

ENZO BIOCHEM INC
Form 10-K
October 14, 2008

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

(Mark one)

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

For the fiscal year ended July 31, 2008

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 Ave.
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

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes No

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

Yes No

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

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

Large accelerated filer Accelerated filer Non-accelerated filer Smaller Reporting Company

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

The aggregate market value of the registrant's voting stock held by non-affiliates of the registrant was approximately \$303,311,000 as of January 31, 2008.

The number of shares of the Company's common stock, \$.01 par value, outstanding at October 6, 2008 was approximately 37,382,300.

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, 2009 are incorporated by reference into Part III of this annual report.

TABLE OF CONTENTS

	Description	Page
Part I		
<u>Item 1.</u>	<u>Business</u>	2
<u>Item 1A.</u>	<u>Risk Factors</u>	24
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	33
<u>Item 2.</u>	<u>Properties</u>	33
<u>Item 3.</u>	<u>Legal Proceedings</u>	34
<u>Item 4.</u>	<u>Submission of Matters to a Vote of Security Holders</u>	36
Part II		
<u>Item 5.</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	36
<u>Item 6.</u>	<u>Selected Financial Data</u>	37
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	38
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	51
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	51
<u>Item 9.</u>	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	52
<u>Item 9A.</u>	<u>Controls and Procedures</u>	52
<u>Item 9B.</u>	<u>Other Information</u>	54
Part III		
<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	54
<u>Item 11.</u>	<u>Executive Compensation</u>	54
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	54
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	54
<u>Item 14.</u>	<u>Principal Accounting Fees and Services</u>	54
Part IV		
<u>Item 15.</u>	<u>Exhibits, Financial Statement Schedules</u>	54
	<u>List of Consolidated Financial Statements and Financial Statements Schedule</u>	F-1
	<u>Report of Independent Registered Public Accounting Firm</u>	F-2
	<u>Consolidated Balance Sheets</u>	F-3
	<u>Consolidated Statements of Operations</u>	F-4
	<u>Consolidated Statements of Stockholders' Equity & Comprehensive Income (Loss)</u>	F-5
	<u>Consolidated Statements of Cash Flows</u>	F-6
	<u>Notes to Consolidated Financial Statements</u>	F-7
	<u>Schedule II - Valuation Accounts and Qualifying Accounts</u>	S-1

PART I

Item 1. Business

Overview

Enzo Biochem, Inc. (the Company we, our or Enzo) is a life sciences and biotechnology company focused on harnessing genetic processes to develop research tools, diagnostics and therapeutics and on serving as a provider of diagnostic services to the medical community. Since our founding in 1976, our strategic focus has been on the development of enabling technologies in the life sciences field. Our pioneering work in genomic analysis coupled with its extensive patent estate and enabling platforms have strategically positioned the Company to play an important role in the rapidly growing life sciences and molecular medicine marketplaces.

In the course of our research and development activities, we have built a substantial portfolio of intellectual property assets, with 236 issued patents worldwide, and 213 pending patent applications, along with extensive enabling technologies and platforms.

Recent Developments

On May 8, 2008, Enzo Life Sciences, Inc. acquired substantially all of the U.S. based assets and certain liabilities of Biomol International, LP through a newly formed US subsidiary Biomol International, Inc. and all of the stock of Biomol's wholly-owned United Kingdom subsidiary, Affinity Limited, by Axxora UK, a wholly-owned subsidiary of Enzo Life Sciences, referred to as Biomol for approximately \$18.1 million in cash and stock, subject to adjustment, exclusive of acquisition costs of approximately \$800,000 and contingent payments of \$2.5 million on each of the next two anniversary dates. Effective May 8, 2008, Biomol became a wholly-owned subsidiary of Enzo Life Sciences. The acquisition was financed with the Company's cash and cash equivalents and Enzo common stock. (See Item 7, Recent Developments and Note 2 in the notes to consolidated financial statements).

Operating Segments

We are comprised of three operating segments, of which the Therapeutics and Life Sciences segments have evolved out of our core competencies: the use of nucleic acids as informational molecules and the use of compounds for immune modulation. Information concerning sales by geographic area and business segments for the years ended July 31, 2008, 2007 and 2006 is located in Note 17 in the notes to consolidated financial statements.

Below are brief descriptions of each of our operating segments:

Enzo Life Sciences is a company that manufactures, develops and markets biomedical research products and tools to research and pharmaceutical customers world-wide 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. We are internationally recognized and acknowledged as a leader in manufacturing, in-licensing, and commercialization of over 8,000 innovative high quality research reagents in key research areas. The division is an established source for a comprehensive panel of products to scientific experts in the fields of gene expression, non-radioactive labeling and detection, adipokines & obesity, apoptosis, bioactive lipids, cell cycle, cytoskeletal research, DNA damage & repair, epigenetics, immunology & cancer research, inflammation, neurobiology, nitric oxide & oxidative stress, and signal transduction.

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. Enzo Therapeutics has focused its efforts on developing treatment regimens for diseases and conditions for 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 New York Metropolitan and New Jersey areas. The Company believes this allows us to capitalize firsthand on our extensive advanced molecular and cytogenetic capabilities and the broader trends in predictive diagnostics. Enzo Clinical Labs offers 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, and search for an otherwise undiagnosed condition.

We operate a full-service clinical laboratory in Farmingdale, New York, a network of 23 patient service centers, a stand alone stat or rapid response laboratory in New York City, and a full-service phlebotomy department.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

The Company's primary sources of revenue have historically been from product revenues and royalty and licensing of Life Sciences' products utilized in life science research and from the clinical laboratory services provided to the healthcare community. The following table summarizes the sources of revenues for the fiscal years ended July 31, 2008, 2007 and 2006, (in \$000's and percentages):

Fiscal year ended July 31,	2008		2007		2006	
Product revenues	\$ 28,087	36%	\$ 6,658	13%	\$ 4,750	12%
Royalty and license fees	7,630	10	5,820	11	3,150	8
Clinical laboratory services	42,078	54	40,430	76	31,926	80
Total	\$ 77,795	100%	\$ 52,908	100%	\$ 39,826	100%

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 ongoing challenge of the scientific research community is to determine the function and relevance of each gene. This information will facilitate the understanding of biological mechanisms and how variations and mutations in such mechanisms may 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 for which a variety of formats, or tools, have been developed that enable 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 continue to 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 been reported by industry sources to be greater than \$22 billion annually. It is comprised of a broad range of tests based on clinical chemistry, microbiology, immunoassay, blood banking and cancer screening assays. 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 a microorganism.

There are several drawbacks to these more traditional technologies. Immunoassays do not allow for early detection of diseases because they require minimum levels of antigens to be produced by the microorganism in order to be identified. 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 has many advantages over the traditional technologies. Since gene-based diagnostics focuses on the identification of diseases at the gene level, it 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.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

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 industry sources, the market for molecular diagnostic tools, assays and other products is currently more than \$4 billion per year, and is acknowledged as one of the fastest growing segments in the in-vitro diagnostic industry. Contributing to this growth are, among other factors:

the increasing 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

As science progresses, we are learning more about biochemical processes and how the cell's machinery is directed towards normal functioning of physiological, genetic and immune system pathways. Disease may result as the consequence of an inappropriate reaction in any of these systems.

In the normal physiologic functioning of the body key modulators interact with membrane-bound proteins and initiate a cascade of biochemical reactions that regulate the cell. How modulators interact with membrane-bound proteins set the stage for a variety of possible activities that the cell then controls. The membrane-bound proteins are multiligand receptors, hence the modulator(s) and their activity at a specific binding docking station determine the ultimate activity of the cell. This constitutes a cell signaling pathway. One of the most notable cell signaling pathways is the Wnt pathway and an associated membrane protein, LDL (low density lipoprotein) receptor-related protein LRP. Recent research by Enzo and others have unlocked the key to the activation/inhibition of the Wnt and/or LRP system resulting in the discovery and subsequent regulation of natural processes, such as development, cell division, and metabolic activity, among others. Manipulation of this system through small molecules, peptides, oligonucleotides or antibodies may possibly correct dysfunctional systems.

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, autoimmune 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.

Still other 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, or overexpression of, a gene that causes the disease. In addition, a number of diseases result from the body's failure to adequately regulate its immune system.

Advances in gene analysis have provided the information and tools necessary to develop drugs that interfere with the disease process at the genetic level. For a broad spectrum of diseases, this approach can be more precise and effective than interfering with downstream events such as protein synthesis or enzyme activation. 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, they are quickly metabolized or eliminated by the body. Consequently, large quantities of oligos must be delivered in multiple treatments, which can be both toxic to the body as well as costly.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

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 introduced to bring about 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 or 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.

Strategy

Our objective is to be a leading developer and provider of the tools and diagnostic technologies used to study and detect disease at the molecular level and to be a provider of therapeutic approaches to manage specific diseases. There can be no assurance that our objective will be met. Key elements of our strategy involving three separate platforms include our ability to:

Apply our innovative technology to a variety of diseases mediated by cell signaling pathways, by the immune system, or, in advanced cases, gene therapy.

We believe our core technologies have broad diagnostic and therapeutic applications. We have focused our efforts on discovering how best to correct pathologies associated with bone or metabolic control, and immune-mediated diseases. Although the cause of disorders such as Crohn's disease, autoimmune uveitis and non-alcoholic steatohepatitis (NASH) remains unknown, various features suggest immune system involvement in their pathogenesis.

We continue to test 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 and intellectual property to develop diagnostic and monitoring tests for various diseases.

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.

During fiscal 2005, we acquired the rights and intellectual property to a candidate drug and technology intended for use in the *treatment* of autoimmune uveitis. We are collaborating with scientists and physicians in the United States and abroad to develop this candidate drug into a product for treating autoimmune uveitis. Through these collaborations and other licensing agreements we continue to develop novel therapeutics for the stimulation and enhancement of bone formation and glucose control, among others. Such products, if any, emanating from this technology could provide potential therapy for bone disorders, including bone loss, bone fractures, periodontitis, diabetes and other indications.

We have research collaborations with other institutions including, 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. Through other collaborations we are developing our candidate drug Optiquel for autoimmune uveitis. 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 specific areas in order to act on opportunities that can be accretive to our efforts in accelerating our development program.

Apply our biomedical research technology to the clinical diagnostics market

We intend to develop our proprietary research technology for use in 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 can permit multiple diagnoses to be performed on the same specimen.

Leverage marketing and distribution infrastructure of leading life sciences companies

Enzo Life Sciences continues to develop its sales and marketing infrastructure to more directly service its end users, while simultaneously positioning the Company for product line expansion. Our acquisitions of Axxora in May 2007 and Biomol in May 2008, have expanded our global sales, marketing, manufacturing, product development and distribution infrastructure. Enzo Life Sciences now operates worldwide through wholly owned subsidiaries (in USA, Switzerland, Benelux, Germany, and UK) and a network of third party distributors in most other significant markets worldwide.

Expand our collaborations with major life sciences companies

We intend to seek opportunities to secure strategic partnerships and assert our intellectual property estate with multiple market participants. Further, we will look to advance proprietary business opportunities.

In fiscal 2007, Enzo Life Sciences and Abbott Molecular, Inc. entered into an agreement covering the supply of certain Enzo Life Science's products to Abbott Molecular for use in their fluorescence in situ hybridization (FISH) product line. Both companies have also entered into a limited non-exclusive royalty bearing cross-licensing agreement of patents for FISH systems, comparative genomic hybridization (CGH) analysis and labeling and detection technologies. The cross-licensing agreement includes the Company's patents directed towards its proprietary labeling and detection systems as they relate to Abbott's FISH platform. The license also provides the Company with limited access to Abbott's FISH technology patents, CGH patents and various patents which relate to particular chromosome targets. These agreements relate to products in the field of molecular diagnostics, which is the fastest-growing segment of the diagnostics market, according to industry sources. FISH involves the use of labeled DNA probes which are used to identify specific genetic conditions. Currently, this technology is used to help diagnose and/or select therapy for certain cancers, such as breast, bladder, and leukemia, as well as to help diagnose genetic disorders. CGH is a molecular cytogenetic method for the analysis of chromosomal copy number changes (gains/losses) which are recognized as the underlying basis for congenital disorders and complex diseases such as cancer. See Note 14 to the notes to consolidated financial statements.

In fiscal 2005, the Company, as plaintiff, finalized and executed a settlement and license agreement with Digene Corporation to settle a patent litigation lawsuit. Digene Corporation was acquired by QIAGEN. The license agreement with the Company was assigned to QIAGEN Gaithersburg Inc. (Qiagen). Under the terms of the license agreement, the Company would earn quarterly running royalties on the net sales of Qiagen products subject to the license until the expiration of the patent on April 24, 2018. In the license agreement, Qiagen was granted a world-wide, non-exclusive license to the Company U.S. Patent number 6,222,581, which is related to the use of a methodology called "hybrid-capture" in which certain nucleic acid probes are hybridized to target nucleic acids and then captured indirectly on a solid surface. The resulting nucleic acid hybrids are then detected by antibodies conjugated to signal-generating molecules which produce an amplified signal allowing for more sensitive detection of the resultant hybrids. This platform is one of the most desirable formats for the detection of nucleic acids in a reliable and economic manner, and has formed the basis for one of the most commonly ordered genomic-based assays. See Note 13 to the notes to consolidated financial statements.

Expand and protect our intellectual property estate

Since our inception, we have followed a strategy of creating 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 2008, we were awarded seven patents and expanded our patent estate in the area of nucleotides, amplification, labeling, detection, among others

Core Technologies

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

Diagnostic Technology Platform

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

Cell Signaling Pathway

Our newest therapeutic technology platform involves the development of pharmaceutical agents that affect with protein-protein interactions. Over the past several years, our scientists and collaborators have unlocked the secrets of a major cell signaling pathway thus producing a means to modify biologic activity in a number of physiological systems. Further investigation into the design and control of this system has allowed our scientists and their collaborators to determine the structure of key regulatory proteins and to identify active sites that then become targets for Enzo's proprietary technology generating system. Our technology is capable of generating active compounds that range from orally delivered small molecules to peptides, oligonucleotides or antibodies. We have performed pioneering work on the structure and function of LRP and its ligands, developed a screening technology to identify active compounds, and have synthesized proprietary molecules capable of producing biological effects in cell-based systems and animal models of disease. Specifically, this system allows the Company to successfully:

- generate biological, genetic, and structural information concerning LRP;
- determine the structure of LRP docking sites of its ligands;
- identify the functionally important residues via site-directed mutagenesis;
- build the fine structure map and employ it as the basis for virtual screening;
- show that compounds specifically bind to wild type LRP5, but not to mutated LRP5;
- generate a cell-based assay capable of identifying active compounds and;
- synthesize proprietary molecules that are active in animal models of disease.

Through this novel, proprietary, functional screening system, we have identified small molecules capable of reversing sclerostin-mediated inhibition of Wnt signaling. Preclinical animal studies with several candidate lead compounds produced the following results:

- significant increases in total and femoral bone density through new bone formation;
- significant reduction in alveolar bone loss and;
- significant reduction in bone resorption.

The anabolic induction of new bone formation and prevention of bone loss by our small molecule compounds may promise new paths for the treatment of osteoporosis.

In addition, our proprietary technology has enabled the generation of novel chemical entities that have significant glucose lowering activity. These effects are separate from its effects on bone metabolism indicating a specificity of action conferred by the interaction of a particular compound with the cell signaling pathway. Therefore, this approach may be broadly applicable to the generation of therapeutic drug candidates for multiple indications.

Immune Regulation

Oral Immune Regulation. We are exploring a novel therapeutic approach based on immune regulation. Our immune regulation technology seeks to control an individual's immune response to a specific antigen in the body. An antigen is a substance that the body perceives as foreign and, consequently, against which the body mounts an immune response. We are developing our technology to treat immune-mediated diseases, specifically autoimmune uveitis and Crohn's Disease.

Gene Regulation

We have developed an 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.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Immunologically Quiet. Transduced or engineered cells (cells containing the gene that was delivered by the vector) often produce non-essential proteins that may trigger an immune response, causing such cells to be cleared from the body before they can produce a therapeutic effect. Cells transduced with our Stealth Vectors have not expressed extraneous proteins.

Smart Vectors. We incorporate into the surface of our vectors proteins that 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 transduce 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. Our 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.

In summary, we have developed proprietary technologies in the areas of cell signaling, immune modulation and gene regulation (genetic antisense or antisense RNA) that we are using as platforms for a portfolio of novel therapeutics. There can be no assurance that we will be able to secure patents or that these programs will be successful. The potential therapeutics we are developing could be used, if successful, for the treatment of a variety of diseases, including osteoporosis, osteonecrosis and other bone pathologies, diabetes, autoimmune uveitis, and inflammatory bowel disease, including Crohn's Disease and ulcerative colitis, among others.

We have developed an immunomodulator agent EGS21 as a potential therapeutic for treating immune mediated disorders. EGS 21 is a glycolid that has been shown by our scientists and collaborators to act as an anti-inflammatory agent in animal model systems and is being evaluated as a drug candidate in the treatment of various immune mediated diseases.

In summary, we have developed proprietary technologies in the areas of cell signaling, immune modulation and gene regulation (genetic antisense RNA) that we are using as platforms for a portfolio of novel therapeutics.

There can be no assurance that we will be able to secure patents or that these programs will be successful. The potential therapies we are developing could be used, if successful for the treatment of a variety of diseases, including osteoporosis, osteonecrosis and other bone pathologies, diabetes, autoimmune uveitis and inflammatory bowel disease, including Crohn's disease and ulcerative colitis, among others.

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 New York Metropolitan and New Jersey area.

Research Products

We are organized to lead in the development, production, marketing and sales of innovative life science research reagents worldwide based on over 30 years of experience in building strong international market recognition, implementing outstanding operational capabilities, and establishing a state of the art electronic information and ordering marketplace. We in-license and manufacture over 8,000 products, and distribute an additional 20,000 products, that may be sold individually or combined in a kit to meet the specific needs of researchers. We market these products to biomedical and pharmaceutical firms as well as academic and government research institutions worldwide. Our comprehensive portfolio of high quality reagents and kits in key research areas are sold to scientific experts in the following fields:

Adipokines	Interferons
Antibiotics	Kinases/Inhibitors
Apoptosis/Cell Death	Leukotrienes/Prostaglandins/Thromboxanes
Biologically Active Peptides	Microarray Labeling
Bone Metabolism	Multidrug Resistance
Cancer Research	Natural Products/Antibiotics
Cell Death	Neuroscience
Cell Cycle	Nitric Oxide Pathway
Chemokines/Cytokines	Nuclear Receptors
Cytoskeletal Research	Oxidative Stress
Dependence Receptors	Proteosome/Ubiquitin
DNA Fragmentation/Damage/Repair	Receptors
DNA Regulation	Signal Transduction
Epigenetics	Stem Cell/Cell Differentiation
FISH	Stress Proteins/Heat Shock Proteins
Growth Factors/Cytokines	TNF/TNF Receptor Superfamily
Hypoxia	Transcription Factors
Immunology	Viral Signaling
Inflammation/Innate Immunity	

Enzo Life Sciences is organized to promote and market its product through its five brands.

Enzo The Enzo brand products and technologies are primarily focused in the areas of microarray analysis, gene regulation and gene modification. Patented Enzo technologies and products are recognized as key tools in non-radioactive gene and protein labeling.

Alexis The Alexis brand is internationally recognized as a leader in producing and commercializing innovative high quality reagents and as an established source for a comprehensive panel of products in many of the fields listed above.

Apotech The Apotech branded product portfolio focuses on the fields of apoptosis and inflammation. These products include high quality recombinant proteins, antibodies and research kits.

Axxora The Axxora brand provides an electronic one-stop information, service and purchasing location for innovative high quality life science research reagents and research kits from the three product brands listed above as well as products from original manufacturers.

Biomol The Biomol branded product portfolio is targeted towards the cellular biochemistry segment with an emphasis on areas related to protein post-translational modification, be it by ubiquitin or the ubiquitinating-like proteins, acetylation, methylation, phosphorylation, sulphation, or glycosylation.

Therapeutic Development Programs

We have a number of therapeutic products in various stages of development that are based on our proprietary cell signaling, immune regulation and gene therapy technologies. Our therapeutic programs are described below.

Osteoporosis (and certain bone disorders) and Diabetes

We have 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. These candidate compounds were identified through an innovative approach, combining structural biology, computational screening, mutational analyses and biological in vitro assays, followed by validation in animal model systems.

Enzo-D58 is one of several compounds found to induce new bone formation in mouse calvaria when injected subcutaneously. When delivered orally the candidate compound was shown to prevent alveolar bone loss in a periodontitis-induced rat model.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

One of the most challenging problems in clinical dentistry chronicled throughout history is the loss of alveolar bone. Alveolar bone loss is characterized by the reduction in height and volume of the maxillary and mandibular bones that underlie and support the teeth. The primary causes of alveolar bone loss are periodontitis and tooth loss, although osteoporosis may also contribute. The lack of an effective treatment for periodontal bone loss has encouraged the continued search for a successful therapeutic approach. Our preliminary results which were presented at the annual meeting of the American Society for Bone and Mineral Research 2007 suggest that Enzo-D58 may be effective in preventing alveolar bone loss. We have continued this effort and have synthesized and developed novel compounds that appear to be active in standard animal models which assess bone density. We continue to develop these drug candidates and progress them along the drug development continuum.

In addition, we and our collaborators have investigated the biochemical pathways involved in glucose homeostasis. Using animal genetic models, and structural and computational biology we have been able to decipher some of the complex cellular machinery that controls glucose, synthesize novel entities that interact at key targets and test them in standard animal models of diabetes. We continue to explore this very exciting line of research and continue activities geared toward the development of potential therapeutics for diabetes with novel mechanisms of action.

