases	\$20,362	\$2,662	\$4,889	\$4,382	\$8,429
Employment agreements	2,358	1,483	875	--	--
Total contractual cash obligations	<u>\$22,720</u>	<u>\$4,145</u>	<u>\$5,764</u>	<u>\$4,382</u>	<u>\$8,429</u>

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.

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

### **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 adjustments, allowance for uncollectible accounts, inventory, 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.

### Product revenues

Revenues from product sales 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 Company did not recognize any revenue from these distributors during the year ended July 31, 2006. During the fiscal years ended July 31, 2005, and 2004, the manufacturing and processing cost of these products sold was \$0.7 million, and \$7.4 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.

### Royalties

Royalty revenues are recorded in the period earned. Royalties received in advance of being earned are recorded as deferred revenues.

### Revenues - 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. These revenues and the associated accounts receivable are based on gross amounts billed or billable for services rendered, net of a contractual adjustment, which is the difference between amounts billed to payers and the expected approved reimbursable settlements from such payers.

The following are tables of the clinical laboratory segment's net revenues and percentages by revenue category for the years ended July 31, 2006 and 2005:

Net revenues Revenue category (In	Year ended July 31, 2006		Year ended July 31, 2005	
	000's	(in %)	(In 000's)	(in %)
Medicare \$7,462		23	\$6,906	21
Third party carriers	17,680	56	17,528	53
Patient self-pay	4,925	15	6,904	21
HMO's 1,859		6	1,519	5
Total \$31,926		100%	\$32,857	100%

The Company provides services to certain patients covered by various third-party payers, including the Federal Medicare program. Revenue, net of contractual adjustments, from direct billings under the Federal Medicare program during the years ended July 31, 2006, 2005 and 2004 were approximately 23%, 21% and 26%, respectively, of the clinical lab segment's revenue. 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.

### Contractual Adjustments

The Company's estimate of contractual adjustments is based on significant assumptions and judgments, such as its interpretation of the applicable payer's reimbursement policies, and bears the risk of change. The estimation process is based on the experience of amounts approved as reimbursable and ultimately settled by payers, versus the corresponding gross amount billed to the respective payers. The contractual adjustment is an estimate that reduces gross revenue, based on gross billing rates, to amounts expected to be approved and reimbursed. The Company adjusts the contractual adjustment estimate periodically, based on its evaluation of historical settlement experience with payers, industry reimbursement trends, and other relevant factors.

During the years ended July 31, 2006, 2005 and 2004, the contractual adjustment percentages, determined using average historical reimbursement statistics, were 75.2%, 72.5% and 70.9%, respectively, of gross billings. The Company estimates (by using a sensitivity analysis) that each 1% point change in the contractual adjustment percentage could have resulted in a change in clinical laboratory services revenues of approximately \$1,288,000 for the year ended July 31, 2006, and could have resulted in a change in the net accounts receivable of approximately \$373,000 as of July 31, 2006.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are reported at realizable value, net of allowances for doubtful accounts, which is estimated and recorded in the period of the related revenue.

For the clinical laboratory segment, the allowance for doubtful accounts represents amounts that the Company does not expect to collect after the Company has exhausted its collection procedures. The Company estimates its allowance for doubtful accounts in the period the related services are billed and adjusts the estimate in future accounting periods as necessary. It bases the estimate for the allowance on the evaluation of historical collection experience, the aging profile of accounts receivable, the historical doubtful account write-off percentages, payer mix, and other relevant factors.

The allowance for doubtful accounts includes the balances, after receipt of the approved settlements from third party payers for the insufficient diagnosis information received from the ordering physician, which result in denials of payment, and the uncollectible portion of receivables from self payers, including deductibles and copayments, which are subject to credit risk and patients' ability to pay. During the years ended July 31, 2006 and 2005, the Company determined an allowance for doubtful accounts less than 210 days and wrote off 100% of accounts receivable (for all payers) over 210 days, as it assumed those accounts are uncollectible. The Company adjusts the historical collection analysis for recoveries, if any, on an ongoing basis.

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 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 allowance 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. Should circumstances change (e.g. shift in payer mix, decline in economic conditions or deterioration in aging of receivables), our estimates of net realizable value of receivables could be reduced by a material amount.

The following is a table of the Company's net accounts receivable by segment. The clinical laboratory segment's net receivables are detailed by billing category and as a percent to its total net receivables. At July 31, 2006 and 2005, approximately 88% and 94%, respectively, of the Company's net accounts receivable relates to its clinical laboratory business, which operates in the New York and New Jersey Metropolitan area.

Net accounts receivable	As of		As of	
	July 31, 2006		July 31, 2005	
Billing category (In	000's)	(in %)	(In 000's) (in	%)
Clinical laboratory				
Medicare	\$1,367	15	\$1,594	13
Third party carriers	4,025	44	6,742	54
Patient self-pay	3,294	36	3,819	30
HMO's	475	5	394	3
Total clinical laboratory	\$9,161	100%	\$12,549	100%
Total life sciences	1,286		872	
Total accounts receivable	<u>\$10,447</u>		<u>\$13,421</u>	

Changes in the Company's allowance for doubtful accounts are as follows:

In 000's	July 31, 2006	July 31, 2005
Beginning balance	\$2,292	\$2,770
Provision for doubtful accounts	3,633	4,967
Write-offs (4,892)	(5,445)	
Ending balance	<u>\$1,033</u>	<u>\$2,292</u>

## *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 not more likely than not the benefits will be realized in the foreseeable future. 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.

## *Inventory*

The Company values inventory at the lower of cost (first-in, first-out) or market. Work-in-process and finished goods inventories consist of material, labor, and manufacturing overhead. On a quarterly basis, we review inventory quantities on hand and analyze the provision for excess and obsolete inventory based on our estimate of sales forecasts based on sales history and anticipated future demand. Our estimate of future product demand may not be accurate and we may understate or overstate the provision for excess and obsolete inventory. Accordingly, unanticipated changes in demand could have a significant impact on the value of our inventory and results of operations. At July 31, 2006 and 2005, our reserve for excess and obsolete inventory was \$238,000 and \$0, respectively.

### Item 7A. Quantitative and Qualitative Disclosures About Market Risk

The Company does not have an exposure to market risk from changes in foreign currency exchange rates, commodity price risk or other market risk. We do not engage in any hedging or market risk management tools. The Company does not have interest risk with respect to interest rates on cash and cash equivalents that could impact our results of operations and financial position since the investments are in highly liquid corporate debt instruments with maturities of three months or less. There have been no material changes with respect to market risk previously disclosed in our Annual Report on Form 10-K for our 2005 fiscal year.

### 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

### **Evaluation of Disclosure Controls and Procedures**

As required by Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of July 31, 2006. This evaluation was carried out under the supervision and with participation of our Chief Executive Officer and Chief Financial Officer. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. Therefore, effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives. Based upon our evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of June 3, 2006, to provide reasonable assurance that information required to be disclosed in the reports that we file under the Exchange Act is recorded, processed, summarized and reported in a timely manner and is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

### **Changes in Internal Control over Financial Reporting**

There was no change in our internal control over financial reporting during the fourth quarter ended July 31, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### **Management's Annual Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) under the Exchange Act.

Our 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 and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of management and our directors; and
- provide reasonable assurance regarding prevention and timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems that are determined to be effective provide only reasonable assurance with respect to financial statement preparation and presentation. 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 assessed the effectiveness of our internal control over financial reporting based on criteria for effective internal control over financial reporting described in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on its assessment, management concluded that we maintained effective internal control over financial reporting as of July 31, 2006. Ernst and Young LLP, our independent registered public accounting firm, has issued an attestation report on management's assessment of the effectiveness of our internal control over financial reporting as of July 31, 2006. This report, in which Ernst and Young has expressed an unqualified opinion, appears in this Item 9A.



## **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 of  
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, 2006, 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, 2006, 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, 2006, 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, 2006 and 2005, and the related consolidated statements of operations, consolidated stockholders' equity and comprehensive (loss) income, and consolidated statements of cash flows for each of the three years in the period ended July 31, 2006 of Enzo Biochem, Inc. and our report dated October 5, 2006 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Melville, New York  
October 5, 2006

## ITEM 9B. OTHER INFORMATION

None

### PART III

#### Item 10. Directors and Executive Officers

The information required under this item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission on or before November 28, 2006 and is incorporated herein by reference.

#### Item 11. Executive Compensation

The information required under this item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission on or before November 28, 2006 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, 2006 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, 2006 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, 2006 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, 2006 and 2005  
Consolidated Statements of Operations- Years ended July 31, 2006, 2005 and 2004  
Consolidated Statements of Stockholders' Equity and Comprehensive (Loss) Income - Years ended July 31, 2006, 2005 and 2004  
Consolidated Statements of Cash Flows - Years ended July 31, 2006, 2005 and 2004  
Notes to Consolidated Financial Statements.

