ENZO BIOCHEM INC
Form 10-K
October 13, 2006

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

(MARK ONE)

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

For the fiscal year ended July 31, 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	13-2866202
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
527 Madison Avenue New York, New York	10022
(Address of principal executive offices)	(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)	(NAME OF EACH EXCHANGE ON WHICH REGISTERED)
Common Stock, $.01 par value	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 |X|

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 |X|

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes |X| No |_|

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

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 |X| 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 |X|

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 consolidated financial statements).

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

ENZO LIFE SCIENCES is a company that manufacturers, 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(TM) 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(R) 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(R) brand name.

LABELING AND SIGNALING REAGENTS. We have developed an extensive line of nucleic acid labeling and detections reagent and kits that are designed for the life sciences research market. The products are used by scientists to detect and identify genes in certain specific formats. Our line of kits for the labeling of nucleic acids for the study of specific gene expression is marketed under the BIOARRAY(R) brand name. This product line also includes a new kit, BIOSCORE(TM), 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(TM) GENE MEDICINE. Enzo's proprietary Stealth Vector(TM) HGTV43(TM) 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(R) HGTV43(TM) 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(TM) our innovative immune regulation medicine for treatment of Crohn's Disease. In this study, subjects were evaluated using the Crohn's Disease Activity Index (CDAI), a standard measure of the severity of the disease, with higher scores indicating more severe disease activity. 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(TM) 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 adverse effect on us.

RESEARCH & DEVELOPMENT

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(R) 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, it's labeling or its manufacturing process.

Although clinical investigations of most devices are subject to the investigational device exemption ("IDE") requirements, clinical investigations of in vitro diagnostic ("IVDs") tests are exempt from the IDE requirements, including the need to obtain the FDA's prior approval, provided the testing is noninvasive, does not require an invasive sampling procedure that presents a significant risk, does not introduce energy into the subject, and is not used as a diagnostic procedure without confirmation by another medically established test or procedure. In addition, the IVD must be labeled for Research Use Only (RUO) or Investigational Use Only (IUO), and distribution controls must be established to assure that IVDs distributed for research or investigation are used only for those purposes. The FDA expressed its intent to exercise heightened enforcement with respect to IUO and RUO devices improperly commercialized prior to receipt of FDA clearance or approval.

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

Any devices that we manufacture or distribute will be subject to a host of regulatory requirements, including the Quality System Regulation (which

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

We are subject to inspection and market surveillance by the FDA to determine compliance with regulatory requirements. If the FDA finds that we have failed to comply, the agency can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as fines, injunction, civil penalties, recall or seizure of our products, the issuance of public notices or warnings, operating restrictions, partial suspension or total shutdown of production, refusal of our requests for 510(k) clearance or PMA approval of new products, withdrawal of 510(k) clearance or PMA approvals already granted, and criminal prosecution.

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

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

We have employees to expedite the preparation and filing of documentation necessary for FDA clearances and approvals, patent issuances and licensing agreements.

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

CLINICAL LABORATORY REGULATIONS

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

CLIA places all tests into one of three categories of complexity (waived, moderate complexity and high complexity) and establishes varying requirements depending upon the complexity category of the test performed. A laboratory that performs high complexity tests must meet more stringent requirements than a laboratory that performs only moderate complexity tests, while those that perform only waived tests may apply for a certificate of waiver from most of the requirements of CLIA. Our facility is certified to perform highly complex tests. In general, the Secretary of Health and Human Services ("HHS") regulations require laboratories that perform high or moderate complexity tests to implement systems that ensure the accurate performance and reporting of test results, establish quality control and quality assurance systems ensure hiring of personnel that meet specified standards, engage in proficiency testing by approved agencies and undergo biennial inspections.

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

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

CLINICAL LABORATORY REIMBURSEMENT

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

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

Containment of health care costs, including reimbursement for clinical laboratory services, has been a focus of ongoing governmental activity. In 1984, Congress established the Medicare fee schedule for clinical laboratory services, which is applicable to patients covered under Part B of the Medicare program as well as patients receiving Medicaid. Clinical laboratories must bill Medicare directly for the services provided to Medicare beneficiaries and may only collect the amounts permitted under this fee schedule. Reimbursement to clinical laboratories under the Medicare Fee Schedule has been steadily declining since its inception.

Furthermore, Medicare has mandated use of the Physicians Current Procedural Terminology ("CPT") for coding of laboratory services which has altered the way we bill these programs for some of our services, thereby reducing the reimbursement that we receive.

In March 1996, HCFA (now, the Center for Medicare and Medicaid Services or CMS) implemented changes in the policies used to administer Medicare payments to clinical laboratories for the most frequently performed automated blood chemistry profiles. Among other things, the changes established a consistent standard nationwide for the content of the automated chemistry profiles. Another change requires laboratories performing certain automated blood chemistry profiles to obtain and provide documentation of the medical necessity of tests included in the profiles for each Medicare beneficiary. Reimbursements have been reduced as a result of this change. Because a significant portion of our costs is fixed, these Medicare reimbursement reductions and changes have a direct adverse effect on our net earnings and cash flows.

Future changes in federal, state and local regulations (or in the interpretation of current regulations) affecting governmental reimbursement for clinical laboratory testing could have a material adverse effect on our business. We cannot predict, however, whether and what type of legislation will be enacted into law. In addition, reimbursement disapprovals by the third party payers, commercial insures and health maintenance organizations, reductions or delays in the establishment of reimbursement rates, and carrier limitations on the insurance coverage of the Company's services or the use of the Company as a service provider could have a negative effect on the Company's future revenues.

ANTI FRAUD AND ABUSE LAWS

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

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

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

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

The Company seeks to structure its arrangements with physicians and other customers to be in compliance with the Anti-Kickback, Stark and state laws, and to keep up-to-date on developments concerning their application by various means, including consultation with legal counsel. In addition, in order to address these various Federal and state laws, the Company has developed its own Corporate Compliance Program based upon the OIG model program. The Company's Program focuses on establishing clear standards, training and monitoring of the Company's billing and coding practices. Furthermore, as part of this Program, the Company's Corporate Compliance Committee meets on a regular basis to review various operations and relationships as well as to adopt policies addressing these issues.

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

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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 p