Autoimmune Uveitis. Autoimmune uveitis, which results from inflammation of a part of the eye known as the uvea, is believed to result from an immune reaction to antigens in the eye, specifically the S-antigen 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 newly 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 also are 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 an open, pilot Phase I clinical trial in Germany with encouraging results.

Using our immune regulation platform and the recently acquired rights to the candidate drug, Optiquel (B27PD), Enzo is currently developing a protocol for a multi-center, double-blind, placebo-controlled, proof-of-concept clinical trial to be carried out in the United States and possibly ex-US. We have begun collaborations with scientists and physicians in both the US and abroad and have assembled an advisory board of consultants who are experts in the management and treatment of uveitis. In addition, we have held a pre-IND meeting with the U.S. Food and Drug Agency (FDA) in preparation for regulatory approval to initiate clinical studies in the US. We will be filing an IND with the FDA assuming all manufacturing, quality and preclinical studies meet FDA requirements.

We previously had filed with the regulatory authorities in Europe, and Optiquel has been granted orphan status under European regulations. We will apply for the same in the U.S. since Orphan status designation can confer both financial and marketing benefits.

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 Crohn's and Colitis 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 may make the body more prone to infection, lymphoma, or other diseases.

Alequel is an individualized protein product mixture produced from autologous tissue and extracted during a routine colonoscopy from a patient. The Enzo protein extract is administered to the patient orally. Interim results of a Phase II clinical study, were presented at the 2007 annual Digestive Disease Week conference. In these studies, 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. Forty-nine patients with moderate to severe Crohn's disease were randomized to receive either placebo or *Alequel*. Patients were monitored on an intent-to-treat basis for remission (a decrease in CDAI to 150 or lower), clinical response (a decrease in CDAI of 100 or greater) and quality of life as measured by the inflammatory bowel disease questionnaire (IBDQ). The results, although not statistically significant, indicated that patients receiving *Alequel* achieved improved rates of clinical remission compared with the placebo group (39% vs. 22%), clinical response (50% vs. 30%) and improved quality of life in the drug study group compared to placebo.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

No treatment-related adverse events were noted. Thus, we concluded that *Alequel* may be a safe and effective method for treatment of patients with moderate to severe Crohn's disease.

An expanded double-blind, placebo-controlled study to broaden the diversity of the patient population is currently being completed at Hadassah Hospital in Jerusalem. We expect results from this study in Fiscal 2009. If the results are positive, we will request a pre-IND meeting with the US FDA to plan for regulatory approval to initiate studies in the US. We have begun collaborations with scientists and physicians and have assembled an advisory board of consultants who are experts in the management and treatment of inflammatory bowel disease.

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 individual 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 2007. There were over 5 million new infections and 3 million deaths from HIV during that same year. More than 20 million have died since the first cases of AIDS were identified in 1981. At present, several classes of products have received FDA marketing approval for HIV-1 infection: reverse transcriptase inhibitors, protease inhibitors, fusion inhibitors and binding inhibitors.

HGTV43 gene medicine. Enzo's proprietary Stealth Vector HGTV43 gene construct is a vehicle designed to carry and deliver anti-HIV-1 antisense RNA genes. These genes produce antisense RNA directed against the genes responsible for viral replication. HGTV43 is designed to deliver the antisense genes to targeted blood cells of subjects infected with HIV-1. These genes are incorporated into the DNA of the blood cells, and subsequent production of the antisense RNA prevents replication of the virus, providing resistance to the virus.

Preclinical *in vitro* studies, performed in conjunction with our academic collaborators, demonstrated resistance to HIV-1 in human immune cells into which the antisense genes had been inserted. Our Phase I clinical trial of the HIV-1 gene medicine is in the long-term safety follow up phase. In this study, white blood cell precursors, known as stem cells, were collected from the subjects. These stem cells were then treated *ex vivo* with our Stealth Vector® HGTV43 transducing vector and infused into the subject. Results of the trial showed that all subjects tolerated the procedure and that:

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;

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, indicating engraftment of the engineered cells;

anti HIV-1 antisense RNA-containing immune cells were detected in the circulation of subjects, the longest at 72 months;

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 initiated a Phase I/II study at University of California San Francisco (UCSF), the site of the Phase I study. This study focuses on a strategy designed to increase the percentage of engineered CD4+ cells that contain the anti-HIV-1 antisense genes. The first patient has undergone treatment and we are monitoring the progress.

Non-Alcoholic SteatoHepatitis (NASH)

We are currently conducting a double-blind, placebo-controlled study at Hadassah Hospital in Jerusalem which is designed to investigate the effects of EGS-21, a glycolipid, as an immune modulator for the alleviation of NASH. We expect to have results from this study by the end of fiscal 2009.

Hepatitis B Virus (HBV)

We have developed a HBV therapeutic 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 may enhance a secondary immune response to clear the viral infection, resulting in reduction in liver damage and decrease in viral load.

Based on both the preclinical and clinical results, the Company began exploring several options for development of the candidate drug. Our current strategy is to seek a commercial partner to continue the drug development. To this end pharmaceutical partnerships are being explored and evaluated, although there can be no assurances that such efforts will be successful

Clinical Laboratory Services

We operate a regional clinical laboratory that offers full diagnostic services to the New York Metropolitan and New Jersey medical community. Our 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. We do 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.

We offer 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 over twenty three strategically located patient service centers and a full service phlebotomy department. Patient service centers collect the specimens as requested by physicians. We also operate a fully equipped 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 proprietary EnzoDirect system or delivered by our logistics department directly to the ordering physicians' offices. Physicians who request that they be called with a particular result are so notified.

For fiscal years ended July 31, 2008, 2007, and 2006, respectively, 54%, 76% and 80% of the Company's revenues were derived from the clinical laboratory. At July 31, 2008 and 2007, respectively, approximately 58% and 68% 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 the Clinical Labs accounts receivable is mitigated by the diversity of its numerous third party payers and individual patient accounts, and is limited to certain large payers that insure individuals that utilize the Clinical Labs services. To reduce risk, the Company routinely assesses the financial strength of these payers and, consequently, believes that its accounts receivable credit risk exposure, with respect to these payers, is limited. While the Company also has receivables due from the Federal Medicare program, the Company does not believe that these receivables represent a credit risk since the Medicare program is funded by the federal government and payment is primarily dependent on our submitting the appropriate documentation.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Revenue, net of contractual adjustment, from direct billings under the Federal Medicare program during the years ended July 31, 2008, 2007 and 2006 were approximately 22%, 21% and 23%, respectively, of the clinical laboratory segment's total revenue. We estimate contractual adjustment based on significant assumptions and judgments, such as the interpretation of payer reimbursement policies which bears the risk of change. The estimation process is based on the experience of amounts approved as reimbursable and ultimately settled by payers, versus the corresponding gross amount billed to the respective payers. The contractual adjustment is an estimate that reduces gross revenue, based on gross billing rates, to amounts expected to be approved and reimbursed. Gross billings are based on a standard fee schedule we set for all third party payers, including Medicare, health maintenance organizations (HMOs) and managed care providers. We adjust the contractual adjustment estimate quarterly, based on our evaluation of current and historical settlement experience with payers, industry reimbursement trends, and other relevant factors. The other relevant factors that affect our contractual adjustment include the monthly and quarterly review of: 1) current gross billings and receivables and reimbursement by payer, 2) current changes in third party arrangements, 3) the growth of in-network provider arrangements and managed care plans specific to our Company. 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. Our provision for uncollectible accounts receivable is within historical expectations.

Other than the Medicare program, revenues from United Healthcare of New York, Inc. represented 26% and 20% of the Clinical Labs segment's net revenue for the fiscal year ended July 31, 2008 and 2007, respectively. Other than the Medicare program, no other provider exceeded 10% of Clinical Labs service revenue for the fiscal year ended July 31, 2006.

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 standard gross 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 and Development

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Our principal research and development efforts are directed toward expanding our research product lines, given our increased manufacturing, distribution capability following the acquisitions of Axxora and Biomol, 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.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

In the fiscal years ended July 31, 2008, 2007 and 2006, the Company incurred costs of approximately \$8,637,000, \$9,393,000 and \$7,896,000, respectively, for research and development activities.

Internal Research Programs

Our professional staff of 58 scientists, including 46 with post graduate 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. Apotech Laboratories, Inc., a wholly owned subsidiary of Axxora Inc., is involved in three EU collaborative projects aimed at developing novel anti-cancer drugs, novel targets for the design of new cancer therapies and developing new diagnostics to significantly improve haematopoietic stem cell transplants. Biomol International Europe is a participant in the RUBICON Network of Excellence which is funded by the Framework Programme 6 of the European Commission focused on the development of reagents and assays facilitating investigation of ubiquitin and ubiquitin-like (Ubl) pathway components. We also have a number of external collaborations around the world to enhance our ongoing therapeutic development program.

Sales and Marketing

Our sales and marketing strategy for Enzo Life Sciences is to sell our life science products through three distinct channels: (i) direct sales to end-users (ii) supply agreements with manufacturers and (iii) through distributors in major geographic markets. We operate with an understanding of local markets and a well-functioning distribution network system across the globe. Scientists around the world recognize the brands (Alexis, Apotech, Axxora, Biomol and Enzo) for innovative high quality products and as a source for life science research reagents from original manufacturers. Our marketing and sales network includes fully-owned subsidiaries (USA, Switzerland, Germany, UK), and a network of third party distributors in most other significant markets worldwide.

For Enzo Clinical Labs, we focus our sales efforts on obtaining and retaining profitable accounts. 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 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. We are focusing our efforts to attract and retain clients who participate with the providers with whom we have regional contracts.

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. 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 2008 we owned or licensed 53 U.S. and 183 foreign patents relating to products, methods and procedures resulting from our internal or sponsored research projects.

There can be no assurance that patents will be issued on pending applications or that any issued patents will not be challenged (see Item 3, Legal Proceedings), or that they 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.

Our 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. We have 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.

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. We plan to utilize its technological expertise to develop a line of products and services designed specifically for the cytogenetics research 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 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.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

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. 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.

Federal requirements are detailed in Title 21 of the Code of Federal Regulations (21 CFR). In addition, the FDA publishes guidance documents with respect to the development of therapeutics protocols.

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 satisfactorily review 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 investigational product. It is the sponsor's responsibility to 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. This may be done using in-house trained personnel or an outside contract research organization (CRO). 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 Panel 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 designation 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 by us, are likely to be regulated by the FDA as medical devices. Unless an exemption applies, medical devices must receive either 510(k) clearance or pre-market approval (PMA) from the FDA before marketing them in the United States. The FDA's 510(k) clearance process usually takes from four to 12 months, but it can last longer. The process of obtaining PMA approval is much more costly, lengthy and uncertain. It generally takes from one to three years or even longer. We cannot be sure that 510(k) clearance or PMA approval will ever be obtained for any product we propose to market.

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

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

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

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

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.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

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.

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. Clinical laboratories must bill Medicare directly for the services provided to Medicare beneficiaries and may only collect the amounts permitted under the Medicare Fee Schedule. Reimbursement to clinical laboratories under the Medicare Fee Schedule has been steadily declining since its inception. Furthermore, Medicare has mandated use of the Physicians Current Procedural Terminology (CPT) for coding of laboratory services which has altered the way we bill these programs for some of our services, thereby reducing the reimbursement that we receive.

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

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

Anti Fraud and Abuse Laws

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

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

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

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

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

Confidentiality of Health Information

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) was signed into law on August 21, 1996, and it includes administrative simplification provisions designed to standardize common electronic transactions in health care and to protect the security and privacy of health information. Congress' purpose in promulgating HIPAA was to increase the efficiency of health care transactions while, at the same time, protecting the confidentiality of patient information. Final regulations have been adopted for electronic transaction, privacy and security standards. Further, final regulations adopting a National Provider 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 was May 23, 2007.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

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). We received 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. We believe that we are in compliance with these HIPAA regulations.

Medical Regulated Waste

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

Occupational Safety

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

Other Regulation

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

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

Manufacturing and Research Facilities

Our internal manufacturing and scientific efforts for our three segments took place primarily at our facility in Farmingdale, New York prior to June 2007. At this facility we have a completely integrated laboratory and manufacturing facility, with special handling capabilities and clean rooms suitable for our operations. In June 2006, we acquired a facility adjacent to our Farmingdale, New York facility that effective July 1, 2008, a major portion became utilized by Life Science for research and manufacturing. In connection with the Axxora acquisition, the Life Sciences segment has added manufacturing and research operations in Switzerland and a research facility in San Diego, California. The Epilanges, Switzerland site houses the research and development laboratories of Apotech. A portion of the San Diego, California facility is used to perform research and development activities. In connection with the Biomol acquisition, the Life Sciences segment has added manufacturing and research operations in Plymouth Meeting, Pa. and a research facility in Exeter, United Kingdom. We also contract with qualified third-party contractors to manufacture our products in cases where we deem it appropriate, for example, when it is not cost-effective to produce a product ourselves or where we seek to leverage the expertise of another manufacturer in a certain area.

Employees

As of July 31, 2008, we employed 439 full-time and 71 part-time employees. Of the full-time employees, 132 were engaged in research, development, manufacturing, and marketing of research products, 13 in therapeutics research, 266 in the clinical laboratories and 28 in finance, legal and administrative functions. Our scientific staff, including 46 individuals with post graduate 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. 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, to complement our proprietary physician connectivity solution, EnzoDirect we have introduced a web portal version which allows physicians to receive laboratory results from any personal computer with a browser and an Internet connection.

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.

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. The Company makes available on its website a link to all filings that it makes with the SEC. You may request a copy of the Company's filings with the SEC (excluding exhibits) at no cost by writing or telephoning us at the following address or telephone number:

Enzo Biochem, Inc.
527 Madison Ave.
New York, New York 10022
Tel: (212) 583-0100
Attn: Investor Relations
Item 1A. Risk Factors

Risks relating to our Company and our industries

We have experienced significant losses in our last two fiscal years and quarter to quarter. If such losses continue, the value of your investment could decline significantly.

We incurred a net loss of \$10.7 million and \$13.3 million for the fiscal years ended July 31, 2008 and 2007, respectively. 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.

Our operating results may vary from period to period.

Our operating results may vary significantly from quarter to quarter and from year to year, depending on a variety of factors including:

- competitive conditions, including changes in third-party reimbursements,
- exchange rate fluctuations,
- changes in tax laws, the results of tax audits or the measurement of tax uncertainties,
- the timing of our research and development, sales and marketing expenses,
- the introduction of new products by us or our competitors,

the success of identifying, acquiring and integrating businesses that complement our product offering, add new technology or add presence in a market,

customer demand for our products due to changes in purchasing requirements and research needs, and general worldwide economic conditions affecting funding of research. Consequently, results for any interim period may not necessarily be indicative of results in subsequent periods.

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

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

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

We may be unable to identify, acquire and integrate acquisition targets.

In the past two fiscal years we have made significant acquisitions. Our strategy envisions that a part our future growth will come from acquiring and integrating similar operations. There can be no assurance that we will be able to identify suitable acquisition candidates and, once identified, to negotiate successfully their acquisition at a price or on terms and conditions favorable to us, or to integrate the operations of such acquired businesses with the existing operations. In addition, we compete for acquisition candidates with other entities, some of which have greater financial resources than ours. Our failure to implement successfully its acquisition strategy would limit our potential growth.

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

The Life Sciences segment continues to implement an aggressive marketing program designed to more directly service its end users, while simultaneously positioning us for product line expansion. We will continue to expand the reach of companies by our direct field sales force, continued attendance at top industry trade meetings, and publications in leading scientific journals, as well as the on-going enhancement of our interactive web sites. In addition to our direct sales, we operate worldwide through wholly-owned subsidiaries (in USA, Switzerland, Germany, and UK) and a network of third-party distributors in most other significant markets. If we are unable to successfully implement these programs, we may be unable to grow and our business could suffer.

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 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. The markets for our products are also subject to competitive risks because markets are highly price competitive. Our competitors have competed in the past by lowering prices on certain products. The 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:

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

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 personnel;

25

Render our biotechnology products uneconomical or obsolete; or

Reduce our revenue.

We depend on distributors and contract manufacturers and suppliers for materials that could impair our ability to manufacture or distribute our products.

Outside distributors, suppliers and contract manufacturers provide key finished goods, components and raw materials used in the sale and manufacture of our products. Our Life Sciences segment distributes product for over 40 unrelated third party manufacturers. To the extent we are unable to maintain or replace a distributor in a reasonable time period, or on commercially reasonable terms, if at all, our operations could be disrupted. Although we believe that alternative sources for components and raw materials are available, any supply interruption in a limited or sole source component or raw material would harm our ability to manufacture our products until a new source of supply is identified and qualified. In addition, an uncorrected defect or supplier's variation in a component or raw material, either unknown to us or incompatible with our manufacturing process, could harm our ability to manufacture products. We might not be able to find a sufficient alternative supplier in a reasonable time period, or on commercially reasonable terms, if at all. If we fail to obtain a supplier for the components of our products, our operations could be disrupted.

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

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

We may not be able to maintain insurance on acceptable terms, or at all. We could be required to incur significant costs to comply with current or future environmental and public and workplace safety and health laws and regulations.

We 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.

Risks relating to our Intellectual Property and Regulatory Approval

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

Our potential revenue and 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.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

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 protection litigation is time-consuming and we have incurred significant legal costs. 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.

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

We also utilize certain unpatented proprietary technology.

We may incur impairment charges on our goodwill and other intangible assets with indefinite lives that would reduce our earnings.

We are subject to Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets, (SFAS 142) which requires that goodwill and other intangible assets that have an indefinite life be tested at least annually for impairment. Goodwill and other intangible assets with indefinite lives must also be tested for impairment between the annual tests if a triggering event occurs that would likely reduce the fair value of the asset below its carrying amount. As of July 31, 2008, goodwill and other intangible assets with indefinite lives represented approximately 25% of our total assets. If we determine that there has been impairment, our financial results for the relevant period would be reduced by the amount of the impairment, net of tax effects, if any.

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

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

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

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

Significant delays in obtaining or failing to obtain required approvals;

Loss of, or changes to, previously obtained approvals;

Failure to comply with existing or future regulatory requirements; and

Changes to manufacturing processes, manufacturing process standards or Good Manufacturing Practices following approval or changing interpretations of these factors.

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

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

Risks relating to our Clinical Labs services segment

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

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

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

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

The health care industry continues to undergo significant change as third-party payers increase their efforts to control the cost, utilization and delivery of health care services. In an effort to address the problem of increasing health care costs, legislation has been proposed or enacted at both the Federal and state levels to regulate health care delivery in general and clinical laboratories in particular. Some of the proposals include managed competition, global budgeting and price controls. Changes that decrease reimbursement rates or coverage, or increase administrative burdens on billing third-party payers could reduce our revenues and increase our expenses.

Changes in provider mix, including a continued growth in capitated managed-cost health care and changes in certain third party provider agreements could have a material adverse impact on the Company's net revenues and profitability.

Certain third party provider companies have adopted national and regional programs which include multiple managed-care reimbursement models. If the Company is unable to participate in these programs or if the Company would lose a material contract, it could have a material adverse impact on the Company's net revenues and profitability.

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

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

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

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

Containment of health care costs, including reimbursement for clinical laboratory services, has been a focus of ongoing governmental activity. Clinical laboratories must bill Medicare directly for the services provided to Medicare beneficiaries and may only collect the amounts permitted under this fee schedule. Reimbursement to clinical laboratories under the Medicare Fee Schedule has been steadily declining since its inception. Furthermore, Medicare has mandated use of the Physicians Current Procedural Terminology, or CPT, for coding of laboratory services which has altered the way we bill these programs for some of our services, thereby reducing the reimbursement that we receive.

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

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

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

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

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

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

the circumstances under which uses and disclosures of protected health information are permitted or required without a specific authorization by the patient, including but not limited to treatment purposes, activities to obtain payments for our services, and our healthcare operations activities;

a patient's rights to access, amend and receive an accounting of certain disclosures of protected health information;

the content of notices of privacy practices for protected health information; and

administrative, technical and physical safeguards required of entities that use or receive protected health information.

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

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

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

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

In the past, the clinical laboratory industry has received negative publicity. This publicity has led to increased legislation, regulation, and review of industry practices. These factors may adversely affect our ability to market our services, require us to change our services and increase the regulatory burdens under which we operate, further increasing the costs of doing business and adversely affecting our operating results. If we experience a significant disruption in our information technology systems, including our website, or if we fail to implement new systems and software successfully, our business could be adversely affected.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

We depend on information systems throughout our Company to control our Life Science manufacturing, distribution and website and the Clinical Lab processes for: processing orders, managing inventory, processing shipments to and collecting cash from our customers, responding to customer inquiries, contributing to our overall internal control processes, maintaining records of our property, plant and equipment, and recording and pay amounts due vendors and other creditors. If we were to experience a prolonged disruption in our information systems that involve interactions with customers and suppliers, it could result in the loss of sales and customers and/or increased costs, which could adversely affect our business.

If we fail to attract and retain key personnel, including our senior management, our business could be adversely affected.

Most of our products and services are highly technical in nature. In general, only highly qualified and trained scientists and technician personnel have the necessary skills to develop proprietary technological products and market our products, support our research and development programs and provide our Clinical Lab services. In addition, some of our manufacturing, quality control, safety and compliance, information technology and e-commerce related positions are highly technical as well. Further, our sales personnel highly trained and are important to retaining and growing our businesses. Our success depends in large part upon our ability to identify, hire, retain and motivate highly skilled professionals.

We face intense competition for these professionals from our competitors, customers, marketing partners and other companies throughout the industries in which we compete. Since our inception an insignificant number of key employees have left us. Any failure on our part to hire, train, and retain a sufficient number of qualified professionals would seriously damage our business.