(2) Financial Statement Schedule

Schedule II - Valuation and Qualifying Accounts

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

(3) Exhibits

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

Exhibit

No. Description

- 3(a) Certificate of Incorporation, as amended March 17, 1980. (1)
- 3(b) June 16, 1981 Certificate of Amendment of the Certificate of Incorporation. (2)
- 3(c) Certificate of Amendment to the Certificate of Incorporation. (3)
- 3(d) Bylaws. (1)
- 10 (c) Employment Agreements with Elazar Rabbani. (5)
- 10(d) Employment Agreement with Shahram Rabbani. (5)
- 10(e) Employment Agreement with Barry Weiner. (5)
- 10(f) 1994 Stock Option Plan. (6)
- 10(g) Agreement with Corange International Limited (Boehringer Mannheim) effective April 1994. (19) (7)
- 10(h) Agreement with Amersham International effective February 1995. (7)
- 10(i) Agreement with Dako A/S effective May 1995. (7)
- 10(j) Agreement with Baxter Healthcare Corporation (VWR Scientific Products) effective September 1995. (7)
- 10(k) Agreement with Yale University and amendments thereto. (7)
- 10(l) Agreement with The Research Foundation of the State of New York effective May 1987. (7)
- 10(m) 1999 Stock Option Plan filed. (8)
- 10 (n) Amendment to Elazar Rabbani's employment agreement. (9)
- 10 (o) Amendment to Shahram Rabbani's employment agreement. (9)
- 10 (p) Amendment to Barry Weiner's employment agreement. (9)
- 10 (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 (13)
- 10 (w) Settlement and Release Agreement between the Company and Sigma Aldrich (14)
- 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.  
Enzo Realty, LLC, 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.
  - (13) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 2006 and is incorporated herein by reference.
  - (14) This exhibit was filed with the Company's current report on Form 8-K on September 21, 2006 and is incorporated herein by reference.
- (b) See Item 15(a) (3), above.  
(c) See Item 15(a) (2), above.

SIGNATURES

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

ENZO BIOCHEM, INC.

Date: October 12, 2006

By: /s/ Elazar Rabbani Ph.D.  
Chairman of the Board

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

By: /s/ Elazar Rabbani Ph.D. October 12, 2006  
Elazar Rabbani  
Chairman of Board of Directors  
(Principal Executive Officer)

By: /s/ Shahram K. Rabbani October 12, 2006  
Shahram K. Rabbani,  
Chief Operating Officer, Secretary and Director

By: /s/ Barry W. Weiner October 12, 2006  
Barry W. Weiner,  
President, Chief Financial Officer, and Director

By: /s/ John B. Sias October 12, 2006  
John B. Sias, Director

By: /s/ John J. Delucca October 12, 2006  
John J. Delucca, Director

By: /s/ Irwin Gerson October 12, 2006  
Irwin Gerson, Director

By: /s/ Melvin F. Lazar October 12, 2006  
Melvin F. Lazar, Director

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FORM 10-K, ITEM 15(a) (1) and (2)  
ENZO BIOCHEM, INC.

LIST OF CONSOLIDATED FINANCIAL STATEMENTS AND  
FINANCIAL STATEMENT SCHEDULE

The following consolidated financial statements and financial statement schedule of Enzo Biochem, Inc. are included in Item 15(a):

Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets -- July 31, 2006 and 2005	F-3
Consolidated Statements of Operations -- Years ended July 31, 2006, 2005 and 2004	F-4
Consolidated Statements of Stockholders' Equity and Comprehensive (Loss) Income -- Years ended July 31, 2006, 2005 and 2004	F-5
Consolidated Statements of Cash Flows -- Years ended July 31, 2006, 2005 and 2004	F-6
Notes to Consolidated Financial Statements	F-7
Schedule II - Valuation and Qualifying Accounts -- Years ended July 31, 2006, 2005 and 2004	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 of  
Enzo Biochem, Inc

We have audited the accompanying consolidated balance sheets of Enzo Biochem, Inc. (the "Company") as of July 31, 2006, and 2005, and the related consolidated statements of operations, consolidated statements of stockholders' equity and comprehensive (loss) income, and consolidated statements of cash flows for each of the three years in the period ended July 31, 2006. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with 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, 2006 and 2005, and the consolidated results of their operations and their cash flows for each of the three years in the period ended July 31, 2006, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, 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 Enzo Biochem, Inc.'s internal control over financial reporting as of July 31, 2006, 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 5, 2006, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Melville, New York  
October 5, 2006



**ENZO BIOCHEM, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
(in thousands, except share and per share data )

ASSETS

	July 31,	
	2006	2005
Current assets:		
Cash and cash equivalents.....	\$69,854	\$76,981
Marketable securities.....	-	6,714
Accounts receivable, net of allowance for doubtful accounts of \$1,033 in 2006 and \$2,292 in 2005.....	10,447	13,421
Inventories.....	2,401	2,876
Prepaid expenses.....	1,465	1,848
Recoverable and prepaid income taxes.....	1,931	1,329
Deferred taxes.....	-	900
Total current assets.....	86,098	104,069
Property, plant, and equipment, net of accumulated depreciation and amortization of \$8,247 in 2006 and \$7,279 in 2005.....	5,848	2,670
Goodwill.....	7,452	7,452
Patent costs, net of accumulated amortization of \$9,770 in 2006 and \$9,695 in 2005.....	1,257	1,333
Other.....	869	942
Total assets.....	\$101,524	\$116,466

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable - trade.....	1,304	2,414
Accrued liabilities.....	4,403	4,866
Other current liabilities.....	230	509
Total current liabilities.....	5,937	7,789
Deferred taxes.....	-	260
Long term installment payable, net of current portion.....	-	150
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, \$.01 par value; authorized 25,000,000 shares; no shares issued or outstanding.....	-	-
Common Stock, \$.01 par value; authorized 75,000,000 shares; shares issued: 32,844,200 at July 31, 2006 and 32,526,800 at July 31, 2005.....	328	325
Additional paid-in capital.....	236,002	230,644
Less treasury stock at cost: 569,700 shares at July 31, 2006 and 384,400 shares at July 31, 2005.....	(8,499)	(5,994)
Accumulated deficit.....	(132,244)	(116,577)
Accumulated other comprehensive loss.....	-	(131)
Total stockholders' equity.....	95,587	108,267
Total liabilities and stockholders' equity.....	\$101,524	\$116,466

**ENZO BIOCHEM, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATION**      **S**  
(in thousands, except per share data)

	Years ended July 31,		
	2006	2005	2004
Revenues:			
Product revenues and royalty income.....	\$7,900	\$10,546	\$12,972
Clinical laboratory services.....	<u>31,926</u>	<u>32,857</u>	<u>28,672</u>
	39,826	43,403	41,644
Costs and expenses and other (income):			
Cost of product revenues.....	2,174	2,197	2,518
Cost of clinical laboratory services.....	13,917	12,548	10,586
Research and development expense.....	7,896	8,452	8,078
Selling, general, and administrative expense.....	24,971	20,069	14,367
Provision for uncollectible accounts receivable.....	3,633	4,967	11,987
Legal expense.....	7,388	5,476	6,340
Interest income.....	(3,144)	(1,523)	(1,152)
Gain on patent litigation settlement.....	-	<u>(14,000)</u>	-
	56,835	38,186	52,724
(Loss) income before income taxes.....	(17,009)	5,217	(11,080)
Benefit (provision) for income taxes.....	<u>1,342</u>	<u>(2,213)</u>	<u>4,848</u>
Net (loss) income.....	<u>(\$15,667)</u>	<u>\$3,004</u>	<u>(\$6,232)</u>
Net (loss) income per common share:			
Basic.....	<u>(\$0.49)</u>	<u>\$0.09</u>	<u>(\$0.20)</u>
Diluted.....	<u>(\$0.49)</u>	<u>\$0.09</u>	<u>(\$0.20)</u>
Weighted average common shares outstanding:			
Basic.....	<u>32,215</u>	<u>32,097</u>	<u>31,700</u>
Diluted.....	<u>32,215</u>	<u>32,763</u>	<u>31,700</u>

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

**ENZO BIOCHEM, INC**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
**AND COMPREHENSIVE (LOSS) INCOME**  
**Years ended July 31, 2006, 2005 and 2004**  
(In thousands, except share data)