We depend heavily on the services of our senior management. We believe that our future success depends on the continued services of such management. Our business may be harmed by the loss of a significant number of our senior management in a short period of time.

The insurance we purchase to cover our potential business risk may be inadequate.

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

Risks relating to our international operations

Foreign currency exchange rate fluctuations may adversely affect our business.

Since we operate as a multinational corporation that sells and sources products in many different countries, changes in exchange rates could in the future, adversely affect our cash flows and results of operations. Furthermore, reported sales and purchases made in non-U.S. currencies by our international businesses, when translated into U.S. dollars for financial reporting purposes, fluctuate due to exchange rate movement. Due to the number of currencies involved, the variability of currency exposures and the potential volatility of currency exchange rates, we cannot predict the effect of exchange rate fluctuations on future sales and operating results.

We are subject to economic, political and other risks associated with our significant international business, which could adversely affect our financial results.

We operate internationally primarily through wholly-owned subsidiaries located in North America and Europe. Revenues outside the United States were approximately 25% of total revenues in fiscal 2008. We expect that sales from international operations will continue to represent a growing portion of our sales as a result of the May 2008 acquisition of Biomol. Our sales and earnings could be adversely affected by a variety of factors resulting from our international operations, including:

- future fluctuations in exchange rates,
- complex regulatory requirements and changes in those requirements,
- trade protection measures and import or export licensing requirements,
- multiple jurisdictions and differing tax laws, as well as changes in those laws,

restrictions on our ability to repatriate investments and earnings from foreign operations,

31

changes in the political or economic conditions in a country or region, particularly in developing or emerging markets, changes in shipping costs, and difficulties in collecting on accounts receivable.

If any of these risks materialize, we could face substantial increases in costs, the reduction of profit and the inability to do business.

Risks Relating to our Common Stock

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

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

fluctuations in our quarterly operating and earnings per share results;

the gain or loss of significant contracts;

loss of key personnel;

announcements of technological innovations or new products by us or our competitors;

delays in the development and introduction of new products;

legislative or regulatory changes;

general trends in the industries we operate;

recommendations and/or changes in estimates by equity and market research analysts;

biological or medical discoveries;

disputes and/or developments concerning intellectual property, including patents and litigation matters;

public concern as to the safety of new technologies;

sales of common stock of existing holders;

securities class action or other litigation;

developments in our relationships with current or future customers and suppliers; and

general economic conditions, both in the United States and worldwide.

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

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

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

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

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

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

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

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

a staggered board of directors, so that it would take three successive annual meetings to replace all directors; and

advance notice requirements for the submission by stockholders of nominations for election to the board of directors and for proposing matters that can be acted upon by stockholders at a meeting.

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

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

Item 1B. Unresolved Staff Comments

None

Item 2. Properties

The following are the principal facilities of the Company:

<u>Location</u>	<u>Primary use</u>	<u>Segments</u>	<u>Leased/owned</u>	<u>Square footage</u>
Farmingdale, NY	Clinical laboratory and research (Note 1 below)	Clinical Labs, Therapeutics	Leased	43,000
Farmingdale, NY	Manufacturing, research, Sales and administrative offices	Life Sciences, Other	Owned	22,000
New York, NY	Corporate headquarters	Other	Leased	6,400
San Diego, CA (Note 2)	Sales, administration, and distribution	Life Sciences	Leased	8,800
Lausen, Switzerland (Note 2)	Operational headquarters in Europe, including sales, warehouse and distribution	Life Sciences	Leased	15,400
Epalinges, Switzerland (Note 2)	Manufacturing and research and development	Life Sciences	Leased	2,100
Plymouth Meeting, Pa. (Note 3)	Sales, manufacturing, research, administration, and distribution	Life Sciences	Leased	19,500
Exeter, United Kingdom (Note 3)	Sales, manufacturing, research, administration, and distribution	Life Sciences	Leased	3,642

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Note 1 - In March 2005, the Company amended and extended the lease for its Farmingdale laboratory for a period of 12 years.

Note 2 The leases for these properties were acquired in connection with the Axxora acquisition in May 2007.

Note 3 The leases for these properties were acquired in connection with the Biomol acquisition in May 2008.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

We believe the current facilities are suitable and adequate for the Company's current operating needs for its clinical laboratories, life science and therapeutics segments, and that the production capacity in various locations is sufficient to manage product requirements.

Item 3. Legal Proceedings

In October 2002, the Company filed suit in the United States District Court of the Southern District of New York against Amersham plc, Amersham Biosciences, Perkin Elmer, Inc., Perkin Elmer Life Sciences, Inc., Sigma-Aldrich Corporation, Sigma Chemical Company, Inc., Molecular Probes, Inc. and Orchid Biosciences, Inc. In January 2003, the Company amended its complaint to include defendants Sigma Aldrich Co. and Sigma Aldrich, Inc. The counts set forth in the suit are for breach of contract; patent infringement; unfair competition under state law; unfair competition under federal law; tortious interference with business relations; and fraud in the inducement of contract. The complaint alleges that these counts arise out of the defendants' breach of distributorship agreements with the Company concerning labeled nucleotide products and technology, and the defendants' infringement of patents covering the same. In April, 2003, the court directed that individual complaints be filed separately against each defendant. The defendants have answered the individual complaints and asserted a variety of affirmative defenses and counterclaims. Fact discovery is ongoing. The court issued a claim construction opinion on July 10, 2006. The Company and Sigma Aldrich (Sigma) entered into a Settlement Agreement and Release effective September 15, 2006 (the Agreement). Pursuant to the Agreement, the Company's litigation with Sigma was dismissed and the Company recognized \$2 million on settlement in the quarter ending October 31, 2006 (See Note 13). On January 3, 2007, the remaining defendants moved for summary judgment on all counts in the individual complaints. During a two-day hearing held on July 17 through July 18, 2007, the defendants subsequently withdrew the invalidity portion of their summary judgment motions. The court has yet to rule on the pending summary judgment motions. There can be no assurance that the Company will be successful with the remaining outstanding litigation. However, even if the Company is not successful, management does not believe that there will be a significant adverse monetary impact to the Company. The Company has not recorded revenue under these distribution agreements in fiscal 2008, 2007 and 2006. The Company recorded other income from Perkin Elmer in fiscal 2007 (See Note 13).

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

Affymetrix also moved to transfer venue of Enzo's action to the Southern District of New York, where other actions commenced by Enzo were pending as well as Affymetrix's subsequently filed action. On January 30, 2004, Affymetrix's motion to transfer was granted. Accordingly, the Enzo and Affymetrix actions are now both pending in the Southern District of New York. Initial pleadings have been completed and discovery has commenced. The Court issued a Markman (claim construction) opinion on July 10, 2006. The Company did not record any revenue from Affymetrix during the fiscal years ended July 31, 2008, 2007 or 2006.

On June 2, 2004, Roche Diagnostic GmbH and Roche Molecular Systems, Inc. (collectively Roche) filed suit in the U.S. District Court of the Southern District of New York against Enzo Biochem, Inc. and Enzo Life Sciences, Inc. (collectively Enzo). The Complaint was filed after Enzo rejected Roche's latest cash offer to settle Enzo's claims for, *inter alia*, alleged breach of contract and misappropriation of Enzo's assets.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

The Complaint seeks declaratory judgment (i) of patent invalidity with respect to Enzo's 4,994,373 patent (the '373 patent'), (ii) of no breach by Roche of its 1994 Distribution and Supply Agreement with Enzo (the '1994 Agreement'), (iii) that non-payment by Roche to Enzo for certain sales of Roche products does not constitute a breach of the 1994 Agreement, and (iv) that Enzo's claims of ownership to proprietary inventions, technology and products developed by Roche are without basis. In addition, the suit claims tortious interference and unfair competition. The Company does not believe that the Complaint has merit and intends to vigorously respond to such action with appropriate affirmative defenses and counterclaims. Enzo filed an Answer and Counterclaims on November 3, 2004 alleging multiple breaches of the 1994 Agreement and related infringement of Enzo's '373 patent. Discovery has commenced. The Court issued a Markman opinion on July 10, 2006. The Company did not record any revenue from Roche during the fiscal years ended July 31, 2008, 2007 or 2006. The Roche agreement remains in force to date.

On June 7, 2004, the Company and Enzo Life Sciences, Inc., filed suit in the United States District Court for the District of Connecticut against Applera Corporation and its wholly-owned subsidiary Tropic, Inc. The complaint alleges infringement of six patents (relating to DNA sequencing systems, labeled nucleotide products, and other technology). Yale University is the owner of four of the patents and the Company is the exclusive licensee. These four patents are commonly referred to as the 'Ward' patents. Accordingly, Yale is also a plaintiff in the lawsuit. Yale and Enzo are aligned in protecting the validity and enforceability of the patents. Enzo Life Sciences is the owner of the remaining two patents. The complaint seeks permanent injunction and damages (including treble damages for willful infringement). Defendants answered the complaint on July 29, 2004. The answer pleads affirmative defenses of invalidity, estoppels and laches and asserts counterclaims of non-infringement and invalidity. A Markman hearing was held on May 25, 2006 and the district court issued a ruling on October 12, 2006. On August 17, 2007, the Company voluntarily dismissed the infringement claims for one of the patents in suit without prejudice. Defendants similarly dismissed their defenses and counterclaims as to that patent. On the same date, the Company conceded a judgment of non-infringement for another of the patents in suit based on the district court's claim construction, reserving the right to appeal their construction. The defendants filed motions for summary judgment for invalidity, laches and non-infringement of the 'Ward' patents on March 5, 2007. The Company and other plaintiff filed a motion for summary judgment on infringement of the 'Ward' patents on March 5, 2007. On August 20, 2007, the district court heard oral arguments on the motions for summary judgment. On September 6, 2007, the court granted defendants' motion for summary judgment of invalidity of three of the remaining 'Ward' patents and entered judgment to that effect. The Company and other plaintiff filed a notice of appeal to the United States Court of Appeals for the Federal Circuit on September 7, 2007. On January 30, 2008, the Court of Appeals for the Federal Circuit granted the Company's alternative motion to dismiss its appeal and remand to the Connecticut Court for further proceedings incident to an entry of a final, appealable judgment. The Company has requested the Connecticut Court to dispose of all outstanding issues (including the Company's claim under the fourth 'Ward' patent and certain counterclaims of Applera's) and enter final judgment. Once the Connecticut Court does this, the Company intends to appeal that judgment. The Company and other plaintiff intend to vigorously pursue this appeal; however, the outcome of the appeal cannot be anticipated at this time. If the appeal is granted, there can be no assurance that the Company will be successful in this litigation. Even if the Company is not successful, management does not believe that there will be a significant adverse monetary impact on the Company.

In January 2006, the Company was named along with certain of its officers and directors among others, in several complaints titled Francis Scott Hunt, et al. v. Enzo Biochem Inc., et al., Index No. 06-CV-00170 (SAS) and Ken Roberts v. Enzo Biochem, Inc. et al., Index No. 06-CV-00213 (SAS), and Paul Lewicki v. Enzo Biochem Inc., et al., Index No. 06-CV-06347 (SAS) based only upon a claim for common law fraud. These three consolidated actions were all filed in the United States District Court for the Southern District of New York. In their amended complaints, plaintiffs collectively seek more than \$8.0 million in damages. Limited discovery has occurred to date. The actions are all based on allegations of a fraudulent scheme to pump and dump Enzo securities as was initially set forth in a previous action (filed by the same attorney) which was dismissed by the Eastern District of Virginia and such dismissal was affirmed by the Fourth Circuit Court of Appeals and is now final since the U.S. Supreme Court denied a petition for certiorari. The Company and the other defendants likewise moved to dismiss all of the Complaints in these actions and that motion was granted by U.S. District Court. As a result, some of the Plaintiffs were no longer able to pursue their claims or choose not to pursue them further. Other Plaintiffs amended their Complaints and the Company and the other defendants moved again to dismiss those Amended Complaints. The Court recently granted in part and denied in part those motions. As a result of the Court's latest decision, however, certain of the defendants, including Enzo Biochem, Inc. are proceeding with discovery. The Company believes that the latest Complaints in these actions have no merit, and intends to move for summary judgment and otherwise to defend these actions vigorously.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

The Company is party to other claims, legal actions and complaints that arise in the ordinary course of business. The Company believes that any liability that may ultimately result from the resolution of these matters will not, individually or in the aggregate, have a material adverse effect on its financial position or results of operations.

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

No matters were brought to a vote of the Company's stockholders in the fourth fiscal quarter ended July 31, 2008.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

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

2007 Fiscal Year (August 1, 2006 to July 31, 2007):

	<u>High</u>	<u>Low</u>
1st Quarter	\$ 14.68	\$ 11.14
2nd Quarter	\$ 16.00	\$ 13.55
3rd Quarter	\$ 17.44	\$ 13.76
4th Quarter	\$ 17.31	\$ 12.44

2008 Fiscal Year (August 1, 2007 to July 31, 2008):

	<u>High</u>	<u>Low</u>
1st Quarter	\$ 18.65	\$ 11.34
2nd Quarter	\$ 14.23	\$ 9.36
3rd Quarter	\$ 10.16	\$ 7.74
4th Quarter	\$ 14.21	\$ 8.71

As of September 26, 2008, the Company had approximately 1,028 stockholders of record of its common stock.

The Company has not paid a cash dividend on its common stock and intends to continue a policy of retaining earnings to finance and build its operations. Accordingly, the Company does not anticipate the payment of cash dividends to holders of common stock in the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth information regarding our existing equity compensation plans as of July 31, 2008.

<u>Plan Category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights</u> (a)	<u>Weighted-average exercise price of outstanding options, warrants and rights</u> (b)	<u>Number of securities remaining available for future issuances under equity compensation plans (excluding securities reflected in column (a))</u> (c)
Equity compensation plans approved by security holders	2,495,656	\$13.06	588,000
Equity compensation plans not approved by security holders			

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Total	2,495,656	\$13.06	588,000
-------	-----------	---------	---------

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Item 6. Selected Financial Data

The following table, which is derived from the audited consolidated financial statements of the Company for the fiscal years 2004 through 2008 should be read together with the discussion in Management's Discussion and Analysis of Financial Condition and Results of Operations and the Company's consolidated financial statements and notes to those statements included elsewhere in this Annual Report on Form 10-K.

Operating Results (1)	For the fiscal year ended July 31, (In thousands, except per share amounts)				
	2008	2007	2006	2005	2004
Operating revenues	\$ 77,795	\$ 52,908	\$ 39,826	\$ 43,403	\$ 41,644
Other income	198	2,699		14,000	
Interest income	3,696	5,092	3,144	1,523	1,152
(Loss) income before income taxes	(10,892)	(13,175)	(17,009)	5,217	(11,080)
Benefit (Provision) for income taxes	239	(85)	1,342	(2,213)	4,848
Net loss	\$ (10,653)	(13,260)	\$ (15,667)	\$ 3,004	\$ (6,232)
Basic net (loss) income per common share: (2)	\$ (0.29)	\$ (0.38)	\$ (0.49)	\$ 0.09	\$ (0.20)
Diluted net (loss) income per common share: (2)	\$ (0.29)	\$ (0.38)	\$ (0.49)	\$ 0.09	\$ (0.20)
Weighted average common shares					
Basic	36,883	35,017	32,215	32,097	31,700
Diluted	36,883	35,017	32,215	32,763	31,700

Financial Position:	July 31, (in thousands)				
	2008	2007	2006	2005	2004
Working capital	\$ 92,392	\$ 113,850	\$ 80,161	\$ 96,280	\$ 92,259
Total assets	154,522	159,002	101,524	116,466	110,334
Long term obligations				150	300
Stockholders' equity	138,289	141,894	95,587	108,267	104,166

Notes to Selected Financial Data

- (1) See Note 2 in the notes to consolidated financial statements regarding the acquisitions in Fiscal 2008 and 2007.
- (2) Effective August 1, 2005, the Company adopted the fair value recognition provisions of SFAS No. 123(R) using the modified prospective application method. The impact of the adoption, increased basic and diluted net loss per common share by

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

\$0.01, \$0.02 and \$0.05 for the fiscal years ended July 31, 2008, 2007 and 2006, respectively.

37

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

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

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

We are comprised of three operating companies that have evolved out of our 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 reportable segments. Below are brief descriptions of each of the three operating segments (see Note 17 in the notes to consolidated financial statements):

Enzo Life Sciences is a company that manufactures, develops and markets biomedical research products and tools to research and pharmaceutical customers around the world and has amassed a large patent and technology portfolio. The company's sources of revenue have been from the direct sales of products consisting of labeling and detection reagents for the genomics and sequencing markets, as well as through non-exclusive distribution agreements with other companies, and royalty and licensing fee income. The pioneering platforms developed by Enzo Life Sciences enable the development of a wide range of products in the research products marketplace. The division is internationally recognized and acknowledged for its manufacturing, in-licensing, and commercialization of over 8,000 innovative high quality research reagents in key research areas. The division is an established source for a comprehensive panel of products to scientific experts in the fields of gene expression, non-radioactive labeling and detection, adipokines and obesity, apoptosis, bioactive lipids, cell cycle, cytoskeletal research, DNA damage and repair, epigenetic immunology and cancer research, inflammation, neurobiology, nitric oxide & oxidative stress, and signal transduction.

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 23 patient service centers, a stand alone stat or rapid response laboratory in New York City, and a full-service phlebotomy department. Payments for clinical laboratory testing services are made by the Medicare program, healthcare insurers and patients. Fees billed to patients, Medicare, and third party payers are billed on the laboratory's standard gross fee schedule, subject to any limitations on fees negotiated with the third party payers or with the ordering physicians on behalf of their patients.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

The following table summarizes the sources of revenues for the fiscal years ended July 31, 2008, 2007 and 2006, (in \$000 s and percentages):

Fiscal year ended July 31,	2008		2007		2006	
Product revenues	\$ 28,087	36%	\$ 6,658	13%	\$ 4,750	12
Royalty and license fees	7,630	10	5,820	11	3,150	8
Clinical laboratory services	42,078	54	40,430	76	31,926	80
Total	\$ 77,795	100%	\$ 52,908	100%	\$ 39,826	100

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

Information systems are used extensively in virtually all aspects of the clinical laboratory operations, including testing, billing, customer service, logistics, and management of medical data. Our success depends, in part, on the continued and uninterrupted performance of our information technology systems. Through maintenance, staffing, and investments in our information technology system, we expect to limit the risk associated with our heavy reliance on these systems.

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

Recent Developments

Biomol International L.P.

On May 8, 2008, Enzo Life Sciences, Inc. acquired substantially all of the U.S. based assets and certain liabilities of Biomol International, LP (Biomol LP) through a newly formed US subsidiary Biomol International, Inc. and all of the stock of Biomol s wholly-owned United Kingdom subsidiary, Affinity Limited by Axxora UK, a wholly-owned subsidiary of Enzo Life Sciences, collectively referred to as Biomol for approximately \$18.1 million in cash and stock, subject to adjustment, exclusive of acquisition costs of approximately \$800,000 and contingent payments which will be accounted for as additional purchase consideration over the next two years if and when the contingencies are resolved beyond a reasonable doubt. At closing, the purchase price was satisfied as follows: \$12.9 million in cash was paid to Biomol LP, issuance of 352,000 shares of Enzo common stock, at fair market value, to Biomol LP, \$1.5 million in cash was paid to an escrow agent for the one-year period following the closing to satisfy any indemnification obligations of the sellers under the Agreement and \$550,000 was paid to an escrow agent, for the 60 day period following the closing to satisfy any specified purchase price adjustments. The \$550,000 was released by the escrow agent in August 2008. The earn-outs of \$2.5 million on each of the next two anniversaries of the acquisition date will be based on attaining certain revenue targets and EBITDA, as defined. Biomol was a privately owned, closely held global manufacturer and marketer of specialty life sciences research products. Effective May 8, 2008, Biomol became a wholly-owned subsidiary of Enzo Life Sciences. The acquisition was financed with the Company s cash and cash equivalents and Enzo common stock. The consolidated financial statements presented herein include the results of operations for Biomol from the date of acquisition.

Results of OperationsComparative Financial Data for the Fiscal Years Ended July 31,
(in 000 s)

	2008	Increase (Decrease)	% Change	2007	Increase (Decrease)	% Change	2006
Revenues:							
Product revenues	\$ 28,087	\$ 21,429	322	\$ 6,658	\$ 1,908	40	\$ 4,750
Royalty and license fee income	7,630	1,810	31	5,820	2,670	85	3,150
Clinical laboratory services	42,078	1,648	4	40,430	8,504	27	31,926
Total revenue	77,795	24,887	47	52,908	13,082	33	39,826
Costs and expenses and other (income):							
Cost of product revenues	19,159	14,125	281	5,034	2,634	110	2,400
Cost of laboratory services	21,063	2,864	16	18,199	4,282	31	13,917
Research and development	8,637	(756)	(8)	9,393	1,497	19	7,896
Selling, general and administrative	34,418	8,118	31	26,300	1,555	6	24,745
Provision for uncollectible accounts receivables	3,716	(937)	(20)	4,653	1,020	28	3,633
Legal expenses	5,588	(4,707)	(46)	10,295	2,907	39	7,388
Interest income	(3,696)	1,396	27	(5,092)	(1,948)	62	(3,144)
Other income	(198)	2,501	93	(2,699)	(2,699)		
Total costs and expenses	88,687	22,604	34	66,083	9,248	16	56,835
(Loss) before income taxes	\$ (10,892)	\$ 2,283		\$ (13,175)	\$ 3,834		\$ (17,009)

*Fiscal 2008 Compared to Fiscal 2007***Consolidated Results**

The 2008 period and the 2007 period refer to the fiscal years ended July 31, 2008 and 2007, respectively. The 2008 period includes the full year results of Axxora which was acquired on May 31, 2007 and the results of Biomol from the May 8, 2008, date of acquisition, to July 31, 2008.

Product revenues during the 2008 period were \$28.1 million compared to \$6.7 million in the year ago period, an increase of \$21.4 million or 322%. The 2008 period increase is primarily due to the contribution of product revenues from the Axxora and Biomol acquisitions.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Royalty and license fee income during the 2008 period was \$7.6 million compared to \$5.8 million in the 2007 period, an increase of \$1.8 million or 31%. Royalties are earned from the reported net sales of Qiagen products subject to a license and from a License Agreement with Abbott which was entered into in the third quarter of fiscal 2007. During the 2008 period, the Company recognized royalties of approximately \$5.5 million from Qiagen, an increase of approximately \$0.7 million over the prior year ago period, and royalties and license fees under the Abbott License Agreement of approximately \$2.1 million, an increase of approximately \$1.1 million over the year ago period. There are no expenses relating to royalty and license fee income.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Clinical laboratory revenues during the 2008 period were \$42.1 million compared to \$40.4 million in the 2007 period, an increase of \$1.7 million or 4%. The Company experienced an increase in service revenues during the 2008 period primarily due to an expansion of an insurance provider agreement with United Healthcare which occurred in January 2007, which was partially offset by an increase in the contractual adjustment, which reduced gross billings by 81.8% as compared to 79.0% in the 2007 period. The increase in the contractual adjustment is due to continued competitive pricing throughout the industry which has negatively impacted reimbursement rates for tests and an increase in revenue mix from lower paying insurance providers.

The cost of product revenues during the 2008 period was \$19.1 million compared to \$5.0 million in the 2007 period, an increase of \$14.1 million. The increase is primarily due to the full year impact of Axxora's and the partial period of Biomol's cost of product revenues of approximately \$13.0 million and \$1.6 million, respectively for the 2008 period, which includes the impact of an inventory fair value adjustment of \$2.0 million related to sales of inventory acquired from Axxora and Biomol offset by decreases at Enzo Life Sciences - New York.

The cost of clinical laboratory services during the 2008 period was \$21.1 million as compared to \$18.2 million in the prior period, an increase of \$2.9 million or 16%. Due to the increased volume of patients serviced and tests performed, the Company incurred increased costs primarily relating to reagent costs of \$1.4 million, laboratory personnel costs of \$1.1 million, outside reference lab costs of \$0.1 million, and other related laboratory costs of \$0.2 million.

Research and development expenses were approximately \$8.6 million during the 2008 period, compared to \$9.4 million in the 2007 period, a decrease of \$0.8 million or 8%. The decrease was due to a decrease of \$0.9 million relating to the timing of clinical trial and related activities at the Therapeutics segment, a decrease of \$0.3 million in research supplies and related costs at Enzo Life Sciences - New York, offset by the increase in research and development incurred by Axxora and Biomol of \$0.4 million.

Selling, general and administrative expenses were approximately \$34.4 million during the 2008 period as compared to \$26.3 million in the 2007 period, an increase of \$8.1 million or 31%. Included in the 2008 period is approximately \$6.8 million of selling, general and administrative expenses increases related to the full year of Axxora and Biomol expenses from the date of acquisition. The increase in the other Companies' operations of approximately \$1.5 million was primarily due to payroll and payroll related costs of \$1.8 million and professional fees of \$0.3 million offset by a decrease in information technology costs of \$0.3 million and a decrease in insurance costs of \$0.3 million.

The provision for uncollectible accounts receivable, primarily relating to the clinical laboratory segment was \$3.7 million for the 2008 period as compared to \$4.6 million in the 2007 period, the decrease of \$0.9 million or 20% was due to improved billing and collections procedures.

Legal expense was \$5.6 million during the 2008 period compared to \$10.3 million in the 2007 period, a decrease of \$4.7 million or 46%, due to a decrease in patent litigation activity in the current period.

Interest income was \$3.7 million during the 2008 period as compared to \$5.1 million during the 2007 period. The Company earns interest by investing primarily in short term and liquid investments, including money market accounts, commercial paper and US government instruments. The Company had higher average invested balances during the 2007 period due to the net proceeds from registered direct offerings of common stock in December 2006 and February 2007 offset by uses of cash for operations and the acquisition of Axxora in May 2007. The 2008 period's invested cash was reduced by the use of \$15.0 million of cash to purchase Biomol in May 2008 and by the use of cash to fund operations. Further, interest income decreased during the 2008 period because the rates declined in response to monetary policy actions taken by the U.S. Federal Reserve.

The Company earned other income of \$0.2 million during the 2008 period versus \$2.7 million in the 2007 period. During the 2007 period, the Company recognized a \$2.0 million gain on a patent litigation settlement and a \$0.7 million payment from a former distributor under an expired distribution agreement which is presently subject to a lawsuit in which the Company is plaintiff.

The Company's effective tax rate (benefit) provision for the 2008 period was 2.2%, compared to (1.0%) during the 2007 period. The tax benefit for the 2008 period was based on state and local taxes, book to tax differences for inventory acquired from Axxora, and taxes and interest incurred from a local tax audit and differed from the expected net operating loss carry forward benefit at the U.S. federal statutory rate of 34% primarily due to the inability to recognize such benefit. The carry forward benefit cannot be recognized because of uncertainties relating to future taxable income, in terms of both its timing and its sufficiency.

The tax provision for the 2007 period was based on state and local taxes, and differed from the expected net operating loss benefit at the U.S. federal statutory rate of 34% primarily due the inability to recognize such benefit. The carry forward benefit cannot be recognized because of uncertainties relating to future taxable income, in terms of both its timing and its sufficiency, which would enable the Company to realize the federal carry forward benefit.

Segment Results

The Life Sciences segment's income before taxes was approximately \$3.4 million for the 2008 period as compared to \$4.0 million in the 2007 period. The decrease is partially due to the recognition in the 2007 period of the Company's \$2.0 million patent litigation settlement with Sigma Aldrich and a \$0.7 million payment from a former distributor under an expired distribution agreement which is presently subject to a lawsuit in which the Company is plaintiff. Product revenues increased by \$21.4 million in the 2008 period due to the contribution of products revenues from Axxora for the full year in 2008 as compared to the two months in 2007 and the Biomol acquisition from the date of acquisition. Royalty and license fee income increased \$1.8 million from the existing Qiagen agreement and the Abbott License Agreement entered into in the third quarter of fiscal 2007. The segment's gross margin of \$16.6 million was negatively impacted by \$2.0 million representing the fair value adjustment attributed to the sale of inventory acquired from Axxora and Biomol. The remaining fair value adjustment attributed to inventory acquired from Biomol of \$1.4 million will negatively impact gross margins through May 2009.

Segment operating expenses, including selling, general and administrative and research and development, increased by approximately \$7.1 million during the 2008 period primarily due to the inclusion of Axxora's and Biomol's expenses.

The Clinical Laboratory segment's income before taxes was \$2.0 million for the 2008 period as compared to \$3.3 million in the 2007 period. The 2008 period was positively impacted by an increase in laboratory service revenues of \$1.6 million or 4%, due to the expansion of an insurance provider agreement effective January 2007. The gross profit was negatively impacted by an increase in the cost of laboratory services of \$2.9 million as compared to the 2007 period. In the 2008 period the selling, general and administrative costs increased by approximately \$1.1 million due primarily due to increases in sales commissions of \$0.3 million and payroll and payroll related costs of \$0.7 million, attributable to the increase in service revenues. The provision for uncollectible accounts receivables decreased by \$1.0 million due to improved billing and collection procedures. The segment also earned interest in the 2008 period of \$0.2 million on its cash generated by operations.

The Therapeutics segment's loss before income taxes was approximately \$5.0 million for the 2008 period as compared to a loss of \$6.0 million for the 2007 period. The decrease in the loss of \$1.0 million was primarily due to decreases in clinical trial activities, consulting, payroll and payroll related costs of \$0.9 million, and the recognition of \$0.1 million from a government grant, included in other income in the consolidated financial statements.

The Other segment's loss before taxes for the 2008 period was approximately \$11.3 a decrease of \$3.1 million as compared to \$14.4 in the 2007 period. The Other segment's 2008 period loss reflects a decrease in legal expenses of \$4.9 million due to a decrease in patent litigation activity in the current period compared to the 2007 period, partially offset by an increase in general and administrative expenses of \$0.2 million, and a decrease in interest income of \$1.5 million due to lower levels of cash available for investment and declining interest rates.

Fiscal 2007 Compared to Fiscal 2006

Consolidated Results

Enzo Life Sciences product revenues during fiscal 2007 were \$6.7 million compared to \$4.8 million in the year ago period, an increase of \$1.9 million or 40%. The increase is due to the inclusion of Axxora product sales of \$3.3 million for the two months ended July 31, 2007 partially offset by a decline of \$1.4 million in the year over year sales of Enzo Life Sciences New York (New York) products due to a decline in unit shipments and the continuing competitiveness in the industry.

Royalty and license fee income during fiscal 2007 was \$5.8 million compared to \$3.2 million in the year ago period, an increase of \$2.6 million or 85%. Royalties are earned from net sales of Qiagen products subject to a license and from a License Agreement with Abbott which was entered into in the fiscal 2007 third quarter. During fiscal 2007, the Company recognized approximately \$0.9 million in royalties under the license agreement and approximately \$0.1 million of the \$1.5 million upfront payment received from the Abbott License Agreement. There are no expenses relating to royalty and license fee income.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Clinical laboratory revenues during fiscal 2007 were \$40.4 million compared to \$31.9 million in the 2006 period, an increase of \$8.5 million or 27%. The Company experienced an increase in service revenues during the 2007 period primarily due to an expansion of an insurance provider agreement with United Healthcare of New York, Inc., which was partially offset by an increase in the contractual adjustment, which reduces gross billings by 79.0% as compared to 75.2% in the prior period. The increase in the contractual adjustment is due to continued competitive pricing from primary third party payers throughout the industry which has unfavorably impacted reimbursement rates.

The cost of products during the fiscal year ended July 31, 2007 was \$5.0 million compared to \$2.4 million in the 2006 period, an increase of \$2.6 million. The increase is primarily due to the inclusion of Axxora's operations for the two months ended July 31, 2007 including the negative impact of an inventory fair value adjustment of \$0.7 million related to the acquisition of the inventory. Gross profit was also negatively affected during the 2007 period as compared to the 2006 period by the decline in product revenues relating to existing New York products.

The cost of clinical laboratory services during the fiscal year ended July 31, 2007 was \$18.2 million as compared to \$13.9 million in the prior period, an increase of \$4.3 million or 31%. Due to the increased volume of patients serviced and tests performed, the Company incurred increased reagent costs of \$2.4 million, laboratory personnel costs of \$1.0 million, and outside testing costs of \$0.7 million.

Research and development expenses were approximately \$9.4 million during the fiscal year ended July 31, 2007, compared to \$7.9 million in the 2006 period, an increase of \$1.5 million or 19%. The increase was primarily due to increases at the Therapeutic segment in clinical trial activities of \$1.1 million and an increase in payroll and payroll related costs approximating \$0.4 million offset by a decrease of \$0.2 million in research and development supplies.

Selling, general and administrative expenses were approximately \$26.3 million during the fiscal year ended July 31, 2007 as compared to \$24.8 million in the 2006 period, an increase of \$1.6 million. Included in the 2007 period is two months of approximately \$1.0 million of selling and general and administrative expenses related to Axxora's operations. The expense increases for the existing Company operations were in consulting, payroll and payroll related personnel costs of \$1.1 million and information technology costs of \$0.2 million, partially offset by declines in corporate governance and professional fees of \$0.8 million and travel, advertising and promotion expenses of \$0.3 million.

The provision for uncollectible accounts receivable primarily relating to the clinical laboratory segment for the fiscal year ended July 31, 2007 was \$4.6 million, compared to \$3.6 million during the year ago period, an increase of \$1.0 million or 28% and is due to the increase in clinical laboratory revenue of 27% and the resulting increase in receivables and the composition of patients being serviced.

Legal expense was \$10.3 million during the fiscal year ended July 31, 2007 compared to \$7.4 million in the year ago period, an increase of \$2.9 million or 39%, due to an increase in ongoing patent litigation.

Other income was \$2.7 million during the fiscal year ended July 31, 2007 versus \$0 in the year ago period. During the 2007 period, the Company as plaintiff and Sigma Aldrich (Sigma) entered into a Settlement Agreement and Release effective September 15, 2006 (the Settlement Agreement). Pursuant to the Settlement Agreement, the Company's litigation with Sigma was dismissed and the Company recognized a \$2 million gain on patent litigation settlement during the fiscal year ended July 31, 2007. In addition, during the 2007 period, the Company received a payment of \$0.7 million from Perkin Elmer for amounts due under a Distribution Agreement which terminated December 31, 2004. The Distribution Agreement is presently subject to a lawsuit for breach of contract, patent infringement, unfair competition under state law, unfair competition under federal law, tortious interference with business relations, and fraud in the inducement of contract.

Interest income increased by \$2.0 million or 62% to \$5.1 million during the fiscal year ended July 31, 2007 compared to \$3.1 million during the 2006 period, due to an increase in invested cash generated from the proceeds of the issuance of common stock from the Offerings in December 2006 and February 2007. The net cash proceeds from the offerings were \$57.0 million. See Recent Developments and Liquidity and Capital Resources. The Company earns interest by investing primarily in short term (30 to 90 days) commercial paper and money market funds with high credit ratings.

The tax provision for the fiscal year ended July 31, 2007 was principally based on state and local taxes, and because of uncertainties relating to future taxable income, in terms of both its timing and its sufficiency differed from the expected net operating loss carryforward benefit at the U.S. federal statutory rate of 34% primarily due to the inability to recognize such benefit. Due to the uncertainties, the Company increased its valuation allowance primarily relating to the federal net operating loss carryforward benefit generated during fiscal 2007.

The tax benefit for the fiscal year ended July 31, 2006 differed from the expected net operating loss carryforward benefit at the U.S. federal statutory rate of 34% primarily due to limitations on the timing of the recognition of the Company's then available federal tax carryback benefit for taxes paid in prior years. The tax benefit also differed from the expected net operating loss carryforward benefit due to the inability to recognize such benefit. The carryforward benefit could not be recognized because of uncertainties relating to future taxable income, in terms of both its timing and its sufficiency. Also due to the uncertainties, the Company recorded during the first period of the 2006 period a valuation allowance equal to its net deferred tax assets, including the federal net operating loss carryforward benefit generated during the first period of the 2006 period. The Company recorded the valuation allowance as it concluded that it was not more likely than not that its net deferred tax assets would be realized in the foreseeable future based on positive and negative evidence available at the time.

Segment Results

The Life Sciences segment's income before taxes was approximately \$4.0 million for the fiscal year ended July 31, 2007 as compared to a loss of \$0.2 million in the 2006 period. The increase is primarily due to the Company's \$2.0 million patent litigation settlement with Sigma Aldrich, a payment of \$0.7 million from Perkin Elmer for amounts due under a Distribution Agreement which terminated December 31, 2004, and an increase in royalties and license fee income. Revenues from product shipments increased by \$1.9 million due to the inclusion of products sales of \$3.3 million, for the two months, from the acquisition of Axxora, offset by a decrease of \$1.4 million in New York product revenues due to a decline in unit shipments and the continuing competitiveness in the industry. Royalty and license income increased \$2.7 million from the existing Qiagen agreement and the Abbott License Agreement entered into in the fiscal 2007 third quarter. The segment's gross margin was negatively impacted by \$0.7 million representing the fair value adjustment attributed to the sale of inventory acquired from the Axxora acquisition. Segment operating expenses, such as selling, general and administrative, increased by approximately \$0.7 million during the 2007 period due to the inclusion of \$1.0 million of Axxora's expenses for the two months ended July 31, 2007, offset by lower payroll and marketing expenses for the existing operations of the segment. The segment's research and development expenses decreased by \$0.3 million due to lower expenditures for supplies and patent filing costs.

The Therapeutics segment's loss before income taxes was approximately \$6.0 million for the fiscal year ended July 31, 2007 as compared to a loss of \$4.2 million for the 2006 period. The increase in the loss of \$1.8 million was primarily due to increases in clinical trial activities of \$1.1 million and consulting, payroll and payroll related other costs of \$0.4 million.

The Clinical Labs segment's income before taxes was \$3.3 million for the fiscal year ended July 31, 2007 as compared to \$0.1 million in the 2006 period. The 2007 period was positively impacted by an increase in laboratory service revenues of \$8.5 million or 27% due to the expansion of an insurance provider agreement, which increased gross profit by approximately \$4.2 million. The increase in gross profit was offset by an increase in the provision for doubtful accounts for the fiscal year ended July 31, 2007 of approximately \$1.0 million over the year ago period. The increase in the provision for doubtful accounts was attributed to the 27% increase in service revenues and increase in receivables.

The Other segment's loss before taxes for the fiscal year ended July 31, 2007 was approximately \$14.4 million as compared to a loss of \$12.6 million in the 2006 period. The segment's increased loss reflects an increase in general, administrative and legal expenses of \$3.6 million. The increases were primarily attributed to legal costs of \$2.9 million due to ongoing patent litigation. Payroll and personnel related costs of \$1.3 million partially offset by decreases in professional fees and corporate governance expenses of \$0.8 million. The increase in general, administrative and legal expenses was partially offset by an increase in interest income of \$1.8 million due to increased invested cash balances resulting from proceeds from the issuance of common stock in 2007.

Liquidity and Capital Resources

At July 31, 2008, our cash and cash equivalents were \$78.3 million, a decrease of \$26.8 million from cash and cash equivalents at July 31, 2007. We had working capital of \$92.4 million at July 31, 2008 compared to \$113.9 million at July 31, 2007. In 2008, the decrease was primarily due to the use of cash for acquisitions of approximately \$16.1 million, cash used in operations of \$8.6 million and \$3.2 million used for capital expenditures.

Net cash used in operating activities for the year ended July 31, 2008 was approximately \$8.6 million as compared to net cash used in operating activities of \$3.8 million for the year ended July 31, 2007. The increase in net cash used in operating activities in fiscal 2008 of \$4.8 million was due to the net change in operating assets and liabilities, primarily due to changes in accounts receivable, accounts payable, accrued liabilities and deferred revenue, as compared to the prior year and the impact of non cash items offset by the decrease in the net loss of \$2.6 million.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

In fiscal 2008, net cash used in investing activities was approximately \$18.8 million as compared to the fiscal 2007 net cash used of \$18.4 million. Fiscal 2008 uses were primarily due to acquisitions of \$16.1, which is principally related to the acquisition of Biomol International LP and subsidiary of \$15.9 million, inclusive of acquisition costs, and capital expenditures of approximately \$3.2 million offset by \$1.1 million proceeds from the termination of officers life insurance policies. In fiscal 2007, the use of cash in investing activities was attributed to acquisitions and capital expenditures.

In fiscal 2008, net cash provided by financing activities was approximately \$0.5 million as compared to \$57.5 million in fiscal 2007 primarily as a result of the proceeds from the issuance of common stock of \$57.0 million in fiscal 2007.

We believe that our current cash and cash equivalents are sufficient for our foreseeable liquidity and capital resource needs over the next 12 months, although there can be no assurance that future events will not alter such view. The Company investment policy limits investments to short-term, low risk and highly liquid instruments, including money market accounts and funds, commercial paper and US government instruments.

Effect of New Accounting Pronouncements

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (SFAS No. 162). SFAS No. 162 is intended to improve financial reporting by identifying a consistent framework, or hierarchy, for selecting accounting principles to be used in preparing financial statements that are presented in conformity with generally accepted accounting principles. SFAS No. 162 will become effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. The Company does not anticipate the adoption of SFAS No. 162 will have a material impact on its results of operations, cash flows or financial condition.

In April 2008, the FASB issued FSP FAS 142-3, *Determination of the Useful Life of Intangible Assets* (FSP FAS 142-3). FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No.142, *Goodwill and Other Intangible Assets*. FSP FAS 142-3 also requires expanded disclosure related to the determination of intangible asset useful lives. FSP FAS 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. The Company is currently evaluating the impact that the adoption of FSP FAS 142-3 will have on its consolidated results of operation, cash flows or financial condition.

In December 2007, the FASB issued Statement No. 141 (revised 2007), *Business Combinations* (SFAS No. 141R). SFAS No. 141R establishes principles and requirements for how the acquirer in a business combination recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any controlling interest in the business and the goodwill acquired. SFAS No. 141R further requires that acquisition-related costs and costs associated with restructuring or exiting activities of an acquired entity will be expensed as incurred. SFAS No. 141R also establishes disclosure requirements that will require disclosure of the nature and financial effects of the business combination. SFAS No. 141R will impact business combinations for the Company that may be completed on or after August 1, 2009. The Company cannot anticipate whether the adoption of SFAS No. 141R will have a material impact on its results of operations and financial condition as the impact is solely dependent on the terms of any business combination entered into by the Company on or after August 1, 2009.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

In September 2006, the FASB issued Statement No. 157, Fair Value Measurements (SFAS 157) which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. In February 2008, the FASB issued FASB Staff Position (FSP) No. 157-2, delaying the effective date of SFAS 157 for nonfinancial assets and nonfinancial liabilities, except for items that are recognized or disclosed at fair value on a nonrecurring basis. The delayed portions of SFAS 157 will be adopted by the Company beginning in its fiscal year ending August 1, 2009, while all other portions of the standard will be adopted by the Company beginning in its fiscal year ending August 1, 2008, as required. The Company does not expect that the adoption SFAS 157 will have a material impact on its consolidated results of operations, cash flows or financial condition.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities - Including an amendment of FASB Statement No. 115. SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. The objective of SFAS No. 159 is to provide opportunities to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply hedge accounting provisions. SFAS No. 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. The Company does not expect the impact of the adoption of SFAS No. 159 will have a material impact on its financial condition or results of operations.