	Common Stock Shares	Treasury Stock Shares	Common Stock Amount	Additional Paid-in Capital	Treasury Stock Amount	Accumulated Comprehensive Deficit (\$89,916)	Other Stockholders' Income (\$85)	Total Comprehensive Equity (\$109,381)
Balance at July 31, 2003.....	29,975,100	---	\$300	\$199,082	---	---	---	---
Net (loss) for the year ended July 31, 2004.....	---	---	---	---	---	(6,232)	---	(6,232)
Unrealized loss on available-for-sale securities, net of tax.....	---	---	---	---	---	---	(161)	(161)
Surrender of common stock for exercise of stock options.....	---	---	---	---	---	---	---	---
Exercise of stock options (see Note 2).....	873,900	---	9	6,556	(\$5,669)	---	---	(5,669)
Issuance of stock for employee 401(k) plan match.....	15,800	---	---	282	---	---	---	6,565
Comprehensive (loss).....	---	---	---	---	---	---	---	282
Balance at July 31, 2004.....	30,864,800	---	309	205,920	(5,669)	(96,148)	(246)	104,166
Net income for the year ended July 31, 2005.....	---	---	---	---	---	\$3,004	---	3,004
Unrealized gain on available-for-sale securities, net of tax.....	---	---	---	---	---	---	43	43
Reclassification adjustment or net loss realized and reported in net income.....	---	---	---	---	---	---	122	122
Valuation reserve.....	---	---	---	---	---	---	(50)	(50)
5% stock dividend (fair value on date declared).....	1,543,600	17,500	15	23,418	(325)	(23,433)	---	(325)
Surrender of common stock for exercise of stock options.....	---	17,000	---	---	---	---	---	---
Tax benefit for stock options exercised.....	---	---	---	124	---	---	---	124
Exercise of stock options (see Note 2).....	100,300	---	7	830	---	---	---	831
Issuance of stock for employee 401(k) plan match.....	18,100	---	---	352	---	---	---	352
Comprehensive income.....	---	---	---	---	---	---	---	---
Balance at July 31, 2005.....	32,526,800	---	325	230,644	(5,994)	(116,577)	(131)	108,267
Net (loss) for the year ended July 31, 2006.....	---	---	---	---	---	(15,667)	---	(15,667)
Realized loss on available-for-sale securities, net of tax.....	---	---	---	---	---	---	131	131
Surrender of common stock for exercise of stock options.....	---	185,300	---	---	(2,505)	---	---	(2,505)
Exercise of stock options (see Note 2).....	285,030	---	3	3,113	---	---	---	3,116
Issuance of stock for employee 401(k) plan match.....	32,370	---	---	402	---	---	---	402
Share based compensation charges.....	---	---	---	1,763	---	---	---	1,763
Stock options issued for consulting services.....	---	---	---	80	---	---	---	80
Comprehensive (loss).....	---	---	---	---	---	---	---	---
Balance at July 31, 2006.....	32,844,200	0	\$328	\$236,002	(\$8,499)	(\$132,244)	---	\$95,587

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

**ENZO BIOCHEM, INC**  
**CONSOLIDATED STATEMENTS OF CASH FLOW**     **S**  
(in thousands)

	Years ended July 31,		
	2006	2005	2004
<b>Operating activities</b>			
Net (loss) income.....	(\$15,667)	\$3,004	(\$6,232)
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:			
Depreciation and amortization of property, plant and equipment.....	1,049	1,020	1,076
Amortization of patent costs.....	75	1,312	1,286
Provision for uncollectible accounts receivable.....	3,633	4,967	11,987
Write-off and/or reserve for obsolete inventory.....	596	---	---
Deferred taxes.....	640	891	(1,651)
Share based compensation charges.....	1,763	---	---
Options issued to consultant.....	80	---	---
Issuance of stock for 401(k) employer match.....	402	352	282
Deferred rent.....	---	(87)	(233)
Realized loss on sales of marketable securities.....	154	200	---
Tax benefit on stock option exercises.....	---	124	---
Other.....	---	(51)	2
Changes in operating assets and liabilities:     Accounts			
receivable.....	(659)	(3,593)	(9,515)
Inventories.....	(120)	558	(13)
Prepaid expenses.....	383	(747)	400
Recoverable and prepaid income taxes.....	(602)	2,578	(3,365)
Accounts payable - trade.....	(1,110)	322	771
Accrued liabilities.....	(463)	1,620	(377)
Other current liabilities.....	(279)	509	---
Adjustments.....	5,542	9,975	650
Net cash (used in) provided by operating activities.....	(10,125)	12,979	(5,582)
<b>Investing activities</b>			
Capital expenditures.....	(4,227)	(1,276)	(1,304)
Patent costs.....	--	(20)	(444)
Sales of marketable securities.....	6,760	10,692	(2,349)
Purchases of marketable securities.....	(69)	(249)	---
Security deposits and other.....	73	---	---
Net cash provided by (used in) investing activities.....	2,537	9,147	(4,097)
<b>Financing activities</b>			
Proceeds from the exercise of stock options.....	611	506	896
Payment of long term installment payable.....	(150)	(150)	---
Other.....	---	---	14
Net cash provided by financing activities.....	461	356	910
Net (decrease) increase in cash and cash equivalents.....	(7,127)	22,482	(8,769)
Cash and cash equivalents at the beginning of year.....	76,981	54,499	63,268
Cash and cash equivalents at the end of year.....	\$69,854	\$76,981	\$54,499

**ENZO BIOCHEM, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**July 31, 2006 and 2005**

**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 and are distributed in the United States and internationally. 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 laboratory that offers and provides diagnostic medical testing services to the health care community in the greater New York and New Jersey area. The Company operates in three segments (see Note 13).

**Summary of significant accounting policies**

*Principles of consolidation*

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Enzo Clinical Labs, Enzo Life Sciences, Enzo Therapeutics and Enzo Realty LLC ("Realty"). Realty was formed in fiscal 2006 to acquire a building (see Note 5). All intercompany transactions and balances have been eliminated.

*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.

*Concentration of credit risk*

Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities. The Company's cash equivalents are invested in diverse financial instruments with high credit ratings. The Company believes the fair value of the aforementioned financial instruments approximates the current value due to the immediate or short-term nature of these items.

Concentration of credit risk with respect to the Company's life sciences segment is mitigated by the diversity of the Company's clients and their dispersion across many different geographic regions. To reduce risk, the Company routinely assesses the financial strength of these customers and, consequently, believes that its accounts receivable credit exposure, with respect to these customers, is limited.

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. The clinical 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.

**ENZO BIOCHEM, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**July 31, 2006 and 2005**

*Revenue Recognition*

Product revenues

Revenues from product sales 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 product revenues. The Company did not recognize any revenue from these distributors during the year ended July 31, 2006. During the years ended July 31, 2005, and 2004, the manufacturing and processing cost of these products sold was \$0.7 million, and \$7.4 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.

Royalties

Royalty revenues are recorded in the period earned. Royalties received in advance of being earned are recorded as deferred revenues.

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. These revenues and the associated accounts receivable are based on gross amounts billed or billable for services rendered, net of a contractual adjustment, which is the difference between amounts billed to payers and the expected approved reimbursable settlements from such payers.

The following are tables of the clinical laboratory segment's net revenues and revenue percentages by revenue category for the years ended July 31, 2006 and 2005:

Net revenues	Year ended July 31, 2006		Year ended July 31, 2005	
<u>Revenue category (In</u>	<u>000's)</u>	<u>(in %)</u>	<u>(In 000's)</u>	<u>(in %)</u>
Medicare \$7,462		23	\$6,906	21
Third party carriers	17,680	56	17,528	53
Patient self-pay	4,925	15	6,904	21
HMO's 1,859	_____	<u>6</u>	<u>1,519</u>	<u>5</u>
Total \$31,926	=====	<u>100%</u>	<u>\$32,857</u>	100% _____

The Company provides services to certain patients covered by various third-party payers, including the Federal Medicare program. Revenue, net of contractual expense, from direct billings under the Federal Medicare program during the years ended July 31, 2006, 2005 and 2004 were approximately 23%, 21% and 26%, respectively, of the Clinical Lab segment's revenue. 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.

**ENZO BIOCHEM, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**July 31, 2006 and 2005**

*Contractual Adjustments*

The Company's estimate of contractual adjustments is based on significant assumptions and judgments, such as its interpretation of the applicable payer's reimbursement policies, and bears the risk of change. The estimation process is based on the experience of amounts approved as reimbursable and ultimately settled by payers, versus the corresponding gross amount billed to the respective payers. The contractual expense is an estimate that reduces gross revenue, based on gross billing rates, to amounts expected to be approved and reimbursed. The Company adjusts the contractual expense estimate periodically, based on its evaluation of historical settlement experience with payers, industry reimbursement trends, and other relevant factors.

*Accounts Receivable and Allowance for Doubtful Accounts*

Accounts receivable are reported at realizable value, net of allowances for doubtful accounts, which is estimated and recorded in the period of the related revenue.