Contractual Obligations

The Company has entered into various real estate and equipment operating leases and has employment agreements with certain executive officers. The real estate lease for the Company's Farmingdale Clinical Lab and Research facility is with a related party. See Item 2, Properties, and Note 15 to the Consolidated Financial Statements for a further description of these various leases.

The following is a summary of future payments under the Company's contractual obligations as of July 31, 2008:

In 000 s	<u>Payments Due by Period</u>				
	<u>Total</u>	<u>Less than 1 year</u>	<u>1-3 years</u>	<u>4-5 years</u>	<u>Over 5 years</u>
Real estate and equipment leases	\$ 21,164	\$ 3,947	\$ 6,658	\$ 4,043	\$ 6,516
Employment agreements	\$ 6,305	\$ 2,691	\$ 3,614		
Total contractual cash obligations	\$ 27,469	\$ 6,638	\$ 10,272	\$ 4,043	\$ 6,516

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

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

Critical Accounting Policies

General

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

Product revenues

Revenues from product sales are recognized when the products are shipped and title transfers, the sales price is fixed or determinable and collectibility is reasonably assured. Revenues from these non-exclusive distribution agreements are recognized when shipments are made to their respective customers and reported to the Company. The Company has certain non-exclusive distribution agreements, which provide for consideration to be paid to the distributors for the manufacture of certain products. The Company records such consideration provided to distributors under these non-exclusive distribution agreements as a reduction to product revenues. The Company did not recognize any revenue from these distributors during the years ended July 31, 2008, 2007 and 2006.

Royalties

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

License fees and multiple element arrangements

When evaluating multiple element arrangements, the Company considers whether the components of the arrangement represent separate units of accounting as defined in Emerging Issues Task Force (EITF) Issue No. 00-21, Revenue Arrangements with Multiple Deliverables (EITF 00-21). Application of this standard requires subjective determinations and requires management to make judgments about the fair value of the individual elements and whether such elements are separable from the other aspects of the contractual relationship.

Revenues - Clinical laboratory services

Revenues from the clinical laboratory are recognized upon completion of the testing process for a specific patient and reported to the ordering physician. These revenues and the associated accounts receivable are based on gross amounts billed or billable for services rendered, net of a contractual adjustment, which is the difference between amounts billed to payers and the expected approved reimbursable settlements from such payers.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

The following is a table of the clinical laboratory segment's net revenues and percentages by revenue category for the years ended July 31, 2008, 2007, and 2006:

Revenue category	Year ended July 31 2008		Year ended July 31 2007		Year ended July 31 2006	
	(In 000 s)	(in %)	(In 000 s)	(in %)	(In 000 s)	(in %)
Medicare	\$ 9,078	22	\$ 8,478	21	\$ 7,462	23
Third-party payers	24,768	59	25,060	62	17,680	56
Patient self-pay	3,582	9	2,952	7	4,925	15
HMO s	4,650	10	3,940	10	1,859	6
Total	\$ 42,078	100%	\$ 40,430	100%	\$ 31,926	100%

The Company provides services to certain patients covered by various third-party payers, including the Federal Medicare program. Laws and regulations governing Medicare are complex and subject to interpretation for which action for noncompliance includes fines, penalties and exclusion from the Medicare programs. The Company believes that it is in compliance with all applicable laws and regulations and is not aware of any pending or threatened investigations involving allegations of potential wrongdoing.

Other than the Medicare program, one provider whose programs are included in the Third-party payer and Health Maintenance Organizations (HMO s) categories represented 26% and 20% of the Clinical Labs services net revenues for the fiscal years ended July 31, 2008 and 2007 respectively. Other than the Medicare program, no other provider included in the Third-party payer and HMO s categories exceeded 10% of the Clinical Labs services net revenues for the fiscal year ended July 31, 2006

Contractual Adjustment

The Company's estimate of contractual adjustment is based on significant assumptions and judgments, such as its interpretation of payer reimbursement policies, and bears the risk of change. The estimation process is based on the experience of amounts approved as reimbursable and ultimately settled by payers, versus the corresponding gross amount billed to the respective payers. The contractual adjustment is an estimate that reduces gross revenue, based on gross billing rates, to amounts expected to be approved and reimbursed. Gross billings are based on a standard fee schedule we set for all third party payers, including Medicare, health maintenance organizations (HMO s) and managed care. The Company adjusts the contractual adjustment estimate quarterly, based on its evaluation of current and historical settlement experience with payers, industry reimbursement trends, and other relevant factors. The other relevant factors that affect our contractual adjustment include the monthly and quarterly review of: 1) current gross billings and receivables and reimbursement by payer, 2) current changes in third party arrangements. 3) the growth of in-network provider arrangements and managed care plans specific to our Company.

Our clinical laboratory business is primarily dependent upon reimbursement from third-party payers, such as Medicare (which principally serves patients 65 and older) and insurers. We are subject to variances in reimbursement rates among different third-party payers, as well as constant changes of reimbursement rates. Changes that decrease reimbursement rates or coverage would negatively impact our revenues. The number of individuals covered under managed care contracts or other similar arrangements has grown over the past several years and may continue to grow in the future. In addition, Medicare and other government healthcare programs continue to shift to managed care. These trends will continue to reduce our revenues per test.

During the years ended July 31, 2008, 2007 and 2006, the contractual adjustment percentages, determined using current and historical reimbursement statistics, were 81.8%, 79.0% and 75.2%, respectively, of gross billings. The Company believes the negative impact on revenues from the decline in reimbursement rates or the shift to managed care, other primary third party payers, or similar arrangements may be offset by the positive impact of an increase in the number of tests we perform. However, there can be no assurance that we can increase the number of tests we perform or that if we do increase the number of tests we perform, that we can maintain that higher number of tests performed, or that an increase in the number of tests we perform would result in increased revenue.

The Company estimates (by using a sensitivity analysis) that each 1% point change in the contractual adjustment percentage could result in a change in clinical laboratory services revenues of approximately \$2,316,000, and \$1,930,000 for the years ended July 31, 2008 and 2007, respectively, and a change in the net accounts receivable of approximately \$301,000 and \$387,000 as of

July 31, 2008 and 2007, respectively.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Our clinical laboratory financial billing system records gross billings using a standard fee schedule for all payers and does not record contractual adjustment by payer at the time of billing. Therefore, we are unable to quantify the effect of contractual adjustment recorded during the current period that relate to revenue recorded in a previous period. However, we can reasonably estimate our contractual adjustment to revenue on a timely basis based on our quarterly review process, which includes:

an analysis of industry reimbursement trends;

an evaluation of third-party reimbursement rates changes and changes in reimbursement arrangements with third-party payers;

a rolling monthly analysis of current and historical claim settlement and reimbursement experience with payers;

an analysis of current gross billings and receivables by payer.

Accounts Receivable and Allowance for Doubtful Accounts

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

The following is a table of the Company's net accounts receivable by segment. The Clinical Labs segment's net receivables are detailed by billing category and as a percent to its total net receivables. As of July 31, 2008 and 2007, approximately 58% and 68%, respectively, of the Company's net accounts receivable relates to its Clinical Labs business, which operates in the New York Metropolitan and New Jersey areas. The Life Sciences segment's accounts receivable, of which \$3.3 million or 51% and \$1.8 million or 39% represents foreign receivables as of July 31, 2008 and 2007 respectively, includes royalty receivables of \$2.1 and \$1.8 million, as of July 31, 2008 and 2007, respectively, of which approximately \$1.5 million and \$1.5 million, respectively is from Qiagen Corporation.

Net accounts receivable

Billing category	As of July 31, 2008		As of July 31, 2007	
	(In 000 s)	(in %)	(In 000 s)	(in %)
Clinical Labs				
Medicare	\$ 1,600	18	\$ 1,628	17
Third party payers	4,610	52	5,856	60
Patient self-pay	2,144	24	1,678	17
HMO s	537	6	671	6
Total clinical labs	\$ 8,891	100%	\$ 9,833	100%
Total life sciences	6,457		4,520	
Total accounts receivable	\$ 15,348		\$ 14,353	

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

In 000 s	July 31, 2008	July 31, 2007
Beginning balance	\$ 1,404	\$ 1,033
Provision for doubtful accounts	3,716	4,653
Write-offs, net	(4,234)	(4,282)
Ending balance	\$ 886	\$ 1,404

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

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

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

The allowance for doubtful accounts includes the balances, after receipt of the approved settlements from third party payers for the insufficient diagnosis information received from the ordering physician, which result in denials of payment and the uncollectible portion of receivables from self payers, including deductibles and copayments, which are subject to credit risk and patients' ability to pay. During the years ended July 31, 2008 and 2007, the Company determined an allowance for doubtful accounts less than 210 days and wrote off 100% of accounts receivable over 210 days, as it assumed those accounts are uncollectible, except for certain fully reserved balances, principally related to Medicare. These accounts have not been written off because the payer's filing date deadline has not occurred or the collection process has not been exhausted. The Company's collection experience on Medicare receivables beyond 210 days has been insignificant. The Company adjusts the historical collection analysis for recoveries, if any, on an ongoing basis.

The Company's ability to collect outstanding receivables from third party payers is critical to its operating performance and cash flows. The primary collection risk lies with uninsured patients or patients for whom primary insurance has paid but a patient portion remains outstanding. The Company also assesses the current state of its billing functions in order to identify any known collection or reimbursement issues in order to assess the impact, if any, on the allowance estimates, which involves judgment. The Company believes that the collectibility of its receivables is directly linked to the quality of its billing processes, most notably, those related to obtaining the correct information in order to bill effectively for the services provided. Should circumstances change (e.g. shift in payer mix, decline in economic conditions or deterioration in aging of receivables), our estimates of net realizable value of receivables could be reduced by a material amount.

Billing for laboratory services is complicated because of many factors, especially: the differences between our standard gross fee schedule for all payers and the reimbursement rates of the various payers we deal with, disparity of coverage and information requirements among the various payers, and disputes with payers as to which party is responsible for reimbursement.

The following tables indicate the Clinical Labs Aged Gross Receivables by Payer Group (in 000's), which is prior to adjustment to gross receivables for 1) contractual adjustment, 2) fully reserved balances not yet written off and 3) other revenue adjustments.

As of July 31, 2008	Total		Medicare		Third Party Payers		Self-pay		HMO's	
	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%
1-30 days	\$ 15,879	56%	\$ 3,278	44%	\$ 7,019	62%	\$ 1,654	29%	\$ 3,928	94%
31-60 days	4,038	14%	725	10%	2,196	19%	960	17%	157	4%
61-90 days	1,836	6%	468	6%	636	6%	682	12%	50	1%
91-120 days	1,460	5%	291	4%	534	5%	614	11%	21	1%
121-150 days	1,074	4%	192	3%	548	5%	323	6%	11	0%
Greater than 150 days*	4,300	15%	2,412	33%	380	3%	1,506	26%	2	0%
Totals	\$ 28,587	100%	\$ 7,366	100%	\$ 11,313	100%	\$ 5,739	100%	\$ 4,169	100%

As of July 31, 2007	Total		Medicare		Third Party Payers		Self-pay		HMO's	
	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%
1-30 days	\$ 18,120	50%	\$ 3,630	40%	\$ 8,561	59%	\$ 2,309	30%	\$ 3,620	69%
31-60 days	5,306	15%	614	7%	2,731	19%	1,434	19%	527	10%
61-90 days	3,795	10%	629	7%	1,735	12%	1,222	16%	209	4%
91-120 days	2,811	8%	530	6%	881	6%	732	10%	668	13%
121-150 days	1,589	4%	405	4%	263	2%	779	10%	142	2%
Greater than 150 days**	4,760	13%	3,246	36%	226	2%	1,173	15%	115	2%
Totals	\$ 36,381	100%	\$ 9,054	100%	\$ 14,397	100%	\$ 7,649	100%	\$ 5,281	100%

* Total includes \$2,796 fully reserved over 210 days as of July 31, 2008.

** Total includes \$2,432 fully reserved over 210 days as of July 31, 2007.

Income Taxes

The Company accounts for income taxes under the liability method of accounting for income taxes. Under the liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. The liability method requires that any tax benefits recognized for net operating loss carry forwards and other items be reduced by a valuation allowance where it is not more likely than not the benefits will be realized in the foreseeable future.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Under the liability method, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

On August 1, 2007, the Company adopted Financial Accounting Standards Board (FASB) Interpretation No. 48, Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109 (FIN 48). FIN 48 prescribes a more-likely-than-not threshold for the recognition and derecognition of tax positions, provides guidance on the accounting for interest and penalties relating to tax positions and requires that the cumulative effect of applying the provisions of FIN 48 be reported as an adjustment to the opening balance of retained earnings or other appropriate components of equity or net assets in the statement of financial position. The Company did not have any significant unrecognized tax positions and there was no material effect on our financial condition or results of operations as a result of implementing FIN 48.

Inventory

The Company values inventory at the lower of cost (first-in, first-out) or market. Work-in-process and finished goods inventories consist of material, labor, and manufacturing overhead. On a quarterly basis, we review inventory quantities on hand and analyze the provision for excess and obsolete inventory based on our estimate of sales forecasts based on sales history and anticipated future demand. Our estimate of future product demand may not be accurate and we may understate or overstate the provision for excess and obsolete inventory. Accordingly, unanticipated changes in demand could have a significant impact on the value of our inventory and results of operations. At July 31, 2008 and 2007, our reserve for excess and obsolete inventory was \$ 637,000 and \$379,000, respectively.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk from changes in foreign currency exchange rates resulting from the recent acquisition of Axxora (See Item 1A. Risk Factors and Note 2 in the notes to consolidated financial statements) and, to a much lesser extent, interest rates on investments in short-term instruments, that could impact our results of operations and financial position. We do not currently engage in any hedging or market risk management tools. There have been no material changes with respect to market risk previously disclosed in our Annual Report on Form 10-K for our 2007 fiscal year except for the impact of the aforementioned Biomol acquisition.

Foreign Currency Exchange Rate Risk

The financial reporting of our non-U.S. subsidiaries is denominated in currencies other than the U.S. dollar. Since the functional currency of our non-U.S. subsidiaries is the local currency, foreign currency translation adjustments are accumulated as a component of accumulated other comprehensive income in stockholders' equity. Assuming a hypothetical aggregate change of 10% in the exchange rates of foreign currencies against the U.S. dollar at July 31, 2008, our assets and liabilities would increase or decrease by \$2,354,000 and \$556,000, respectively, and our net sales and net earnings would increase or decrease by \$1,555,000 and \$83,000, respectively, on an annual basis.

We also maintain intercompany balances and loans receivable with subsidiaries with different local currencies. These amounts are at risk of foreign exchange losses if exchange rates fluctuate. Assuming a hypothetical aggregate change of 10% in the exchange rates of foreign currencies against the U.S. dollar at July 31, 2008, our pre-tax earnings would be favorably or unfavorably impacted by approximately \$80,000, on an annual basis.

Interest Rate Risk

Our excess cash is invested in highly liquid short term money market funds and US government instruments with high credit ratings. Changes in interest rates may affect the investment income we earn on cash and cash equivalents debt and therefore affect our cash flows and results of operations. As of July 31, 2008, we were exposed to interest rate change market risk with respect to our money market accounts of \$73.4 million. The short-term investments bear interest rates ranging from 2.2 to 2.5%. Each 100 basis point (or 1%) fluctuation in interest rates will increase or decrease interest income on the short-term investments by approximately \$0.7 million on an annual basis.

As of July 31, 2008, we did not maintain any fixed or variable interest rate financing.

Item 8. Financial Statements and Supplementary Data

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

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

Not applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act), we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of July 31, 2008. This evaluation was carried out under the supervision and with participation of our Chief Executive Officer and Chief Financial Officer. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. Therefore, effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives. Based upon our evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective at that reasonable assurance level as of July 31, 2008, and that information required to be disclosed in the reports that we file under the Exchange Act is recorded, processed, summarized and reported in a timely manner and is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during the fourth quarter ended July 31, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

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

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of management and our directors; and

provide reasonable assurance regarding prevention and timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems that are determined to be effective provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting based on criteria for effective internal control over financial reporting described in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Management's evaluation did not include assessing the effectiveness of internal controls over financial reporting at Biomol International Inc, and its wholly-owned subsidiary (Biomol), which was acquired May 8, 2008, and whose financial statements reflect total assets and net revenues of 13.3% and 3.0% respectively, of the consolidated financial statements as of and for the year ended July 31, 2008. Management has opted to exclude Biomol from its assessment based upon the SEC's comments in Management's Report on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, Frequently Asked Questions (FAQ) (revised October 6, 2004). The response to FAQ No. 3 states that the SEC would not object to management referring in the report to a discussion in the registrant's Form 10-K or 10-KSB regarding the

scope of the assessment and to such disclosure noting that management excluded the acquired business from management's report on internal control over financial reporting .

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Based on its assessment, management concluded that we maintained effective internal control over financial reporting as of July 31, 2008. Ernst & Young LLP, our independent registered public accounting firm, has issued an attestation report on our internal control over financial reporting as of July 31, 2008. This report, in which Ernst & Young LLP has expressed an unqualified opinion, appears in this Item 9A.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Enzo Biochem, Inc.

We have audited Enzo Biochem, Inc.'s (the Company) internal control over financial reporting as of July 31, 2008, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Enzo Biochem, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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

As indicated in the accompanying Management's Annual Report on Internal Control over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Biomol International, Inc. and subsidiary which is included in the 2008 consolidated financial statements of Enzo Biochem, Inc., and constituted 13.3% and 6.4% of total and net assets, respectively, as of July 31, 2008 and \$2,673,000 and \$6,300 of revenues and net income, respectively, for the year then ended. Our audit of internal control over financial reporting of Enzo Biochem, Inc. also did not include an evaluation of the internal control over financial reporting of Biomol International, Inc. and subsidiary.

In our opinion, Enzo Biochem, Inc. maintained, in all material respects, effective internal control over financial reporting as of July 31, 2008 based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Enzo Biochem, Inc. as of July 31, 2008 and 2007 and the related consolidated statements of operations, consolidated statements of stockholders' equity and comprehensive income (loss) and consolidated statements of cash flows for each of the three years in the period ended July 31, 2008 of Enzo Biochem, Inc. and our report dated October 14, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP
Melville, New York
October 14, 2008

Item 9B. Other Information
None

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required under this item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission on or before November 28, 2008 and is incorporated herein by reference.

Item 11. Executive Compensation

The information required under this item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission on or before November 28, 2008 and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required under this item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission on or before November 28, 2008 and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required under this item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission on or before November 28, 2008 and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required under this item will be set forth in the Company's proxy statement expected to be filed with the Securities and Exchange Commission on or before November 28, 2008 and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

- (a) (1) Consolidated Financial Statements
 - Consolidated Balance Sheets - July 31, 2008 and 2007
 - Consolidated Statements of Operations- Years ended July 31, 2008, 2007 and 2006
 - Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss) - Years ended July 31, 2008, 2007 and 2006
 - Consolidated Statements of Cash Flows - Years ended July 31, 2008, 2007 and 2006
 - Notes to Consolidated Financial Statements.
- (2) Financial Statement Schedule

Schedule II - Valuation and Qualifying Accounts

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

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

(3) Exhibits

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

<u>Exhibit No.</u>	<u>Description</u>
3(a)	Certificate of Incorporation, as amended March 17, 1980. (1)
3(b)	June 16, 1981 Certificate of Amendment of the Certificate of Incorporation. (2)
3(c)	Certificate of Amendment to the Certificate of Incorporation. (3)
3(d)	Amended and restated Bylaws. (14)
10 (c)	Employment Agreements with Elazar Rabbani. (5)
10(d)	Employment Agreement with Shahram Rabbani. (5)
10(e)	Employment Agreement with Barry Weiner. (5)
10(f)	1994 Stock Option Plan. (6)
10(g)	1999 Stock Option Plan. (7)
10 (h)	Amendment to Elazar Rabbani s employment agreement. (8)
10 (i)	Amendment to Shahram Rabbani s employment agreement. (8)
10 (j)	Amendment to Barry Weiner s employment agreement. (8)
10 (k)	2005 Equity Compensation Incentive Plan (10)
10 (l)	Lease agreement with Pari Management (11)
10 (m)	Settlement and Release Agreement between the Company and Sigma Aldrich (12)
10 (n)	Stock Purchase Agreement By and Among Enzo Life Sciences, Inc., Axxora Life Sciences Inc., and the Stock holders, Option holders and Warrant holders (13)
10 (o)	Stock Asset Purchase Agreement By and Among Buyer Parties and Seller Parties (14)
14 (a)	Code of Ethics (10)

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

- 21 Subsidiaries of the registrant:
Enzo Clinical Labs, Inc., a New York corporation.
Enzo Life Sciences, Inc., a New York corporation.
Enzo Therapeutics, Inc., a New York corporation.
Enzo Realty, LLC, a New York Corporation
- 23 Consent of Independent Registered Public Accounting Firm filed herewith.
- 31 (a) Certification of CEO Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 filed herewith.
- 31 (b) Certification of CFO Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 filed herewith.
- 32 (a) Certification of CEO Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 filed herewith.
- 32 (b) Certification of CFO Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 filed herewith.