For the Clinical Labs segment, the allowance for doubtful accounts represents amounts that the Company does not expect to collect after the Company has exhausted its collection procedures. The Company estimates its allowance for doubtful accounts in the period the related services are billed and adjusts the estimate in future accounting periods as necessary. It bases the estimate for the allowance on the evaluation of historical collection experience, the aging profile of accounts receivable, the historical doubtful account write-off percentages, payer mix, and other relevant factors.

The allowance for doubtful accounts includes the balances, after receipt of the approved settlements from third party payers for the insufficient diagnosis information received from the ordering physician which result in denials of payment, and the uncollectible portion of receivables from self payers, including deductibles and copayments, which are subject to credit risk and patients' ability to pay. During the years ended July 31, 2006 and 2005, the Company determined an allowance for doubtful accounts less than 210 days and wrote off 100% of accounts receivable (for all payers) over 210 days, as it assumed those accounts are uncollectible. The Company adjusts the historical collection analysis for recoveries, if any, on an ongoing basis.

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 also assesses the current state of its billing functions in order to identify any known collection issues in order to assess the impact, if any, on the allowance 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. Should circumstances change (e.g. shift in payer mix, decline in economic conditions or deterioration in aging of receivables), our estimates of net realizable value of receivables could be reduced by a material amount.

**ENZO BIOCHEM, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**July 31, 2006 and 2005**

The following is a table of the Company's net accounts receivable by segment. The Clinical Labs segment's net receivables are detailed by billing category and as a percent to its total net receivables: At July 31, 2006 and 2005, approximately 88% and 94%, respectively, of the Company's net accounts receivable relates to its clinical labs business, which operates in the greater New York and New Jersey area.

Net accounts receivable	As of July 31, 2006		As of July 31, 2005	
<u>Billing category</u> (In <u>Clinical Labs</u> )	<u>000's</u>	<u>(in %)</u>	<u>(In 000's)</u>	<u>(in %)</u>
Medicare	\$1,367	15	\$1,594	13
Third party carriers	4,025	44	6,742	54
Patient self-pay	3,294	36	3,819	30
HMO's	475	5	394	3
Total Clinical Labs	9,161	<u>100%</u>	12,549	100%
Total Life Sciences	<u>1,286</u>		<u>872</u>	
Total accounts receivable	<u>\$10,447</u>		<u>\$13,421</u>	

Changes in the Company's allowance for doubtful accounts are as follows:

<u>In 000's</u>	<u>July 31, 2006</u>	<u>July 31, 2005</u>
Beginning balance	\$2,292	\$2,770
Provision for doubtful accounts	3,633	4,967
Write-offs (4,892)	(5,445)	_____
Ending balance	<u>\$1,033</u>	<u>\$2,292</u>

*Cash and cash equivalents*

Cash and cash equivalents include highly liquid corporate debt instruments with maturities of three months or less at the time acquired by the Company.

*Marketable securities*

Investments with a maturity greater than three months at the date of purchase are designated as marketable securities. During the year ended July 31, 2006, the Company sold all investments designated as marketable securities and had no investments in marketable securities as of July 31, 2006.

At July 31, 2005, management designated marketable securities held by the Company as available-for-sale securities, in accordance with of Statement of Financial Accounting Standards ("SFAS") No. 115 "Accounting for Certain Investments in Debt and Equity Securities". Available-for-sale securities were carried at fair value with the unrealized losses reported in stockholders' equity under the caption "Accumulated other comprehensive loss". The Company periodically reviewed its investment portfolio to determine if there was 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 was based on the original cost basis plus any reinvested dividends.

*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 and manufacturing overhead.



**ENZO BIOCHEM, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**July 31, 2006 and 2005**

*Property, plant and equipment*

Property, plant and equipment is stated at cost, and depreciated on the straight-line basis over the estimated useful lives of the various asset classes. The useful life for the building is 30 years. The useful life for laboratory machinery and equipment and office furniture and computer equipment ranges from 3-5 years. Leasehold improvements are amortized over the term of the related leases or estimated useful lives of the assets, whichever is shorter.

*Goodwill*

Goodwill represents the cost of acquired businesses in excess of the fair value of assets acquired, including separately recognized intangible assets, less the fair value of liabilities assumed in the business acquisition. The Company uses a non-amortization approach to account for purchased goodwill. Under this approach, goodwill is not amortized, but instead is reviewed for impairment. All of the Company's goodwill is related to its clinical laboratory segment. Prior to adopting SFAS No. 142, "Goodwill and Other Intangibles" ("SFAS 142"), the Company recorded amortization of goodwill aggregating approximately \$9.8 million.

Under the non-amortization provisions of SFAS 142, goodwill is subject to at least an annual assessment for impairment by applying a fair-value based test. The Company performs the annual impairment testing during the fourth quarter of its fiscal year. Based on this testing, there has been no impairment to Goodwill recorded on the accompanying balance sheets as of July 31, 2006 and 2005.

*Impairment of Long-Lived Assets*

The Company reviews the recoverability of the carrying value of long-lived assets, primarily property, plant and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. Should indicators of impairment exist, the carrying values of the assets are evaluated in relation to the operating performance and future undiscounted cash flows of the underlying business. The net book value of an asset is adjusted to fair value if its expected future undiscounted cash flow is less than its book value. No impairment losses were identified during the years ended July 31, 2006, 2005 or 2004.

*Patent costs*

The Company capitalizes certain legal costs directly incurred in pursuing patent applications as patent costs. 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. The Company estimates amortization for patent costs at July 31, 2006 to be at approximately \$79,000 in each of the next five fiscal years.

*Comprehensive (loss) income*

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

**ENZO BIOCHEM, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**July 31, 2006 and 2005**

*Shipping and Handling Costs*

Product revenue shipping and handling costs included in selling expense amounted to approximately \$226,000, \$299,000, and \$384,000 for years ended July 31, 2006, 2005, and 2004, respectively.

*Research and Development*

Research and development costs are charged to expense as incurred.

*Advertising*

All costs associated with advertising are expensed as incurred. Advertising expense, included in Selling, general and administrative expense approximated \$128,000, \$57,000 and \$18,000 for the years ended July 31, 2006, 2005 and 2004, respectively.

*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 when 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.

*Segment Reporting*

The Company follows SFAS No. 131, "Disclosures About Segments of an Enterprise and Related Information" ("SFAS 131") 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. The Company's operating activities are reported in three segments (see Note 13).

*Net (loss) income per share*

The Company applies SFAS No. 128, "Earnings per Share." ("SFAS 128"). SFAS 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 128. Diluted weighted average shares outstanding for 2006 and 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 in fiscal 2006 and 2004. The number of potential common shares ("in the money options") excluded from the calculation of diluted earnings per share during the years ended July 31, 2006, 2005 and 2004 was 423,000, 0, and 798,000 shares, respectively.

**ENZO BIOCHEM, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**July 31, 2006 and 2005**

The following table sets forth the computation of basic and diluted net (loss) income per share pursuant to SFAS 128 for the years ended July 31:

<u>In 000's</u> 2006	_____	2005	2004	_____
Numerator:				
Net (loss) income	<u>\$(15,667)</u>	<u>\$3,004</u>		<u>\$(6,232)</u>
Denominator:				
Weighted-average common shares outstanding- Basic	32,215	32,097		31,700
Effect of dilutive stock options	--	666 -		-
Weighted-average common shares outstanding - Diluted	<u>32,215</u>	<u>32,763</u>		<u>31,700</u>
Net (loss) income per share				
Basic	<u>\$(.49)</u>	<u>\$.09</u>	\$(.20)	=====
Diluted	<u>\$(.49)</u>	<u>\$.09</u>	\$(.20)	=====

For the years ended July 31, 2006, 2005 and 2004, the effect of approximately 1,916,000, 818,000, and 554,000 respectively, of outstanding "out of the money" options to purchase common shares were excluded from the calculation of diluted net (loss) income per share because their effect would be anti-dilutive.

*Share - Based Compensation*

Effective August 1, 2005, the Company adopted SFAS No. 123(R), "Share-Based Payment" ("SFAS 123(R)") and related interpretations which superseded the provisions of Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") and related interpretations. SFAS 123(R) requires that all share-based compensation be recognized as an expense in the financial statements and that such cost be measured at the fair value of the award. SFAS 123(R) was adopted using the modified prospective method, which requires the Company to recognize compensation expense on a prospective basis. Therefore, prior period financial statements have not been restated. Under this method, in addition to reflecting compensation expense for new share-based awards, expense is also recognized to reflect the remaining service period of awards that had been included in pro-forma disclosures in prior periods.