Notes to exhibits

- (1) The exhibits were filed as exhibits to the Company's Registration Statement on Form S-18 (File No. 2-67359) and are incorporated herein by reference.
- (2) This exhibit was filed as an exhibit to the Company's Form 10-K for the year ended July 31, 1981 and is incorporated herein by reference.
- (3) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 1989 and is incorporated herein by reference.
- (5) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 1994 and is incorporated herein by reference.
- (6) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 1995 and is incorporated herein by reference.
- (7) This exhibit was filed with the Company's Registration Statement on Form S-8 (333-87153) and is incorporated herein by reference.
- (8) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 2000 and is incorporated herein by reference.
- (9) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 2004 and is incorporated herein by reference.
- (10) This exhibit was filed as an exhibit to the Company's Proxy Statement of Schedule 14A filed on January 19, 2005 and is incorporated herein by reference.
- (11) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 2006 and is incorporated herein by reference.
- (12) This exhibit was filed with the Company's Current Report on Form 8-K on September 21, 2006 and is incorporated herein by reference.
- (13) This exhibit was filed with the Company's Current Report on Form 8-K May 30, 2007 and is incorporated herein by reference.
- (14) This exhibit was filed with the Company's Current Report on Form 8-K May 8, 2008 and is incorporated herein by reference.
- (b) See Item 15(a) (3), above.
- (c) See Item 15(a) (2), above.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

SIGNATURES

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

ENZO BIOCHEM, INC.

Date: October 14, 2008

By: /s/ Elazar Rabbani Ph.D.

Chairman of the Board

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

By: /s/ Elazar Rabbani Ph.D. October 14, 2008

Elazar Rabbani,
Chairman of Board of Directors
(Principal Executive Officer)

By: /s/ Barry W. Weiner October 14, 2008

Barry W. Weiner,
President, Chief Financial Officer, and Director

By: /s/ Shahram K. Rabbani October 14, 2008

Shahram K. Rabbani,
Secretary, Treasurer and Director

By: /s/ Irwin Gerson October 14, 2008

Irwin Gerson, Director

By: /s/ Stephen B. H. Kent Ph.D. October 14, 2008

Stephen B. H. Kent, Director

By: /s/ Bernard L. Kasten Ph.D. October 14, 2008

Bernard Kasten, Director

By: /s/ Melvin F. Lazar October 14, 2008

Melvin F. Lazar, Director

By: /s/ John B. Sias October 14, 2008

John B. Sias, Director

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

**LIST OF CONSOLIDATED FINANCIAL STATEMENTS AND
FINANCIAL STATEMENT SCHEDULE**

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

<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets July 31, 2008 and 2007</u>	F-3
<u>Consolidated Statements of Operations Years ended July 31, 2008, 2007 and 2006</u>	F-4
<u>Consolidated Statements of Stockholders Equity and Comprehensive Income (Loss) Years ended July 31, 2008, 2007 and 2006</u>	F-5
<u>Consolidated Statements of Cash Flows Years ended July 31, 2008, 2007 and 2006</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7
<u>Schedule II - Valuation and Qualifying Accounts Years ended July 31, 2008, 2007 and 2006</u>	S-1

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

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Enzo Biochem, Inc.

We have audited the accompanying consolidated balance sheets of Enzo Biochem, Inc. (the Company) as of July 31, 2008 and 2007, and the related consolidated statements of operations, consolidated statements of stockholders' equity and comprehensive income (loss), and consolidated statements of cash flows for each of the three years in the period ended July 31, 2008. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Enzo Biochem, Inc. at July 31, 2008 and 2007, and the consolidated results of their operations and their cash flows for each of the three years in the period ended July 31, 2008, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, present fairly in all material respects the information set for the therein.

As discussed in Note 9 to the consolidated financial statements, effective August 1, 2007, the Company adopted the provisions of Financial Accounting Standards Board Interpretation No. 48, Accounting for Uncertainty in Income Taxes.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Enzo Biochem Inc.'s internal control over financial reporting as of July 31, 2008, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated October 14, 2008 expressed an unqualified opinion.

/s/ Ernst & Young LLP

Melville, New York
October 14, 2008

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

	<u>July 31,</u> <u>2008</u>	<u>July 31,</u> <u>2007</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 78,322	\$ 105,149
Accounts receivable, net of allowance for doubtful accounts of \$886 in 2008 and \$1,404 in 2007	15,348	14,353
Inventories	9,514	7,022
Prepaid expenses	2,496	1,767
	<u> </u>	<u> </u>
Total current assets	105,680	128,291
Property, plant, and equipment, net	9,053	6,621
Goodwill	21,321	13,676
Intangible assets, net	17,656	9,338
Other	812	1,076
	<u> </u>	<u> </u>
Total assets	<u>\$ 154,522</u>	<u>\$ 159,002</u>
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable trade	\$ 4,299	\$ 4,111
Accrued liabilities	7,370	8,446
Other current liabilities	1,161	1,287
Deferred taxes	458	597
	<u> </u>	<u> </u>
Total current liabilities	13,288	14,441
Deferred revenue	512	938
Deferred taxes	2,433	1,729
Commitments and contingencies		
Stockholders equity:		
Preferred Stock, \$.01 par value; authorized 25,000,000 shares; no shares issued or outstanding		
Common Stock, \$.01 par value; authorized 75,000,000 shares; shares issued: 38,007,581 at July 31, 2008 and 37,280,723 at July 31, 2007	380	372
Additional paid-in capital	303,811	295,899
Less treasury stock at cost: 777,719 shares at July 31, 2008 and 596,456 shares at July 31, 2007	(11,331)	(8,915)
Accumulated deficit	(156,157)	(145,504)
Accumulated other comprehensive income	1,586	42
	<u> </u>	<u> </u>
Total stockholders equity	138,289	141,894
	<u> </u>	<u> </u>
Total liabilities and stockholders equity	<u>\$ 154,522</u>	<u>\$ 159,002</u>

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

	Years ended July 31,		
	2008	2007	2006
Revenues:			
Product revenues	\$ 28,087	\$ 6,658	\$ 4,750
Royalty and license fee income	7,630	5,820	3,150
Clinical laboratory services	42,078	40,430	31,926
	<u>77,795</u>	<u>52,908</u>	<u>39,826</u>
Costs and expenses and other (income):			
Cost of product revenues	19,159	5,034	2,400
Cost of clinical laboratory services	21,063	18,199	13,917
Research and development expense	8,637	9,393	7,896
Selling, general, and administrative expense	34,418	26,300	24,745
Provision for uncollectible accounts receivable	3,716	4,653	3,633
Legal expense	5,588	10,295	7,388
Interest income	(3,696)	(5,092)	(3,144)
Other income	(198)	(2,699)	
	<u>88,687</u>	<u>66,083</u>	<u>56,835</u>
Loss before income taxes	(10,892)	(13,175)	(17,009)
Benefit (provision) for income taxes	239	(85)	1,342
Net loss	<u>(\$ 10,653)</u>	<u>(\$ 13,260)</u>	<u>(\$ 15,667)</u>
Net loss per common share:			
Basic	<u>(\$ 0.29)</u>	<u>(\$ 0.38)</u>	<u>(\$ 0.49)</u>
Diluted	<u>(\$ 0.29)</u>	<u>(\$ 0.38)</u>	<u>(\$ 0.49)</u>
Weighted average common shares outstanding:			
Basic	<u>36,883</u>	<u>35,017</u>	<u>32,215</u>
Diluted	<u>36,883</u>	<u>35,017</u>	<u>32,215</u>

F-4

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

ENZO BIOCHEM, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY
AND COMPREHENSIVE INCOME (LOSS)
Years ended July 31, 2008, 2007, and 2006
(In thousands, except share data)

	Common Stock Shares	Treas- ury Stock Shares	Common Stock Amount	Additional Paid-in Capital	Treas- ury Stock Amount	Accumulated Comprehensive Deficit	Other Comprehensive Income	Total Stockholders Equity	Comprehensive income (loss)
Balance at July 31, 2005	32,526,800	384,400	\$ 325	\$ 230,644	\$ (5,994)	\$ (116,577)	\$ (131)	\$ 108,267	
Net (loss) for the year ended July 31, 2006						(15,667)		(15,667)	\$ (15,667)
Realized loss on available for-sale securities, net of tax							131	131	131
Purchase of treasury stock		185,300			(2,505)			(2,505)	
Exercise of stock options	285,030		3	3,113				3,116	
Issuance of stock for employee 401(k) plan match	32,370			402				402	
Stock based compensation charges				1,763				1,763	
Stock based compensation for consulting services				80				80	
Comprehensive (loss)									(15,536)
Balance at July 31, 2006	32,844,200	569,700	328	236,002	(8,499)	(132,244)		95,587	
Net (loss) for the year ended July 31, 2007						(13,260)		(13,260)	\$ (13,260)
Net proceeds from issuance	4,285,715		43	56,954				56,997	

of common
stock

Purchase of treasury stock	26,756			(416)			(416)
Exercise of stock options	95,525	1	915				916
Issuance of stock for employee 401(k) plan match	29,370		421				421
Vesting of restricted stock	25,913						
Stock based compensation charges			1,477				1,477
Stock based compensation for consulting services			130				130
Foreign currency translation adjustments					42	42	42
Comprehensive (loss)							(13,218)

Balance at July 31, 2007	37,280,723	596,456	372	295,899	(8,915)	(145,504)	42	141,894
--------------------------	------------	---------	-----	---------	---------	-----------	----	---------

Net (loss) for the year ended July 31, 2008						(10,653)	(10,653)	\$(10,653)
Purchase of treasury stock	181,263					(2,416)		(2,416)
Exercise of stock options	267,345	3	2,881					2,884
Vesting of restricted stock	70,963	1						1
Stock based compensation charges			1,566					1,566
Issuance of stock for employee 401(k) plan match	36,550		481					481
Issuance of	352,000	4	2,996					3,000

stock for acquisition								
Common stock issuance costs adjustment.			(12)					(12)
Foreign currency translation adjustments						1,544	1,544	<u>1,544</u>
Comprehensive (loss)								<u>\$ (9,109)</u>

Balance at July 31, 2008	<u>38,007,581</u>	<u>777,719</u>	<u>\$ 380</u>	<u>\$ 303,811</u>	<u>\$(11,331)</u>	<u>\$(156,157)</u>	<u>\$ 1,586</u>	<u>\$ 138,289</u>
--------------------------	-------------------	----------------	---------------	-------------------	-------------------	--------------------	-----------------	-------------------

F-5

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

ENZO BIOCHEM, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Years ended July 31,		
	2008	2007	2006
Cash flows from operating activities:			
Net loss	(\$ 10,653)	(\$ 13,260)	\$ (15,667)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of property, plant and equipment	1,488	1,038	1,049
Amortization of other intangible assets	658	151	75
Provision for uncollectible accounts receivable	3,716	4,653	3,633
Write-off and/or reserve for obsolete inventory	283	360	596
Deferred income tax (benefit) provision	(644)	(178)	640
Share based compensation charges	1,566	1,477	1,763
Issuance of common stock for 401(k) employer match	481	421	402
Deferred revenue recognized	(426)		
Gain on termination of officers life insurance policies	(313)		
Options issued to consultants		130	80
Loss on marketable securities			154
Other		10	
Changes in operating assets and liabilities:			
Accounts receivable	(2,837)	(6,086)	(659)
Inventories	1,012	533	(120)
Prepaid expenses	(574)	31	332
Recoverable and prepaid income taxes		1,931	(602)
Accounts payable trade	(1,060)	429	(1,110)
Accrued liabilities	(1,066)	2,892	(463)
Other current liabilities	(195)	74	(279)
Deferred revenue		1,628	
Adjustments	2,089	9,494	5,491
Net cash used in operating activities	(8,564)	(3,766)	(10,176)
Cash flows from investing activities:			
Capital expenditures	(3,231)	(1,448)	(4,227)
Proceeds from termination of officers life insurance	1,085		
Sales of marketable securities			6,760
Purchases of marketable securities			(69)
(Increase) decrease in cash surrender values		(75)	51
(Increase) decrease in security deposits and other	(491)	(14)	73
Acquisitions, net of cash acquired	(16,144)	(16,888)	
Net cash (used in) provided by investing activities	(18,781)	(18,425)	2,588
Cash flows from financing activities:			
Net proceeds from issuance of common stock		56,997	
Proceeds from the exercise of stock options	470	500	611
Issuance costs from issuance of common stock	(12)		
Payment of long term installment payable			(150)

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Net cash provided by financing activities	458	57,497	461
	<u> </u>	<u> </u>	<u> </u>
Effect of exchange rate changes on cash and cash equivalents	60	(11)	
	<u> </u>	<u> </u>	<u> </u>
(Decrease) increase in cash and cash equivalents	(26,827)	35,295	(7,127)
Cash and cash equivalents - beginning of year	105,149	69,854	76,981
	<u> </u>	<u> </u>	<u> </u>
Cash and cash equivalents - end of year	\$ 78,322	\$ 105,149	\$ 69,854
	<u> </u>	<u> </u>	<u> </u>

F-6

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

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2008 and 2007

Note 1 - Summary of significant accounting policies

Nature of business

Enzo Biochem, Inc. (the Company) is engaged in research, development, manufacturing and marketing of diagnostic and research products based on genetic engineering, biotechnology and molecular biology. These products are designed for the diagnosis of and/or screening for infectious diseases, cancers, genetic defects and other medically pertinent diagnostic information and are distributed in the United States and internationally. The Company is conducting research and development activities in the development of therapeutic products based on the Company's technology platform of genetic modulation and immune modulation. The Company also operates a clinical laboratory that offers and provides diagnostic medical testing services to the health care community in the New York Metropolitan and New Jersey areas. The Company operates in three segments (see Note 17).

On May 8, 2008, Enzo Life Sciences, Inc. (Enzo Life Sciences), a wholly-owned subsidiary of the Company, acquired substantially all assets and certain liabilities of Biomol International L.P. (Biomol LP) and the issued and outstanding capital stock of Affiniti, Limited, a wholly owned subsidiary of Biomol LP., referred to as Biomol. Biomol is a developer, manufacturer and distributor of reagents for the research and biochemical industries and is based in the U.S. and its wholly-owned subsidiary is located in Exeter, United Kingdom. Biomol utilizes third-party distributors located in other major markets throughout the world. As a result of this transaction, Enzo Life Sciences has expanded its product offerings, both through internal manufacturing and distribution, and increases its geographic distribution (see Note 2).

Effective May 31, 2007, Enzo Life Sciences completed the acquisition of all of the issued and outstanding capital stock of Axxora Life Sciences, Inc. (Axxora). Axxora is a developer, manufacturer and distributor of reagents for the research and biochemical industries and is based in the U.S. with wholly-owned subsidiaries in the U.S., Switzerland, Germany and the United Kingdom. Axxora utilizes third-party distributors located in other major markets throughout the world. Axxora's electronic marketplace enables customers to purchase research reagents from internationally recognized manufacturers covering all areas of the life sciences research reagents field. As a result of this transaction, Enzo Life Sciences has expanded its product offerings both through internal manufacturing and distribution and increases its geographic distribution (see Note 2).

Principles of consolidation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States (U.S. GAAP) and include the accounts of the Company and its wholly-owned subsidiaries, Enzo Clinical Labs, Inc., Enzo Life Sciences, Inc., Enzo Therapeutics, Inc. and Enzo Realty LLC (Realty). All intercompany transactions and balances have been eliminated. The results of operations for companies acquired are included in the consolidated financial statements from the effective date of acquisition.

Use of Estimates

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

Foreign Currency Translation

In accordance with Statement of Financial Accounting Standards (SFAS) No. 52, Foreign Currency Translation (SFAS No. 52), the Company has determined that the functional currency for its foreign subsidiaries is the local currency. Assets and liabilities denominated in foreign currencies are translated at current exchange rates and profit and loss accounts are translated at weighted average exchange rates. Resulting translation gains and losses are included as a separate component of stockholders equity as accumulated other comprehensive income or loss.

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2008 and 2007

Cash and cash equivalents

Cash and cash equivalents include highly liquid money market funds and US Government instruments with maturities of three months or less at the time acquired by the Company.

Concentration of credit risk

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

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

The Company believes that the concentration of credit risk with respect to the Clinical Labs accounts receivable is mitigated by the diversity of its numerous third party payers and individual patient accounts and is limited to certain large payers that insure individuals that utilize the Clinical labs services. To reduce risk, the Company routinely assesses the financial strength of these payers and, consequently, believes that its accounts receivable credit risk exposure, with respect to these payers, is limited. While the Company also has receivables due from the Federal Medicare program, the Company does not believe that these receivables represent a credit risk since the Medicare program is funded by the federal government and payment is primarily dependent on our submitting the appropriate documentation.

Revenue Recognition

Product revenues

Revenues from product sales are recognized when the products are shipped and title transfers, the sales price is fixed or determinable and collectibility is reasonably assured. Revenues from non-exclusive distribution agreements are recognized when shipments are made to their respective customers and reported to the Company. The Company has certain non-exclusive distribution agreements, which provide for consideration to be paid to the distributors for the manufacture of certain products. The Company records such consideration provided to distributors under these non-exclusive distribution agreements as a reduction to product revenues. The Company did not recognize any revenue from these distributors during the years ended July 31, 2008, 2007 and 2006.

Royalties

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

License Fees and Multiple Element Arrangements

When evaluating multiple element arrangements, the Company considers whether the components of the arrangement represent separate units of accounting as defined in Emerging Issues Task Force (EITF) Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). Application of this standard requires subjective determinations and requires management to make judgments about the fair value of the individual elements and whether such elements are separable from the other aspects of the contractual relationship.

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2007 and 2006

Clinical laboratory services

Revenues from the clinical laboratory are recognized upon completion of the testing process for a specific patient and reported to the ordering physician. These revenues and the associated accounts receivable are based on gross amounts billed or billable for services rendered, net of a contractual adjustment, which is the difference between amounts billed to payers and the expected approved reimbursable settlements from such payers.

The following are tables of the Clinical Lab segment's net revenues and revenue percentages by revenue category for the years ended July 31, 2008, 2007 and 2006:

Revenue category	2008		Years ended July 31 2007		2006	
	(In 000 s)	(in %)	(In 000 s)	(in %)	(In 000 s)	(in %)
Medicare	\$ 9,078	22	\$ 8,478	21	\$ 7,462	23
Third-party payers	24,768	59	25,060	62	17,680	56
Patient self-pay	3,582	9	2,952	7	4,925	15
HMO s	4,650	10	3,940	10	1,859	6
Total	\$ 42,078	100%	\$ 40,430	100%	\$ 31,926	100%

The Company provides services to certain patients covered by various third-party payers, including the Federal Medicare program. Laws and regulations governing Medicare are complex and subject to interpretation for which action for noncompliance includes fines, penalties and exclusion from the Medicare programs. The Company believes that it is in compliance with all applicable laws and regulations and is not aware of any pending or threatened investigations involving allegations of potential wrongdoing.

Other than the Medicare program, United Healthcare of New York whose programs are included in the Third-party payers and Health Maintenance Organizations (HMO s) categories, represents 26% and 20% of the Clinical labs segment net revenue for the fiscal year ended July 31, 2008 and 2007 respectively. Other than the Medicare program, no other provider included in the Third party payers and HMO s categories exceeded 10% of Clinical labs service revenue for the fiscal year ended July 31, 2006.

Contractual Adjustment

The Company's estimate of contractual adjustment is based on significant assumptions and judgments, such as its interpretation of payer reimbursement policies, and bears the risk of change. The estimation process is based on the experience of amounts approved as reimbursable and ultimately settled by payers, versus the corresponding gross amount billed to the respective payers. The contractual adjustment is an estimate that reduces gross revenue, based on gross billing rates, to amounts expected to be approved and reimbursed. Gross billings are based on a standard fee schedule the Company sets for all third-party payers, including Medicare, HMO s and managed care providers. The Company adjusts the contractual adjustment estimate quarterly, based on its evaluation of current and historical settlement experience with payers, industry reimbursement trends, and other relevant factors which include the monthly and quarterly review of: 1) current gross billings and receivables and reimbursement by payer, 2) current changes in third party arrangements and 3) the growth of in-network provider arrangements and managed care plans specific to our Company.

During the years ended July 31, 2008, 2007 and 2006, the contractual adjustment percentages, determined using current and historical reimbursement statistics, were 81.8%, 79.0% and 75.2%, respectively, of gross billings.

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2008 and 2007

Accounts Receivable and Allowance for Doubtful Accounts

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

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

During the years ended July 31, 2008 and 2007, the Company determined an allowance for doubtful accounts for customers whose accounts receivable have been outstanding less than 210 days and wrote off 100% of accounts receivable over 210 days, as it determined based on historical trends that those accounts were uncollectible, except for certain fully reserved balances, principally related to Medicare. These accounts have not been written off because the payer's filing date deadline has not occurred or the collection process has not been exhausted. The Company adjusts the historical collection analysis for recoveries, if any, on an ongoing basis.

The Company's ability to collect outstanding receivables from third-party payers is critical to its operating performance and cash flows. The primary collection risk lies with uninsured patients or patients for whom primary insurance has paid but a patient portion remains outstanding. The Company also assesses the current state of its billing functions in order to identify any known collection issues and to assess the impact, if any, on the allowance estimates which involves judgment. The Company believes that the collectibility of its receivables is directly linked to the quality of its billing processes, most notably, those related to obtaining the correct information in order to bill effectively for the services provided. Should circumstances change (e.g. shift in payer mix, decline in economic conditions or deterioration in aging of receivables), our estimates of net realizable value of receivables could be reduced by a material amount.

The following is a table of the Company's net accounts receivable by segment. The Clinical Labs segment's net receivables are detailed by billing category and as a percent to its total net receivables. At July 31, 2008 and 2007, approximately 58% and 68%, respectively, of the Company's net accounts receivable relates to its Clinical Labs business, which operates in the New York Metropolitan and New Jersey areas.