With the adoption of SFAS 123(R), the Company is required to record the fair value of share-based compensation awards as an expense. In order to determine the fair value of stock options on the date of grant, the Company utilizes the Black-Scholes option-pricing model. Inherent in this model are assumptions related to expected stock-price volatility, option life, risk-free interest rate and dividend yield. While the risk-free interest rate and dividend yield are less subjective assumptions, typically based on factual data derived from public sources, the expected stock-price volatility and option life assumptions require a greater level of judgment which make them critical accounting estimates. The Company uses an expected stock-price volatility assumption that is primarily based on historical realized volatility of the underlying stock during a period of time. No employee or director stock options were granted during the year ended July 31, 2006.

**ENZO BIOCHEM, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**July 31, 2006 and 2005**

In November 2005, the FASB issued FSP FAS 123(R)-3, "Transition Election Related to Accounting for the Tax Effects of Share-Based Payment Awards", to provide an alternate transition method for the implementation of SFAS No. 123(R). Because some entities do not have, and may not be able to re-create, information about the net excess tax benefits that would have qualified as such had those entities adopted SFAS No. 123(R) for recognition purposes, this FSP provides an elective alternative transition method. The method comprises (a) a computational component that establishes a beginning balance of the additional paid in capital pool ("APIC pool") related to employee compensation and (b) a simplified method to determine the subsequent impact on the APIC pool of employee awards that are fully vested and outstanding upon the adoption of SFAS No. 123(R). The Company is evaluating the principles set forth in this FSP to determine its APIC pool. The implementation date is one year from the later of the initial adoption of SFAS No. 123(R) or the effective date of FSP FAS 123(R)-3.

Prior to August 1, 2005, the Company accounted for employee stock option plans under the intrinsic value method in accordance with APB 25. Under APB 25, generally no compensation expense is recorded when terms of the award are fixed and the exercise price of employee and director stock options equals or exceeds the fair value of the underlying stock on the date of the grant.

As a result of adopting SFAS 123(R), the Company's net loss for the year ended July 31, 2006 was approximately \$1.6 million higher, than if the Company had continued to account for share-based compensation under APB No. 25. Basic and diluted loss per share for the year ended July 31, 2006 were increased by \$0.05 per share as a result of adopting SFAS 123(R). SFAS 123(R) also requires that excess tax benefits related to stock option exercises be reflected as financing cash inflows instead of operating cash inflows. For the year ended July 31, 2006, no excess tax benefits were recognized. Other share-based compensation expense relating to the fair value of restricted shares and restricted stock units issued and vested during the year ended July 31, 2006 was approximately \$172,000 (see Note 8).

The following table sets forth the amount of expense related to share-based payment arrangements included in specific line items in the accompanying Statement of operations for the year ended July 31, 2006:

<u>In 000's</u>	
Cost of products	\$21
Research and development	249
Selling, general and administrative	<u>1,493</u>
\$1,763	<u>=====</u>

As of July 31, 2006, there was \$2.0 million of total unrecognized compensation cost related to nonvested share-based compensation arrangements granted under the Company's stock option and restricted stock plans, which will be recognized over a weighted average remaining life of approximately one and a half years.

During the 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 148 amends SFAS No. 123, "Accounting for Stock-Based Compensation," ("SFAS 123") to provide alternative methods of transition to SFAS 123's fair value method of accounting for stock-based employee compensation. SFAS 148 also amends the disclosure provisions of SFAS 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 148 did not amend SFAS 123 to require companies to account for employee stock options using the fair value method, as SFAS 123(R) did, the disclosure provisions of SFAS 148 are applicable to all companies with share-based employee compensation method of SFAS 123 or the intrinsic value method of APB 25.

**ENZO BIOCHEM, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**July 31, 2006 and 2005**

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 more than the closing price of the Company’s common stock on June 3, 2005 of \$14.82. 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 represented approximately 21% of the Company’s then outstanding stock options) became exercisable immediately. The accelerated options ranged 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 included 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 the “out of the money” options did not result in a charge in the Company’s statement of operations for the 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 year ended July 31, 2005, of which \$6.0 million was applicable to the accelerated “out of the money” options.

Pro forma information regarding net income (loss) applicable to common stockholders is required under SFAS 123, as if the Company has accounted for its stock options under the fair value method. 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 and 2004: 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 71% and 74%, respectively, for all grants.

The following table illustrates the effect on net income (loss) if the Company had applied the fair value recognition provisions of SFAS 123 (in 000’s, except per share):

<u>Years ended July 31, 2005</u>	<u>2004</u>	
Reported net income (loss)	\$3,004	\$(6,232)
Pro forma compensation expense	<u>(10,129)</u>	(3,239)
Pro forma net (loss)	<u>\$(7,125)</u>	<u>\$(9,471)</u>
Pro forma net (loss) per share:		
Basic \$(.22)	\$(.30)	
Diluted	\$(.22)	\$(.30)

*Effect of new accounting pronouncements*

In June 2005, the FASB issued SFAS No. 154, “Accounting Changes and Error Corrections (“SFAS 154”), a replacement of APB Opinion No. 20, Accounting Changes, and FASB Statement No. 3, Reporting Accounting Changes in Interim Financial Statements.” SFAS 154 changes the requirements for the accounting for and reporting of a change in accounting principle. Previously, most voluntary changes in accounting principles required recognition via a cumulative effect adjustment within net income for the period of the change. SFAS 154 requires retrospective application to prior periods’ financial statements, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. SFAS 154 is effective for accounting changes made in fiscal years beginning after December 15, 2005; however, SFAS 154 does not change the transition provisions of any existing accounting pronouncements. The adoption of SFAS 154 is not expected to have a material impact on the Company’s financial condition or results of operations.

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In June 2006, the FASB issued FASB Interpretation No. 48 ("FIN 48"), "Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109, "Accounting for Income Taxes" ("SFAS 109")", to clarify the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109. This Interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. The provisions of FIN 48 are effective for fiscal years beginning after December 15, 2006. The Company has not evaluated the impact of FIN 48 on its financial statements at this time.

*Reclassifications*

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

**Note 2 - Supplemental disclosure for statement of cash flows**

In the years ended July 31, 2006, 2005 and 2004, net income taxes paid by or (refunded to) the Company approximated (\$1,374,000), \$3,566,000 and \$219,000 respectively.

In fiscal 2006, certain officers of the Company exercised 227,800 stock options in a non-cash transaction. The officers surrendered 185,300 shares of previously owned shares of the Company's common stock to exercise the stock options. The Company recorded approximately \$2.5 million, the market value of the surrendered shares, as treasury stock.

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

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

In fiscal 2004, the Company purchased the assets of a privately held company for \$650,000, of which \$350,000 was paid during fiscal 2004 and \$150,000 during fiscal 2006. The remaining \$150,000 is to be paid in fiscal 2007 on the thirty-sixth month anniversary date of the acquisition.

**Note 3 - Marketable securities**

Marketable securities are recorded at fair value. The Company had no investments in marketable securities at July 31, 2006. The following is a summary of available-for-sale securities at July 31, 2005:

<u>In 000's Fair</u>	<u>Value</u>	<u>Unrealized holding (loss)</u>
Income bond mutual fund	\$5,639	\$(126)
Marketable debt securities:		
U.S. Government and agency securities	449	-
Corporate debt securities	<u>626</u>	<u>(5)</u>
(Average of remaining maturity of debt securities was approximately four months at July 31, 2005)	<u>\$6,714</u>	<u>\$(131)</u>

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During fiscal 2006, the Company realized proceeds of approximately \$6.8 million from maturities and sales of marketable securities, on which it realized a loss of approximately \$154,000, based on the average cost. 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. The Company's cost basis in marketable securities as of July 31, 2005 was approximately \$6.8 million.