Net accounts receivable Billing category	As of July 31, 2008		As of July 31, 2007	
	(In 000 s)	(in %)	(In 000 s)	(in %)
Clinical Labs				
Medicare	\$ 1,600	18	\$ 1,628	17
Third party payers	4,610	52	5,856	60
Patient self-pay	2,144	24	1,678	17
HMO s	537	6	671	6
Total Clinical Labs	8,891	100%	9,833	100%
Total Life Sciences	6,457		4,520	
Total accounts receivable	\$ 15,348		\$ 14,353	

The Life Sciences segment's accounts receivable includes royalties receivable of \$2.1 million and \$1.8 million, as of July 31, 2008 and 2007, respectively, of which approximately \$1.5 million and \$1.5 million, respectively is from Qiagen Corporation (see Note 13).

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2008 and 2007

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

<u>In 000 s</u>	<u>July 31, 2008</u>	<u>July 31, 2007</u>
Beginning balance	\$ 1,404	\$ 1,033
Provision for doubtful accounts	3,716	4,653
Write-offs, net of recoveries	(4,234)	(4,282)
Ending balance	<u>\$ 886</u>	<u>\$ 1,404</u>

Inventories

Inventories are stated at the lower of cost (first-in, first-out) or market. Appropriate consideration is given to obsolescence and other factors in evaluating net realizable value. Work-in-process and finished goods inventories consist of material, labor and manufacturing overhead.

Property, plant and equipment

Property, plant and equipment is stated at cost, and depreciated on the straight-line basis over the estimated useful lives of the various asset classes as follows: building and building improvements 15-30 years and laboratory machinery and equipment and office furniture and computer equipment - ranges from 3-10 years. Leasehold improvements are amortized over the term of the related leases or estimated useful lives of the assets, whichever is shorter.

Impairment of Long-Lived Assets

The Company reviews the recoverability of the carrying value of long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. Should indicators of impairment exist, the carrying values of the assets are evaluated in relation to the operating performance and future undiscounted cash flows of the underlying business. The net book value of an asset is adjusted to fair value if its expected future undiscounted cash flow is less than its book value. No impairment losses were identified during the years ended July 31, 2008, 2007 or 2006.

Goodwill and Intangible Assets

Goodwill, representing the cost of acquired businesses in excess of the fair value of assets acquired, and indefinite-lived intangibles are not amortized, but are evaluated annually for impairment. The Company performs its annual impairment test as of the first day of its fiscal fourth quarter, or earlier if indicators of potential impairment exist, to evaluate goodwill and indefinite lived intangibles. Goodwill is considered impaired if the carrying amount of the reporting unit exceeds its estimated fair value. In assessing the recoverability of goodwill, the Company reviews both quantitative as well as qualitative factors to support its assumptions with regard to fair value. The fair value of a reporting unit is estimated using both a discounted cash flow model and a weighted average multiple of earnings before interest and taxes from comparable companies. In determining fair value, the Company makes certain judgments, including the identification of reporting units and the selection of comparable companies. If these estimates or their related assumptions change in the future as a result of changes in strategy and/or market conditions, the Company may be required to record an impairment charge. To date, there has been no impairment of these assets.

Intangible Assets

Intangible assets (exclusive of patents), arose primarily from acquisitions (See Note 2), and primarily consist of customer relationships, trademarks, licenses, employment and non-compete agreements, and website and database content. Finite-lived intangible assets are amortized according to their estimated useful lives, which range from 4 to 15 years.

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2008 and 2007

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

Comprehensive income (loss)

SFAS No. 130, Reporting Comprehensive Income (SFAS 130), requires reporting and displaying of comprehensive income (loss) and its components. In accordance with SFAS 130, the Accumulated Other Comprehensive Income (Loss), which is comprised of foreign currency translation adjustments, is disclosed as a separate component of stockholders' equity. Comprehensive loss consists of net loss and foreign currency translation adjustments. Foreign currency translation adjustments included in comprehensive loss were not tax effected as investments in international affiliates are deemed to be permanent.

Shipping and Handling Costs

Shipping and handling costs associated with the distribution of finished goods to customers are recorded in cost of goods sold.

Research and Development

Research and development costs are charged to expense as incurred.

Advertising

All costs associated with advertising are expensed as incurred. Advertising expense, included in Selling, general and administrative expense, approximated \$113,000, \$12,000 and \$128,000 for the years ended July 31, 2008, 2007 and 2006, respectively.

Income Taxes

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

It is the Company's policy to provide for uncertain tax positions and the related interest and penalties based upon management's assessment of whether a tax benefit is more likely than not to be sustained upon examination by tax authorities. At July 31, 2008, the Company believes it has appropriately accounted for any unrecognized tax benefits. To the extent the Company prevails in matters for which a liability for an unrecognized tax benefit is established or is required to pay amounts in excess of the liability, the Company's effective tax rate in a given financial statement period may be affected.

Segment Reporting

The Company follows SFAS No. 131, Disclosures About Segments of an Enterprise and Related Information (SFAS 131) which establishes standards for reporting information on operating segments in interim and annual financial statements. An enterprise is required to separately report information about each operating segment that engages in business activities from which the segment may earn revenues and incur expenses, whose separate operating results are regularly reviewed by the chief operating decision maker regarding allocation of resources and performance assessment and which exceed specific quantitative thresholds related to revenue and profit or loss. The Company's operating activities are reported in three segments (see Note 17).

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2008 and 2007

Net income (loss) per share

The Company applies SFAS No. 128, Earnings per Share (SFAS 128). SFAS 128 establishes standards for computing and presenting earnings per share. Basic net income (loss) per share represents net income (loss) divided by the weighted average number of common shares outstanding during the period. The dilutive effect of potential common shares, consisting of outstanding stock options and unvested restricted stock, is determined using the treasury stock method in accordance with SFAS 128. Diluted weighted average shares outstanding for fiscal 2008, 2007 and 2006 do not include the potential common shares from stock options and unvested restricted stock because to do so would have been antidilutive. Accordingly, basic and diluted net loss per share is the same in fiscal 2008, 2007 and 2006. The number of potential common shares (in the money options) and unvested restricted stock excluded from the calculation of diluted earnings per share during the years ended July 31, 2008, 2007, and 2006 was 240,000, 619,000, and 423,000, respectively.

For the years ended July 31, 2008, 2007 and 2006, the effect of approximately 1,734,000, 873,000 and 1,916,000 respectively, of outstanding out of the money options to purchase common shares were excluded from the calculation of diluted net (loss) income per share because their effect would be anti-dilutive.

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

<u>In 000 s</u>	<u>2008</u>	<u>2007</u>	<u>2006</u>
Numerator:			
Net loss	\$ (10,653)	\$ (13,260)	\$ (15,667)
Denominator:			
Weighted-average common shares outstanding- Basic	36,883	35,017	32,215
Add: effect of dilutive stock options and restricted stock			
Weighted-average common shares outstanding - Diluted	36,883	35,017	32,215
Net loss per share			
Basic	\$ (0.29)	\$ (0.38)	\$ (0.49)
Diluted	\$ (0.29)	\$ (0.38)	\$ (0.49)

Share-Based Compensation

The Company records compensation expense associated with stock options and restricted stock in accordance with SFAS No. 123(R), Share-Based Payment. The Company adopted the modified prospective application method provided for under SFAS 123(R) and consequently did not retroactively adjust results from prior periods. Under this transition method, compensation cost associated with stock options and awards recognized in the fiscal years ended July 31, 2008, 2007 and 2006, includes: (a) compensation cost of all stock-based payments granted prior to, but not yet vested as of July 31, 2005 (based on grant-date fair value estimated in accordance with the original provisions of SFAS No. 123(R), and (b) compensation cost for all stock-based payments granted on or after August 1, 2005 (based on the grant-date fair value estimated in accordance with the new provision of SFAS No. 123(R)).

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2008 and 2007

For the years ended July 31, 2008, 2007 and 2006, share-based compensation expense relating to the fair value of restricted shares and restricted stock units vested during the years ended July 31, 2008, 2007 and 2006 was approximately \$1,316,000, \$649,000, and \$172,000, respectively (see Note 11). No excess tax benefits were recognized for the year ended July 31, 2008, 2007 and 2006.

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

<u>In 000 s</u>	<u>2008</u>	<u>2007</u>	<u>2006</u>
Cost of products	\$ 14	\$ 10	\$ 21
Research and development	97	162	249
Selling, general and administrative	1,455	1,305	1,493
	<u>\$ 1,566</u>	<u>\$ 1,477</u>	<u>\$ 1,763</u>

As of July 31, 2008, there was \$1.9 million of total unrecognized compensation cost related to nonvested share-based payment arrangements granted under the Company's stock option and restricted stock plans, which will be recognized over a weighted average remaining life of approximately 1.75 years.

Effect of new accounting pronouncements

In May 2008, the FASB issued SFAS No. 162, The Hierarchy of Generally Accepted Accounting Principles (SFAS No. 162). SFAS No. 162 is intended to improve financial reporting by identifying a consistent framework, or hierarchy, for selecting accounting principles to be used in preparing financial statements that are presented in conformity with generally accepted accounting principles. SFAS No. 162 will become effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles . The Company does not anticipate the adoption of SFAS No. 162 will have a material impact on its results of operations, cash flows or financial condition.

In April 2008, the FASB issued FSP FAS 142-3, Determination of the Useful Life of Intangible Assets (FSP FAS 142-3). FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, Goodwill and Other Intangible Assets. FSP FAS 142-3 also requires expanded disclosure related to the determination of intangible asset useful lives. FSP FAS 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. The Company is currently evaluating the impact that the adoption of FSP FAS 142-3 will have on its consolidated results of operation, cash flows or financial condition.

In December 2007, the FASB issued Statement No. 141 (revised 2007), Business Combinations (SFAS No. 141R). SFAS No. 141R establishes principles and requirements for how the acquirer in a business combination recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any controlling interest in the business and the goodwill acquired. SFAS No. 141R further requires that acquisition-related costs and costs associated with restructuring or exiting activities of an acquired entity will be expensed as incurred. SFAS No. 141R also establishes disclosure requirements that will require disclosure of the nature and financial effects of the business combination. SFAS No. 141R will impact business combinations for the Company that may be completed on or after August 1, 2009. The Company cannot anticipate whether the adoption of SFAS No. 141R will have a material impact on its results of operations and financial condition as the impact is solely dependent on the terms of any business combination entered into by the Company on or after August 1, 2009.

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2008 and 2007

In September 2006, the FASB issued Statement No. 157, Fair Value Measurements (SFAS 157) which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. In February 2008, the FASB issued FASB Staff Position (FSP) No. 157-2, delaying the effective date of SFAS 157 for nonfinancial assets and nonfinancial liabilities, except for items that are recognized or disclosed at fair value on a nonrecurring basis. The delayed portions of SFAS 157 will be adopted by the Company beginning in its fiscal year ending August 1, 2009, while all other portions of the standard will be adopted by the Company beginning in its fiscal year ending August 1, 2008, as required. The Company does not expect that the adoption SFAS 157 will have a material impact on its consolidated results of operations, cash flows or financial condition.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities - Including an amendment of FASB Statement No. 115. SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. The objective of SFAS No. 159 is to provide opportunities to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply hedge accounting provisions. SFAS No. 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. The Company does not expect the impact of the adoption of SFAS No. 159 will have a material impact on its financial condition or results of operations.

Reclassifications

Certain amounts in prior years have been reclassified to conform to current year presentation. In Fiscal 2007, the Company reclassified shipping and handling cost previously included in selling, general and administrative expense to cost of sales. The shipping and handling costs reclassified were approximately \$226,000 for the year ended July 31, 2006.

NOTE 2 - Acquisitions

Biomol International, L.P.

On May 8, 2008, Enzo Life Sciences, Inc. acquired substantially all of the U.S. based assets and certain liabilities of Biomol International, LP (Biomol LP) through a newly formed US subsidiary Biomol International, Inc. and all of the stock of Biomol s wholly-owned United Kingdom subsidiary, Affinity Limited by Axxora UK, a wholly-owned subsidiary of Enzo Life Sciences, collectively referred to as Biomol for approximately \$18.1 million in cash and stock, subject to adjustment, exclusive of acquisition costs of approximately \$800,000 and contingent payments which will be accounted for as additional purchase consideration over the next two years if and when the contingencies are resolved beyond a reasonable doubt. At closing, the purchase price was satisfied as follows: \$12.9 million in cash was paid to Biomol LP, issuance of 352,000 shares of Enzo common stock, at fair market value, to Biomol LP, \$1.5 million in cash was paid to an escrow agent for the one-year period following the closing to satisfy any indemnification obligations of the sellers under the Agreement and \$550,000 was paid to an escrow agent, for the 60 day period following the closing to satisfy any specified purchase price adjustments. The \$550,000 was released by the escrow agent in August 2008. The earn-outs of \$2.5 million on each of the next two anniversaries of the acquisition date will be based on attaining certain revenue targets and EBITDA, as defined. Biomol was a privately owned, closely held global manufacturer and marketer of specialty life sciences research products.

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2008 and 2007

Effective May 8, 2008, Biomol became a wholly-owned subsidiary of Enzo Life Sciences. The acquisition was financed with the Company's cash and cash equivalents and Enzo common stock. The consolidated financial statements presented herein include the results of operations for Biomol from the date of acquisition.

The following table presents the estimated fair values of the assets acquired and liabilities assumed (in thousands):

Current assets	\$ 5,167
Property and equipment	694
Other assets	18
Intangible assets	8,035
Goodwill	6,659
	<hr/>
Total assets acquired	20,573
	<hr/>
Less:	
Current liabilities	1,100
Deferred tax liabilities	609
	<hr/>
Total liabilities assumed	1,709
	<hr/>
Net assets acquired	\$ 18,864
	<hr/>

The preliminary purchase price allocation is based on a valuation of acquired tangible and intangible assets and will be adjusted based on the final valuations to be completed in fiscal 2009. The Company determined the estimated fair value of the identifiable intangible assets based on various factors including: cost, discounted cash flow and relief from royalty approaches in determining the purchase price allocation. The excess of the total purchase price over the fair value of the net assets acquired, including the estimated fair value of the identifiable intangible assets, has been allocated to goodwill.

Axxora Life Sciences, Inc.

On May 29, 2007, Enzo Life Sciences entered into a Stock Purchase Agreement (the Agreement), by and among Enzo Life Sciences, Axxora and the stockholders, option holders and warrant holders of Axxora who own all of the issued and outstanding capital stock, options and warrants, respectively, of Axxora (collectively, the Security holders). Pursuant to the Agreement, Enzo Life Sciences purchased all of the issued and outstanding capital stock of Axxora from the Security holders for an aggregate purchase price of \$16,322,000, exclusive of acquisition costs of \$1,023,000, \$475,000 previously advanced to Axxora to repay outstanding debt, and acquired cash of \$881,000, which is included in current assets below. Effective May 31, 2007, Axxora became a wholly-owned subsidiary of Enzo Life Sciences. The acquisition was financed with the Company's cash and cash equivalents. The consolidated financial statements presented herein include the results of operations for Axxora from the date of acquisition.

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2008 and 2007

The following table presents the fair values of the assets acquired and liabilities assumed (in thousands):

Current assets	\$ 9,033
Property and equipment	360
Other assets	82
Intangible assets	8,220
Goodwill	6,470
	<hr/>
Total assets acquired	24,165
	<hr/>
Less:	
Current liabilities	3,919
Deferred tax liabilities	2,426
	<hr/>
Total liabilities assumed	6,345
	<hr/>
Net assets acquired	<u>\$ 17,820</u>

The purchase price allocation is based on a valuation of acquired intangible assets based on the final valuation completed in fiscal 2008. The Company determined the fair value of the identifiable intangible assets based on various factors including: cost, discounted cash flow and relief from royalty approaches in determining the purchase price allocation. The excess of the total purchase price over the fair value of the net assets acquired, including the estimated fair value of the identifiable intangible assets, has been allocated to goodwill.

On March 7, 2008, Axxora acquired 100% of the outstanding stock of a distributor of life science products in Belgium for a total consideration of approximately \$229,000 in cash, net of cash acquired, including transaction costs. Liabilities assumed aggregated \$369,000. Prior to the acquisition, the acquired company was a distributor of Enzo Life Science's products as well as other unrelated manufacturers. The Company recorded goodwill of \$232,000 and intangibles for customer relationships of \$174,000 related to this acquisition. The consolidated financial statements presented herein include the results of operations for the acquired company from the date of acquisition. For financial reporting purposes, useful lives for the Biomol and Axxora acquisition have been assigned as follows:

Customer relationships	8 -15 years
Trademarks	Indefinite
Other intangibles	4-5 years

The following unaudited pro forma financial information presents the combined results of operations of the Company and acquisitions completed in 2008 and 2007 as if the acquisitions had occurred as of August 1, 2006. The pro forma financial information reflects appropriate adjustments for amortization of intangible assets and interest expense. The pro forma financial information presented is not necessarily indicative of either the actual consolidated operating results had the acquisition been completed at the beginning of each period or future operating results of the consolidated entities.

	Year Ended July 31,	
	<u>2008</u>	<u>2007</u>
Net revenues	\$ 86,922	\$ 77,939
Net loss	\$ (9,574)	\$ (13,895)
Net loss per common share:		

Basic and diluted

F-17

\$ (.26) \$ (0.39)

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2008 and 2007

Note 3- Supplemental disclosure for statement of cash flows

In the years ended July 31, 2008, 2007, and 2006, net income taxes (refunded to) or paid by the Company approximated \$233,000, (\$1,670,000), and \$1,374,000 respectively.

In fiscal 2008, certain officers and a director of the Company exercised 220,158 stock options in non-cash transactions. The officers and director surrendered 181,263 previously owned shares of the Company's common stock to exercise the stock options. The Company recorded approximately \$2.4 million, the market value of surrendered shares, as treasury stock.

In fiscal 2007, certain officers of the Company exercised 43,112 stock options in non-cash transactions. The officers surrendered 26,756 shares of previously owned shares of the Company's common stock to exercise the stock options. The Company recorded approximately \$0.4 million, the market value of the surrendered shares, as treasury stock.

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

Note 4 Marketable securities

The Company had no investments in marketable securities at July 31, 2008 or 2007.

Note 5 Accumulated Other Comprehensive Income (Loss)

The following is a summary of accumulated other comprehensive loss, relating to the effect of foreign currency translation:

In 000 s	Accumulated income (loss) before tax	Tax (expense) or benefit	Accumulated income (loss) net of tax
Balance July 31, 2005	(131)		(131)
Fiscal 2006 realized losses, net	131		131
Balance - July 31, 2006			
Fiscal 2007 gain on foreign currency translation	42		42
Balance - July 31, 2007	\$ 42	\$	\$ 42
Fiscal 2008 gain on foreign currency translation	1,544		1,544
Balance July 31, 2008	\$ 1,586	\$	\$ 1,586

Note 6 - Inventories

At July 31, 2008 and 2007 inventories, net of reserves of \$637,000 and \$379,000, respectively, consist of:

In 000 s	2008	2007
Raw materials	\$ 341	\$ 34
Work in process	899	1,221
Finished products	8,274	5,767

\$ 9,514 \$ 7,022

F-18

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2008 and 2007

Note 7 Property, plant, and equipment

At July 31, 2008 and 2007 property, plant, and equipment consist of:

<u>In 000 s</u>	<u>2008</u>	<u>2007</u>
Building and building improvements	\$ 4,785	\$ 3,053
Laboratory machinery and equipment	3,616	2,967
Office furniture and computer equipment	8,417	7,506
Leasehold improvements	4,281	3,211
	<u>21,099</u>	<u>16,737</u>
Accumulated depreciation and amortization	(12,758)	(10,828)
	<u>8,341</u>	<u>5,909</u>
Land and land improvements	712	712
	<u>\$ 9,053</u>	<u>\$ 6,621</u>

Note 8 Goodwill and intangible assets

The Company's change in the net carrying amount of goodwill by business segment is as follows (in thousands):

	<u>Enzo Life Sciences</u>	<u>Enzo Clinical Labs</u>	<u>Total</u>
August 1, 2006	\$	\$ 7,452	\$ 7,452
Acquisition see Note 2	6,224		6,224
July 31, 2007	6,224	7,452	13,676
Acquisitions see Note 2	7,137		7,137
Foreign currency translation	508		508
July 31, 2008	<u>\$ 13,869</u>	<u>\$ 7,452</u>	<u>\$ 21,321</u>

Intangible assets, all of which are included in the Life Science segment, consist of the following (in thousands):

	<u>July 31, 2008</u>			<u>July 31, 2007</u>		
	<u>Gross</u>	<u>Accumulated Amortization</u>	<u>Net</u>	<u>Gross</u>	<u>Accumulated Amortization</u>	<u>Net</u>
Finite-lived intangible assets:						
Patents	\$ 11,027	\$ (9,929)	\$ 1,098	\$ 11,027	\$ (9,849)	\$ 1,178
Customer relationships	8,314	(392)	7,922	3,890	(36)	3,854
Non-compete and employment agreements	481	(126)	355	360	(15)	345

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Website and acquired content	984	(117)	867	270	(9)	261
Licensed technology and other	737	(29)	708			
Indefinitely-lived intangible assets:						
Trademarks	6,706		6,706	3,700		3,700
Total	\$ 28,249	\$ (10,593)	\$ 17,656	\$ 19,247	\$ (9,909)	\$ 9,338

F-19

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Estimated amortization expense related to these finite-lived intangible assets for the five succeeding fiscal years ending July 31 is as follows (in thousands):

2009	\$	1,077
2010		1,036
2011		1,002
2012		918
2013		837

At July 31, 2008, the weighted average useful lives of amortizable intangible assets was approximately 11 years.

Amortization expense for the years ended July 31, 2008, 2007, and 2006 was \$658,000, \$151,000, and \$75,000, respectively.