The following is a summary of accumulated other comprehensive loss, relating to the Company's investments in marketable securities which were classified as available for sale securities:

<u>In 000's</u> Accumulated	<u>loss</u> <u>before tax</u>	Tax (expense) <u>or benefit</u>	Accumulated loss <u>net of tax</u>
Fiscal 2003 – unrealized losses	\$(139)	\$54	\$(85)
Balance – July 31, 2003	\$(139)	\$54	\$(85)
Fiscal 2004 – unrealized losses	(262)	101	(161)
Balance – July 31, 2004	\$(401)	\$155	\$(246)
Fiscal 2005 - realized losses	200	(78)	
Fiscal 2005 – unrealized gain and valuation allowances	<u>70</u>	<u>(77)</u>	<u>115</u>
Balance - July 31, 2005	(131)	-	(131)
Fiscal 2006 – realized losses, net	<u>131</u>	-	<u>131</u>
Balance - July 31, 2006	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>

**Note 4 - Inventories**

At July 31, 2006 and 2005 inventories – net of reserves of \$238,000 and \$0, respectively, consist of:

<u>In 000's</u> 2006	2005	2005
Raw materials	\$38	\$52
Work in process	1,518	1,767
Finished products	845	1,057
	<u>\$2,401</u>	<u>\$2,876</u>

**Note 5 – Property, plant, and equipment**

At July 31, 2006 and 2005 property, plant, and equipment consist of:

<u>In 000's</u> 2006	2005	2005
Laboratory machinery and equipment	2,242	\$2,098
Office furniture and computer equipment	5,696	5,080
Leasehold improvements	2,975	2,771
	13,383	9,949
Accumulated depreciation and amortization	<u>(8,247)</u>	<u>(7,279)</u>
	5,136	\$2,670
Land and land improvements	<u>712</u>	-
	<u>\$5,848</u>	<u>\$2,670</u>

In June 2006, the Company acquired land and building aggregating \$3,182,000, which upon completion of improvements, will be primarily used for the Company's Life Sciences and Therapeutics research and development and manufacturing operations.

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**Note 6 - Income taxes**

The Company accounts for income taxes under the provisions of SFAS 109. The benefit (provision) for income taxes is as follows:

<u>Fiscal year ended July 31, (in 000's) 2006</u>	_____	<u>2005</u>	2004	_____
Current benefit (provision):				
Federal	\$2,047	\$(1,386)		\$3,287
State and local	(65)	64		(191)
Deferred (provision) benefit	<u>(640)</u>	<u>(891)</u>	1,752	
Benefit (provision) for income taxes	<u>\$1,342</u>	<u>\$(2,213)</u>	\$4,848	=====

Deferred tax assets and liabilities arise from temporary differences between the tax basis of assets and liabilities and their reported amounts in the financial statements. The components of deferred tax assets (liabilities) as of July 31, 2006 and 2005 are as follows:

<u>In 000's</u>	<u>July 31, 2006</u>	<u>July 31, 2005</u>
Deferred tax assets:		
Federal tax carryforward losses	\$3,315	-
Provision for uncollectible accounts receivable	404	\$889
State and local tax carry forward losses	1,080	245
Depreciation	14	33
Research and development and other tax credit carryforwards	405	-
Realized and unrealized losses on marketable securities	138	129
Gross deferred tax assets	<u>5,356</u>	1,296
Deferred tax liabilities:		
Deferred patent costs	(280)	(293)
Other, net	<u>(220)</u>	(234)
Gross deferred tax liabilities	<u>(500)</u>	(527)
Net deferred tax assets – before valuation allowance	\$4,856	\$769
Less: valuation allowance	<u>(4,856)</u>	<u>(129)</u>
Deferred tax assets, net	=	<u>\$640</u>

Pursuant to SFAS 109, the Company recorded a valuation allowance during the year ended July 31, 2006 equal to its net deferred tax assets at July 31, 2005 and for net deferred tax assets generated in fiscal 2006. The Company believes that the valuation allowance is necessary as it is not more likely than not that the deferred tax assets will be realized in the foreseeable future based on positive and negative evidence available at this time. This conclusion was reached because of uncertainties relating to future taxable income, in terms of both its timing and its sufficiency, which would enable the Company to realize the deferred tax assets. During fiscal 2005, the Company determined that it was not more likely than not that it would generate taxable income against which the deferred tax asset for the realized and unrealized losses on marketable securities could be applied. Therefore, the Company established a valuation reserve against that deferred tax asset.

As of July 31, 2006, the Company had a U.S. federal net operating loss carryforward of approximately \$9.7 million. The U.S. federal tax loss expires in 2024 if not fully utilized by then. Utilization is dependent on generating sufficient taxable income prior to expiration of the tax loss carryforward. There was no U.S. federal net operating loss carryforward as of July 31, 2005. As of July 31, 2006 and 2005, the Company has state and local tax carry forward losses of approximately \$21.1 million and \$5.1 million, respectively.



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

<u>Year ended July 31, 2006</u>		<u>2005</u>	<u>2004</u>	
Federal statutory rate	34%	(34%)		34%
Expenses not deductible for income tax return purposes	(4%)	(2%)		(3%)
State income taxes, net of (benefit) of federal tax deduction.	5%	(6%)		4%
Change in valuation allowance	(28%)	-		-
Benefit of foreign sales	-	1%		2%
Fixed asset basis difference	-	-		8%
Other 1%		(1%)	(1%)	
	<u>8%</u>	<u>(42%)</u>	44%	

**Note 7 – Accrued Liabilities and Other Current Liabilities**

At July 31, 2006 and 2005, Accrued liabilities consist of:

<u>In 000's</u>	<u>2006</u>	<u>2005</u>	
Legal	\$1,974	\$2,717	—
Payroll, benefits, and commissions	868		652
Research and development	408		286
Professional fees	369		413
Outside reference lab testing	122		30
Other	<u>662</u>	<u>768</u>	—
	<u>\$4,403</u>	<u>\$4,866</u>	

At July 31, 2006 and 2005 other current liabilities consist of:

<u>In 000's</u>	<u>2006</u>	<u>2005</u>	
Installment payable	\$150		\$150
Deferred revenue	<u>80</u>	<u>359</u>	—
	<u>\$230</u>	<u>\$509</u>	

**Note 8 – Stockholders' equity**

*Treasury stock*

In fiscal 2006, certain officers of the Company exercised 227,800 stock options in a non-cash transaction. The officers surrendered 185,300 shares of previously owned shares of the Company's common stock to exercise the stock options. The Company recorded approximately \$2.5 million, the market value of the surrendered shares, as treasury stock.

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

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

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*Incentive stock option plans*

The Company has incentive stock option plans ("1994 plan", "1999 plan" and "2005 plan") under which the Company may grant options for up to 1,336,745 shares (1994 plan), up to 2,312,356 shares (1999 plan) and up to 1,000,000 shares (2005 plan) of common stock. No additional options may be granted under the 1994 plan. 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. Stock options generally become exercisable at 25% per year after one year and expire ten years after the date of grant. The 2005 plan provides for the issuance of restricted stock and restricted stock unit awards which generally vest over a two to four year period.

A summary of the information pursuant to the Company's stock option plans for the years ended July 31, 2006, 2005 and 2004 is as follows:

	<u>2006</u>	Weighted - Average Exercise Price	<u>2005</u>	Weighted - Average Exercise Price	<u>2004</u>	Weighted - Average Exercise Price
	<u>Options</u>		<u>Options</u>		<u>Options</u>	
Outstanding at beginning of year	3,154,125	\$12.61	2,856,801	\$11.86	3,397,087	\$9.88
Granted	100,000	\$24.84	431,975	\$16.57	428,925	\$17.02
Exercised	(285,030)	\$10.93	(100,332)	\$7.39	(917,539)	7.16
Cancelled	<u>(91,368)</u>	\$12.61	<u>(34,319)</u>	\$11.64	<u>(51,672)</u>	\$10.13
Outstanding at end of year	<u>2,877,727</u>	\$13.20	<u>3,154,125</u>	\$12.61	<u>2,856,801</u>	\$11.86
Exercisable at end of year	<u>2,554,148</u>	\$12.78	<u>2,126,442</u>	\$11.28	<u>1,770,492</u>	\$10.54
Weighted average fair value of options granted during year		<u>\$1.01</u>		<u>\$11.76</u>		<u>\$12.40</u>

The aggregate intrinsic value of stock options exercised during the years ended July 31, 2006 and 2005, including the non-cash transactions (see Note 2) was \$0.7 million and \$0.9 million, respectively. The aggregate intrinsic value of options both outstanding and exercisable at July 31, 2006 is approximately \$3.7 million.

The following table summarizes information for stock options outstanding at July 31, 2006:

Range of Exercise prices	Shares	Options outstanding		Options exercisable	
		Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price
\$5.45-8.08	289,020	2.2 years	\$5.64	289,020	\$5.64
\$8.33-12.25	1,502,111	4.4 years	\$11.09	1,378,906	\$10.91
\$12.93-19.02	906,719	7.4 years	\$16.82	806,345	\$16.60
\$20.20-24.84	161,644	2.9 years	\$23.02	61,644	\$21.42
\$36.05	18,233	3.4 years	\$36.05	<u>18,233</u>	\$36.05
	<u>2,877,727</u>			<u>2,554,148</u>	

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During the year ended July 31, 2006, the Company granted 100,000 options to a consultant with an exercise price of \$24.84, which vest over six months and have a two year term. The fair value of these options at July 31, 2006 is \$101,000. The fair value of the options, which will be accounted for as a variable instrument, will be fair valued and recognized as expense over the six month vesting term. The assumptions used to fair value this option grant as of July 31, 2006 were as follows: risk free interest rate of 4.97%, expected term of 2 years, expected volatility of 49%, and no dividend yield. In connection with the options issued to this consultant, the Company recognized an expense of approximately \$80,000 in selling, general and administrative expense in the accompanying statements of operations for the year ended July 31, 2006.

*Restricted Stock Awards*

During fiscal 2006, the compensation committee of the Company's board of directors approved grants of 84,950 restricted stock and restricted stock unit awards (the "Awards") under the 2005 Plan to the Company's directors and certain officers and employees. The Awards vest in full upon the recipient's continued employment or director service over either two, three or four years. Share-based compensation expense is recorded over the vesting period on a straight-line basis. The Awards will be forfeited if the recipient ceases to be employed by or serve as a director of the Company, as defined in the Award grants. The Awards settle in shares of the Company's common stock on a one-for-one basis. As of July 31, 2006, all Awards were unvested.

A summary of the information pursuant to the Company's Awards for the year ended July 31, 2006 is as follows:

	Awards	Weighted - Average Award Price
Outstanding at beginning of year	--	--
Awarded	84,950	\$12.29
Forfeited	<u>(7,500)</u>	\$13.13
Outstanding at end of year	<u>77,450</u>	\$12.21
Weighted average market value of Awards granted during year		<u>\$12.29</u>

As of July 31, 2006, there were approximately 629,000 shares available for grant under the Company's stock option plans.

*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. The Company recorded a charge to accumulated deficit and offsetting credits to both common stock and additional paid-in capital of \$23,433,400 in fiscal 2005, which reflects the fair value of the stock dividends on the dates of declaration.

**Note 9 - 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, 2006, 2005 and 2004, 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 \$402,300, \$351,600, and \$282,200, in fiscal years 2006, 2005, and 2004, respectively.

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**Note 10 – Gain on Patent Litigation Settlement, License Agreement and Royalty Income**

In fiscal 2005, the Company as plaintiff finalized and executed a settlement and license agreement with Digene Corporation to settle a patent litigation lawsuit (the “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 are 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 is 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 during the year ended July 31, 2005 and deferred \$2 million, which was earned from net sales of the Company’s licensed products covered by the Agreement during the first annual period. During the years ended July 31, 2006 and 2005, the Company recorded royalty income under the Agreement of approximately \$3.1 million and \$1.6 million, respectively, which is included in the Life Sciences segment.

**Note 11 – Commitments**

*Leases*

The Company leases equipment, office and laboratory space under several non-cancelable operating leases that expire between January 2007 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 laboratory, research, and manufacturing operations. 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, inclusive of real estate taxes, under this renewed lease and the prior lease approximated \$1,337,000, \$1,289,000, and \$1,370,000 during fiscal years 2006, 2005, and 2004, respectively.

Total consolidated rent expense incurred by the Company during fiscal 2006, 2005, and 2004 was approximately \$2,257,000, \$2,140,000, and \$1,801,000 respectively. Minimum future annual rentals under non-cancelable operating leases as of July 31, 2006, are as follows:

Years ended July 31, In	000's
2007 \$2,663	
2008 2,505	
2009 2,384	
2010 2,337	
2011 2,044	
Thereafter 8,429	_____
\$20,362	=====

**Employment Agreements**

The Company has employment agreements with certain executive officers that are cancelable at any time but provide for severance pay in the event an executive officer is terminated by the Company without cause, as defined in the agreements. Unless cancelled earlier, the contracts expire through May 2008. Aggregate minimum compensation commitments, exclusive of any severance provisions, for the years ended July 31, 2007 and 2008 are \$1,490,000 and \$870,000, respectively

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**Note 12- Contingences**

**Litigation**

In October 2002, the Company filed suit in the United States District Court of the Southern District of New York against Amersham plc, Amersham Biosciences, Perkin Elmer, Inc., Perkin Elmer Life Sciences, Inc., Sigma-Aldrich Corporation, Sigma Chemical Company, Inc., Molecular Probes, Inc. and Orchid Biosciences, Inc. In January 2003, the Company amended its Complaint to include defendants Sigma Aldrich Co. and Sigma Aldrich, Inc. The counts set forth in the suit are for breach of contract; patent infringement; unfair competition under state law; unfair competition under federal law; tortious interference with business relations; and fraud in the inducement of contract. The Complaint alleges that these counts arise out of the defendants' breach of distributorship agreements with the Company concerning labeled nucleotide products and technology, and the defendants' infringement of patents covering the same. In April, 2003, the Court directed that individual Complaints be filed separately against each defendant. The defendants have answered the individual Complaints and asserted a variety of affirmative defenses and counterclaims. Fact discovery is ongoing. The Court issued a claim construction opinion on July 10, 2006. The Company and Sigma Aldrich ("Sigma") entered into a Settlement Agreement and Release effective September 15, 2006 (the "Agreement"). Pursuant to the Agreement, the Company's litigation with Sigma was dismissed and the Company will recognize \$2 million on settlement in the first quarter ending October 31, 2006. There can be no assurance that the Company will be successful with the remaining outstanding 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 has not recorded revenue under these distribution agreements in fiscal 2006. The Company recorded revenue from only Perkin Elmer in fiscal 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 issued a Markman (claim construction) opinion on July 10, 2006. The Company did not record any revenue from Affymetrix during the fiscal years ended July 31, 2006, 2005 and 2004.

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**July 31, 2006 and 2005**

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 issued a Markman opinion on July 10, 2006. The Company did not record any revenue from Roche during the fiscal year ended July 31, 2006. The Roche agreement remains in force to date.

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, Dean Engelhardt, Richard Keating, Doug Yates, and Does I-50, Case No. CA-02-1242-A (the "Glasser Action"), 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. On September 16, 2006, the United States Court of Appeals for the Fourth Circuit affirmed the dismissal of the Complaint relating to the Glasser Action. Although the Glasser plaintiffs still have the option of requesting a rehearing before the Fourth Circuit or petitioning for a writ of certiorari from the United States Supreme Court, absent such further relief, the Glasser Action will be closed. The Company continues to believe that the Glasser Action and the remaining complaint have no merit whatsoever and intends to continue to defend the actions 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, estoppels and laches and asserts counterclaims of non-infringement and invalidity. Fact discovery is ongoing. A one-day Markman hearing was held on May 25, 2006 and the parties are currently waiting for a Markman ruling. Dispositive motions due dates are based on the Markman ruling date.

**ENZO BIOCHEM, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**July 31, 2006 and 2005**

The trial date is currently scheduled for December 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.

**Note 13 – Segment reporting**

The Company has three reportable segments: Life Sciences, Therapeutics, and Clinical Labs. The Company's Life Sciences segment develops, manufactures, and markets products to research and pharmaceutical customers. The Company's Therapeutic segment conducts research and development activities for therapeutic drug candidates. The Clinical Labs segment provides diagnostic services to the health care community. Prior to fiscal 2006, the Life Sciences and Therapeutics segments were reported together as the Research and Development segment. The fiscal 2005 and 2004 segment information has been restated to reflect this change. The Company evaluates segment performance based on segment income (loss) before taxes. Costs excluded from segment income (loss) before taxes and reported as other consist of corporate general and administrative costs which are not allocable to the three 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 following financial information (in thousands) represents the operating results of the reportable segments of the Company:

**Year ended July 31, 2006**

	<u>Sciences</u>	<u>Therapeutics</u>	<u>Clinical Labs</u>	<u>Othe</u>	<u>r</u>	<u>Consolidated</u>
Revenues: Life						
Product revenues and royalty income	\$7,900	--	--		--	\$7,900
Clinical laboratory services	--	--	\$31,926	--	--	31,926
7,900		31,926	--		--	39,826
<u>Cost and expenses and other (income):</u>						
Cost of products 2,174		--	--		--	2,174
Cost of clinical laboratory services	--	--	13,917	--		13,917
Research and development 3,659		\$4,237	--	--		7,896
Provision for uncollectible accounts	--	--	3,633		--	3,633
Selling, general and administrative and legal 2,260		--	14,322	15,777		32,359
Interest income	--	--	--	(3,144)		(3,144)
(Loss) income before income taxes	<u>(\$193)</u>	<u>(\$4,237)</u>	<u>\$54</u>	<u>\$(12,633)</u>		<u>\$(17,009)</u>
Depreciation and amortization included above	<u>\$180</u>	<u>\$12</u>	<u>\$897</u>	<u>\$35</u>	<u>---</u>	<u>\$1,124</u>
<u>Share- based compensation included in above:</u>						
Cost of products \$21		--	--		--	\$21
Research and development	106	\$143	--		--	249
Selling, general and administrative and legal	87	--	\$539	\$867		1,493
Total	<u>\$214</u>	<u>\$143</u>	<u>\$539</u>	<u>\$867</u>	<u>---</u>	<u>\$1,763</u>
Capital expenditures \$3,332	<u>---</u>	<u>\$6</u>	<u>\$860</u>	<u>\$29</u>	<u>---</u>	<u>\$4,227</u>

**ENZO BIOCHEM, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**July 31, 2006 and 2005**

**Year ended July 31, 2005**

Life	<u>Sciences</u>	<u>Therapeutics</u>	<u>Clinical Labs</u>	<u>Other</u>	<u>Consolidated</u>
<b>Revenues:</b>					
Product revenues and royalty income	\$10,546	--	--	--	\$10,546
Clinical laboratory services	--	--	\$32,857	--	32,857
10,546		32,857			43,403
<b>Cost and expenses and other (income)</b>					
Cost of products 2,197		--	--	--	2,197
Cost of clinical laboratory services	--	--	12,548	--	12,548
Research and development 5,340		\$3,112	--	--	8,452
Provision for uncollectible accounts	--	--	4,967	--	4,967
Selling, general and administrative and legal 2,405		--	12,505	\$10,635	25,545
Interest income	--	--	--	(1,523)	(1,523)
Gain on patent litigation settlement	(14,000)	--	--	--	(14,000)
Income (loss) before income taxes	<u>\$14,604</u>	<u>(\$3,112)</u>	<u>\$2,837</u>	<u>(\$9,112)</u>	<u>\$5,217</u>
Depreciation and amortization included above	<u>\$1,382</u>	<u>\$13</u>	<u>\$887</u>	<u>\$50</u>	<u>\$2,332</u>
Capital expenditures	<u>\$126</u>	<u>\$40</u>	<u>\$1,100</u>	<u>\$10</u>	<u>\$1,276</u>

**Year ended July 31, 2004**

Life	<u>Sciences</u>	<u>Therapeutics</u>	<u>Clinical Labs</u>	<u>Other</u>	<u>Consolidated</u>
<b>Revenues:</b>					
Product revenues	\$12,972	--	--	--	\$12,972
Clinical laboratory services	--	--	\$28,672	--	28,672
12,972		28,672			41,644
<b>Cost and expenses and other (income)</b>					
Cost of products 2,518		--	--	--	2,518
Cost of clinical laboratory services	--	--	10,586	--	10,586
Research and development 5,661		\$2,417	--	--	8,078
Provision for uncollectible accounts 1,753		--	10,234	--	11,987
Selling, general and administrative and legal 1,922		--	9,331	\$9,454	20,707
Interest income	--	--	--	(1,152)	(1,152)
(Loss) income before income taxes	<u>\$1,118</u>	<u>\$(2,417)</u>	<u>(\$1,479)</u>	<u>(\$8,302)</u>	<u>(\$11,080)</u>
Depreciation and amortization included above	<u>\$1,397</u>	<u>\$17</u>	<u>\$903</u>	<u>\$45</u>	<u>\$2,362</u>
Total capital expenditures	<u>\$70</u>	<u>\$7</u>	<u>\$1,142</u>	<u>\$85</u>	<u>\$1,304</u>

The Company's reportable segments are determined based on the services they perform, the products they sell, and the royalties they earn, not on the geographic area in which they operate. The Company's Clinical Labs segment operates 100% in the United States with all revenue derived from this country. The Life Sciences segment earns product revenue both in the United States and foreign countries and royalty income in the United States. The following is a summary of the Life Sciences segment revenues attributable to customers located in the United States and foreign countries:

In 000's 2006	2005	2004
United States	\$6,361	\$7,985
Foreign countries	1,539	2,561
\$7,900	<u>\$10,546</u>	<u>\$12,972</u>



**ENZO BIOCHEM, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**July 31, 2006 and 2005**

**Note 14 – Summary of Selected Quarterly Financial Data (unaudited)**

The following table contains statement of operations information for each quarter of the years ended July 31, 2006 and 2005. 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 2006 and 2005 is summarized as follows:

<b>Fiscal 2006</b>	<u>Quarter</u>			
	<u>October 31,</u> <u>2005</u>	<u>January 31,</u> <u>2006</u>	<u>April 30,</u> <u>2006</u>	<u>July 31,</u> <u>2006</u>
Total revenues	\$10,165	\$10,116	\$9,630	\$9,915
Gross profit	6,143	6,300	5,658	5,634
Loss before income taxes	(3,163)	(5,098)	(3,793)	(4,955)
Net loss	(3,286)	(4,439)	(3,436)	(4,506)
Basic loss per common share	(\$0.10)	(\$0.14)	(\$0.11)	(\$0.14)
Diluted loss per common share	(\$0.10)	(\$0.14)	(\$0.11)	(\$0.14)

<b>Fiscal 2005</b>	<u>Quarter</u>			
	<u>October 31,</u> <u>2004</u>	<u>January 31,</u> <u>2005</u>	<u>April 30,</u> <u>2005</u>	<u>July 31,</u> <u>2005</u>
Total revenues	\$10,301	\$11,235	\$11,000	\$10,867
Gross profit	6,812	7,820	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)

ENZO BIOCHEM, INC  
SCHEDULE II - VALUATION  
AND QUALIFYING ACCOUNTS  
Years ended July 31, 2006, 2005 and 2004  
(in thousands)

Year ended July 31, Description	Balance at Beginning of period	Charged (credited) to costs and expenses	Charged to other accounts- describe	Deductions- describe	Balance at end of period
2006 Allowance for doubtful accounts receivable	\$2,292	\$3,633	---	\$4,892(1)	\$1,033
2005 Allowance for doubtful accounts receivable	2,770	4,967	---	5,445(1)	2,292
2004 Allowance for doubtful accounts receivable	2,257	11,987	---	11,474 (1)	2,770
2006 Deferred tax asset valuation allowance	129	4,727	---	-	4,856
2005 Deferred tax asset valuation allowance	-	129	---	-	129
2006 Reserve for obsolete inventory	-	596	---	358(2)	238
		---			
		---			

(1) Write-off of uncollectible accounts receivable.

(2) Write off of obsolete inventory.

## 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 5, 2006, 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, 2006.

/s/ Ernst & Young LLP  
Melville, New York  
October 13, 2006

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**CERTIFICATIONS**

In connection with the Annual Report on Form 10-K of Enzo Biochem, Inc. (“the Company”) for the fiscal year ended July 31, 2006 as filed with the Securities and Exchange Commission on the date hereof, I, Elazar Rabbani, Ph.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 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 fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Company’s internal control over financial reporting; and
5. The Company’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company’s auditors and the audit committee of the Company’s board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company’s ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company’s internal control over financial reporting.

Date: October 12, 2006

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

**CERTIFICATIONS**

In connection with the Annual Report on Form 10-K of Enzo Biochem, Inc. (“the Company”) for the fiscal year ended July 31, 2006 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 12, 2006      By:

/s/ Barry Weiner  
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, 2006 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 12, 2006

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.

**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, 2006 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Barry Weiner, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 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.

Date: October 12, 2006

By: /s/ Barry Weiner

Barry Weiner  
Chief Financial Officer

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



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## Corporate Information

### Board of Directors

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

Carl W. Balezentis, Ph.D.  
President  
Enzo Life Sciences, Inc.

Gary C. Cupit, Pharm.D.  
President  
Enzo Therapeutics, Inc.

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

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

Andrew Crescenzo, CPA  
Senior Vice President, Finance

Herbert B. Bass  
Vice President, Finance

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

David C. Goldberg  
Vice President,  
Business Development

Natalie Bogdanos  
General and Patent Counsel

Ronald Fedus  
Patent Counsel

## Corporate Offices

### Enzo Biochem, Inc.

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)

## 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.

	High	Low
<b>2005 Fiscal Year (August 1, 2004 to July 31, 2005):</b>		
1 <sup>st</sup> Quarter	\$17.69	\$11.15
2 <sup>nd</sup> Quarter	\$20.40	\$17.27
3 <sup>rd</sup> Quarter	\$19.27	\$13.62
4 <sup>th</sup> Quarter	\$18.24	\$14.08
<b>2006 Fiscal Year (August 1, 2005 to July 31, 2006):</b>		
1 <sup>st</sup> Quarter	\$17.30	\$12.92
2 <sup>nd</sup> Quarter	\$14.10	\$12.40
3 <sup>rd</sup> Quarter	\$13.55	\$11.67
4 <sup>th</sup> Quarter	\$15.08	\$9.30

As of September 30, 2006, the Company had approximately 1,070 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 the 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. 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 in fiscal 2005 which reflects the fair value of the stock dividend on the date of declaration.



*Enzo Biochem, Inc.  
527 Madison Avenue  
New York, NY 10022  
(212) 583-0100*