Note 9 - Income taxes

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

Fiscal year ended July 31, (in 000 s)	2008	2007	2006
Current (provision) benefit:			
Federal	\$	\$	\$ 2,047
State and local	(320)	(261)	(65)
Foreign	(85)	(2)	
Deferred benefit (provision)	644	178	(640)
	\$ 239	\$ (85)	\$ 1,342

Deferred tax assets and liabilities arise from temporary differences between the tax basis of assets and liabilities and their reported amounts in the financial statements. The components of deferred tax assets (liabilities) as of July 31, 2008 and 2007 are as follows:

In 000 s	July 31, 2008	July 31, 2007
Deferred tax assets:		
Federal tax carryforward losses	\$ 10,693	\$ 6,941
Provision for uncollectible accounts receivable	309	531
State and local tax carry forward losses	1,478	1,543
Accrued royalties	456	543
Stock compensation	505	279
Depreciation	46	73
Research and development and other tax credit carryforwards	530	460
Realized and unrealized losses on marketable securities	138	138
Other, net	236	198
	14,391	10,706
Deferred tax liabilities:		
Deferred patent costs	(252)	(271)
Inventory	(265)	(325)
Intangibles	(3,039)	(2,409)
Prepaid expenses	(686)	(552)
Other, net	(75)	(90)
	(4,317)	(3,647)
Gross deferred tax liabilities		
	(4,317)	(3,647)
Net deferred tax assets (liabilities) before valuation allowance	10,074	7,059

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Less: valuation allowance	(12,965)	(9,385)
Net deferred tax assets (liabilities)	\$ (2,891)	\$ (2,326)

At July 31, 2008, the Company had net deferred tax liabilities of approximately \$2,891,000 which consists primarily of identifiable intangible assets, inventory valuation differences and cumulative tax deductions in excess of book expenses recognized by foreign subsidiaries attributed to Axxora and Biomol LP (see Note 2).

F-20

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2008 and 2007

Deferred tax liabilities are included in the consolidated balance sheets as follows:

	<u>July 31, 2008</u>	<u>July 31, 2007</u>
Deferred taxes:		
Current	\$ 458	\$ 597
Non-current	2,433	1,729
	<u>\$ 2,891</u>	<u>\$ 2,326</u>

Pursuant to SFAS 109, the Company recorded a valuation allowance during the year ended July 31, 2008 and 2007 equal to domestic and certain foreign net deferred tax assets. The Company believes that the valuation allowance is necessary as it is not more likely than not that the deferred tax assets will be realized in the foreseeable future based on positive and negative evidence available at this time. This conclusion was reached because of uncertainties relating to future taxable income, in terms of both its timing and its sufficiency, which would enable the Company to realize the deferred tax assets.

As of July 31, 2008, the Company had U.S. federal net operating loss carryforwards of approximately \$30.0 million. The U.S. federal tax loss carryforwards, if not fully utilized, expire between 2011 and 2028. Utilization is dependent on generating sufficient taxable income prior to expiration of the tax loss carryforwards. As of July 31, 2008, the Company has state and local tax loss carryforwards of approximately \$39.7 million.

As a result of the acquisition described in Note 2 Axxora Acquisition, approximately \$1.4 million of the Company's U.S. federal net operating loss carryforwards are subject to an annual limitation under Internal Revenue Code Section 382 due to the ownership change. However, management does not believe that such a change would have a significant impact on the Company's ability to utilize its tax loss carryforwards.

The components of (loss) income before income taxes consisted of the following for the years ended July 31:

	<u>2008</u>	<u>2007</u>	<u>2006</u>
United States operations	\$ (9,605)	\$ (12,595)	\$ (17,009)
International operations	(1,287)	(580)	
(Loss) income before taxes	<u>\$ (10,892)</u>	<u>\$ (13,175)</u>	<u>\$ (17,009)</u>

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

<u>Year ended July 31,</u>	<u>2008</u>	<u>2007</u>	<u>2006</u>
Federal statutory rate	34%	34%	34%
Expenses not deductible for income tax return purposes	(1.1%)	(3%)	(4%)
State income taxes, net of (benefit) of federal tax deduction	1.4%	(1%)	5%
Change in valuation allowance	(32.9%)	(30%)	(28%)
Other	.8%	(1%)	1%
	<u>2.2%</u>	<u>(1%)</u>	<u>8%</u>

U.S. federal income taxes have not been provided on the undistributed earnings of approximately \$244,000 at July 31, 2008 of the Company's foreign subsidiaries, because the determination of the amount of unrecognized US income tax liability with respect to such earnings is not practicable.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

The Company adopted the provisions of FIN 48 on August 1, 2007. The cumulative effect of adopting FIN 48 did not have a material impact on the Company's financial position or results of operations. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

Balance at August 1, 2007	\$ 261,014
Additions for tax positions related to prior years	91,335
Tax audit settlements	(61,335)
	<hr/>
Balance at July 31, 2008	\$ 291,014
	<hr/>

F-21

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2008 and 2007

Approximately, \$157,000 of the FIN 48 liability at July 31, 2008 which relates to acquisition described in Note 2 Axxora Acquisition can be completely reduced within the next two months with the lapse of the statute of limitations. The amount, if recognized, would not affect the Company's effective tax rate.

Interest and penalties related to income tax liabilities are included in income tax expense. During the fiscal year ended July 31, 2008, the Company recognized a net increase of approximately \$29,000. The Company has accrued approximately \$68,000 for the payment of interest and penalties as of July 31, 2008 and had accrued approximately \$39,000 for the payment of interest at August 1, 2007 upon the adoption of FIN 48.

The Company files income tax returns in the U.S. Federal jurisdiction, various U.S. state jurisdictions and several foreign jurisdictions. With few exceptions, the years that remain subject to examination are fiscal July 31, 2005 through fiscal 2007.

Note 10 Accrued Liabilities and Other Current Liabilities

At July 31, 2008 and 2007, accrued liabilities consist of:

<u>In 000 s</u>	<u>2008</u>	<u>2007</u>
Legal	\$ 1,702	\$ 4,542
Payroll, benefits, and commissions	1,989	1,417
Research and development	1,200	344
Professional fees	584	986
Outside reference lab testing	46	276
Other	1,849	881
	<u>\$ 7,370</u>	<u>\$ 8,446</u>

At July 31, 2008 and 2007, other current liabilities consist of:

<u>In 000 s</u>	<u>2008</u>	<u>2007</u>
Deferred revenue	\$ 1,089	\$ 770
Other	72	517
	<u>\$ 1,161</u>	<u>\$ 1,287</u>

Note 11 Stockholders' equity

Common stock offerings

During fiscal 2007, the Company entered into two Placement Agent Agreements with Lazard Capital Markets LLC, as exclusive placement agent, relating to registered direct offerings (Offerings) of shares of the Company's common stock. In December 2006, the Company entered into a definitive Subscription Agreement with various institutional investors relating to the sale of an aggregate of 3,285,715 shares of common stock for a purchase price of \$14.00 per share. Net proceeds from the Offering aggregating \$42.9 million, net of placement fees and financing costs of \$3.1 million, were credited to common stock and additional paid-in capital. In February 2007, the Company entered into the second definitive Subscription Agreement with an investor for the sale of an aggregate of 1,000,000 shares of common stock for a purchase price of \$15.00 per share. Net proceeds from this Offering aggregated \$14.1 million, net of placement fees and financing costs of \$0.9 million, and were credited to common stock and additional paid in capital. The Company filed prospectus supplements with the SEC relating to the Offerings under a Registration Statement filed and supplement thereto.

Treasury stock

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

In fiscal 2008, certain officers and a director of the Company exercised 220,158 stock options in a non-cash transaction. The officers and director surrendered 181,263 previously owned shares of the Company's common stock to exercise the stock options. The Company recorded approximately \$2.4 million, the market value of surrendered shares, as treasury stock.

In fiscal 2007, certain officers of the Company exercised 43,112 stock options in a non-cash transaction. The officers surrendered 26,756 shares of previously owned shares of the Company's common stock to exercise the stock options. The Company recorded approximately \$0.4 million, the market value of the surrendered shares, as treasury stock.

F-22

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2008 and 2007

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

Incentive stock option plans

The Company has incentive stock option plans (the 1994 Plan and 1999 Plan) and an incentive stock option and restricted stock award plan (the 2005 Plan), collectively the Plans, under which the Company may grant options for up to 1,336,745 common shares under the 1994 plan, options for up to 2,312,356 common shares under the 1999 Plan and options and restricted stock awards for up to 1,000,000 common shares under the 2005 Plan. No additional options may be granted under the 1994 Plan. The exercise price of options granted under such plans is equal to or greater than fair market value of the common stock on the date of grant. The options granted pursuant to the plans may be either incentive stock options or non statutory options. Stock options generally become exercisable at 25% per year after one year and expire ten years after the date of grant. The 2005 Plan provides for the issuance of restricted stock and restricted stock unit awards which generally vest over a two to four year period.

As of July 31, 2008, there were approximately 588,000 shares available for grant under the Company's 1999 and 2005 Plans.

A summary of the information pursuant to the Company's stock option plans for the years ended July 31, 2008, 2007, and 2006 is as follows:

	2008		2007		2006	
	Options	Weighted - Average Exercise Price	Options	Weighted - Average Exercise Price	Options	Weighted - Average Exercise Price
Outstanding at beginning of year	2,700,457	\$ 13.32	2,877,727	\$ 13.20	3,154,125	\$ 12.61
Granted		\$	27,761	\$ 17.06	100,000	\$ 24.84
Exercised	(267,345)	\$ 10.80	(95,525)	\$ 9.60	(285,030)	\$ 10.93
Cancelled	(157,697)	\$ 20.42	(109,506)	\$ 14.36	(91,368)	\$ 12.61
Outstanding at end of year	2,275,415	\$ 13.13	2,700,457	\$ 13.32	2,877,727	\$ 13.20
Exercisable at end of year	2,250,483	\$ 13.12	2,670,680	\$ 13.32	2,554,148	\$ 12.78
Weighted average fair value of options granted during year		\$		\$ 4.42		\$ 1.01

The aggregate intrinsic value of stock options exercised during the years ended July 31, 2008, 2007 and 2006, including the non-cash transactions (see Note 3) was \$0.7 million, \$0.7 million and \$0.9 million, respectively. The aggregate intrinsic value of options both outstanding and exercisable at July 31, 2008 is approximately \$5.7 million.

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2008 and 2007

The following table summarizes information for stock options outstanding at July 31, 2008:

Range of Exercise prices	Options outstanding			Options exercisable	
	Shares	Weighted- Average Remaining Contractual Life	Weighted- Average Exercise Price	Shares	Weighted- Average Exercise Price
\$5.45-6.68	248,908	0.2 years	\$ 5.57	248,908	\$ 5.57
\$8.33-12.25	1,133,312	3.1 years	\$ 11.12	1,133,312	\$ 11.12
\$12.93-19.02	813,318	5.5 years	\$ 17.10	788,386	\$ 17.20
\$20.20-24.84	61,644	3 years	\$ 21.42	61,644	\$ 21.42
\$36.05	18,233	1.5 years	\$ 36.05	18,233	\$ 36.05
	2,275,415			2,250,483	

During the year ended July 31, 2007, the Company granted 27,761 options under a two year consulting arrangement with a former employee with an exercise price of \$17.06 which were fully vested at the inception of the arrangement. The assumptions used to fair value this option grant as of May 2, 2007 were as follows: risk free interest rate of 4.65%, expected term of 2 years, expected volatility of 40%, and no dividend yield. The fair value of the options of approximately \$123,000 was recognized as an expense and included in selling, general and administrative expense in the accompanying statement of operations for the year ended July 31, 2007.

During the year ended July 31, 2006, the Company granted 100,000 options to a consultant with an exercise price of \$24.84, which vest over six months and have a two year term. The fair value of these options was \$88,000. The fair value of the options, which was accounted for as a variable instrument, was fair valued and recognized as expense over the six month vesting term. The assumptions used to fair value this option grant as of July 31, 2006 were as follows: risk free interest rate of 4.97%, expected term of 2 years, expected volatility of 49%, and no dividend yield. In connection with the options issued to this consultant, the Company recognized an expense of approximately \$8,000 and \$80,000 in selling, general and administrative expense in the accompanying statements of operations for the years ended July 31, 2007 and 2006 respectively.

Restricted Stock Awards

During fiscal 2008, 2007 and 2006, the compensation committee of the Company's board of directors approved grants of 160,140, 97,700 and 84,950 of restricted stock and restricted stock unit awards (the Awards), respectively, under the 2005 Plan to the Company's directors, certain officers and employees. The Awards vest upon the recipient's continued employment or director service ratably over either two, three or four years. Share-based compensation expense is recorded over the vesting period on a straight-line basis. The Awards will be forfeited if the recipient ceases to be employed by or serve as a director of the Company, as defined in the Award grants. The Awards settle in shares of the Company's common stock on a one-for-one basis. As of July 31, 2008, 220,240 shares were unvested.

A summary of the information pursuant to the Company's Restricted Stock Awards for the years ended July 31, 2008, 2007 and 2006 is as follows:

	2008		2007		2006	
	Awards	Weighted - Average Award Price	Awards	Weighted - Average Award Price	Awards	Weighted - Average Award Price
Outstanding at beginning of year	141,062	\$ 14.15	77,450	\$ 12.21		
Awarded	160,140	\$ 11.42	97,700	\$ 15.16	84,950	\$ 12.29
Vested	(70,962)	\$ 13.55	(25,913)	\$ 12.34		

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Forfeited	<u>(10,000)</u>	\$	14.73	<u>(8,175)</u>	\$	13.60	<u>(7,500)</u>	\$	13.13
Outstanding at end of year	<u>220,240</u>	\$	12.34	<u>141,062</u>	\$	14.15	<u>77,450</u>	\$	12.21
Weighted average market value of awards granted during year		\$	<u>11.42</u>		\$	<u>15.16</u>		\$	<u>12.29</u>

F-24

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2008 and 2007

Note 12 - Employee benefit plan

The Company has a qualified Salary Reduction Profit Sharing Plan (the Plan) for eligible U.S. employees under Section 401(k) of the Internal Revenue Code. The Plan provides for voluntary employee contributions through salary reduction and voluntary employer contributions at the discretion of the Company. For the years ended July 31, 2008, 2007, and 2006, the Company authorized employer matched contributions of 50% of the employees' contribution up to 10% of the employees' compensation, payable in Enzo Biochem, Inc. common stock. The 401(k) employer matched contributions expense was approximately \$481,000, \$421,800, and \$402,300, in fiscal years 2008, 2007, and 2006, respectively.

The Company's Swiss operations provide a pension plan under the Swiss government's social security system for Swiss employees. Employees are required to contribute based on a formula and the Company's Swiss operations make contributions of at least 50% of the employee contribution. During the year ended July 31, 2008 and the two months ended July 31, 2007, the period after the acquisition of Axxora Life Sciences, Inc., the employer contributions related to the Swiss benefit pension plan was approximately \$325,000 and \$58,000 respectively.

Note 13 Royalty and other income

In fiscal 2007, The Company as plaintiff and Sigma Aldrich (Sigma) entered into a Settlement Agreement and Release (the Settlement Agreement). Pursuant to the Settlement Agreement, the Company's litigation with Sigma was dismissed and the Company recognized a \$2 million gain on patent litigation settlement which is included in Other income in the accompanying statement of operations for the year ended July 31, 2007 (see Note 16).

In fiscal 2007, the Company received a payment of approximately \$699,000 from Perkin Elmer Inc. (Perkin Elmer) for amounts due under a Distribution Agreement (the Distribution Agreement) which terminated December 31, 2004. The Distribution Agreement is presently subject to a lawsuit for breach of contract, patent infringement, unfair competition under state law, unfair competition under federal law, tortious interference with business relations, and fraud in the inducement of contract (See Note 16). Perkin Elmer advised in a letter to the Company that the payment was owed under the Distribution Agreement and was delayed because of changes to their accounting system and personnel changes and that it was always their intent to comply with the Distribution Agreement. The Company advised Perkin Elmer that the payment did not represent all amounts owed under the Distribution Agreement. Accordingly, the payment is included in Other income in the accompanying statement of operations for the year ended July 31, 2007.

In fiscal 2005, the Company as plaintiff finalized and executed a settlement and license agreement with Digene Corporation to settle a patent litigation lawsuit (the Agreement). Under the terms of the Agreement, the Company received an initial payment of \$16.0 million, would earn in the first annual period (October 1, 2004 to September 30, 2005) a minimum royalty payment of \$2.5 million, and receive a minimum royalty of \$3.5 million in each of the next four annual periods. Digene Corporation was acquired by QIAGEN. The license agreement with the Company was assigned to QIAGEN Gaithersburg Inc. (Qiagen).

In addition, the Agreement provides for the Company to receive quarterly running royalties on the net sales of Qiagen products subject to the license until the expiration of the patent on April 24, 2018. These quarterly running royalties are fully creditable against the minimum royalty payments due in the first five years of the Agreement. The balance, if any, of the minimum royalty payment is recognized in the final quarter of the applicable annual royalty period. As a result of the Qiagen Agreement, the Company recorded a gain on patent litigation settlement of \$14.0 million during the year ended July 31, 2005 and deferred \$2 million, which was earned from net sales of the Company's licensed products covered by the Agreement during the first annual period. During the years ended July 31, 2008, 2007 and 2006, the Company recorded royalty income under the Agreement of approximately \$5.5 million, \$4.7 million, and \$3.1 million, respectively, which is included in the Life Sciences segment.

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2008 and 2007

Note 14 - Licensing and Supply Agreement:

On April 27, 2007 (the Effective Date) Enzo Life Sciences, Inc. (Life Sciences) and Abbott Molecular Inc. (Abbott) entered into a 5 year agreement covering the supply of certain of Enzo Life Sciences products to Abbott for use in their product line. The parties also entered into a limited non-exclusive royalty bearing cross-licensing agreement (Licensing Agreement) for various patents. The Licensing Agreement requires each party to pay royalties, as defined through the lives of the related covered patents. In connection with a component of the License Agreement, Abbott paid a one-time fee of \$1.5 million relating to a fully paid-up license and sublicense, as defined. The one-time fee will be recognized as revenue over the longest expected patent life. At July 31, 2008, the Company's balance sheet includes current and non-current deferred revenue of approximately \$0.4 and \$0.5 million, respectively, relating to the one-time fee. During the years ended July 31, 2008 and 2007, the Company recorded approximately \$2.1 million and \$1.0 million in royalties and license fee income under the Licensing Agreement.

Note 15 Commitments*Leases*

The Company leases equipment, office and laboratory space under several non-cancelable operating leases that expire between September 2008 and March 2017. Certain leases include renewal options and rent escalation clauses. An entity owned by certain executive officers/directors of the Company owns the building that the Company leases as its main facility for laboratory operations and certain research operations. In March 2005, the Company amended and extended the lease for another 12 years. In addition to the minimum annual rentals of space, the lease is subject to annual increases, based on the consumer price index. Annual increases are limited to 3% per year. Rent expense, inclusive of real estate taxes, under this renewed lease and the prior lease approximated \$1,395,000, \$1,376,000, and \$1,337,000 during fiscal years 2008, 2007, and 2006.

Total rent expense incurred by the Company during fiscal 2008, 2007 and 2006 was approximately \$2,885,000, \$2,510,000, and \$2,257,000, respectively. Minimum future annual rentals under non-cancelable operating leases as of July 31, 2008, are as follows:

Years ended July 31,	In 000 s
2009	\$ 3,947
2010	3,427
2011	3,231
2012	2,110
2013	1,933
Thereafter	6,516
	\$ 21,164

Employment Agreements

The Company has employment agreements with certain officers that are cancelable at any time but provide for severance pay in the event an officer is terminated by the Company without cause, as defined in the agreements. Unless cancelled earlier, the contracts expire through May 2010. Aggregate minimum compensation commitments, exclusive of any severance provisions, for the years ending July 31, 2009, 2010 and 2011 are \$2,691,000, \$2,175,000 and \$1,439,000, respectively.

Note 16 Contingences

In October 2002, the Company filed suit in the United States District Court of the Southern District of New York against Amersham plc, Amersham Biosciences, Perkin Elmer, Inc., Perkin Elmer Life Sciences, Inc., Sigma-Aldrich Corporation, Sigma Chemical Company, Inc., Molecular Probes, Inc. and Orchid Biosciences, Inc. In January 2003, the Company amended its complaint to include defendants Sigma Aldrich Co. and Sigma Aldrich, Inc. The counts set forth in the suit are for breach of contract; patent infringement; unfair competition under state law; unfair competition under federal law; tortious interference with business relations; and fraud in the inducement of contract. The complaint alleges that these counts arise out of the defendants' breach of

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

distributorship agreements with the Company concerning labeled nucleotide products and technology, and the defendants infringement of patents covering the same. In April, 2003, the court directed that individual complaints be filed separately against each defendant. The defendants have answered the individual complaints and asserted a variety of affirmative defenses and counterclaims.

F-26

Fact discovery is ongoing. The court issued a claim construction opinion on July 10, 2006. The Company and Sigma Aldrich (Sigma) entered into a Settlement Agreement and Release effective September 15, 2006 (the Agreement). Pursuant to the Agreement, the Company's litigation with Sigma was dismissed and the Company recognized \$2 million on settlement in the quarter ending October 31, 2006 (See Note 13). On January 3, 2007, the remaining defendants moved for summary judgment on all counts in the individual complaints. During a two-day hearing held on July 17 through July 18, 2007, the defendants subsequently withdrew the invalidity portion of their summary judgment motions. The court has yet to rule on the pending summary judgment motions. There can be no assurance that the Company will be successful with the remaining outstanding litigation. However, even if the Company is not successful, management does not believe that there will be a significant adverse monetary impact to the Company. The Company has not recorded revenue under these distribution agreements in fiscal 2008, 2007 and 2006. The Company recorded other income from Perkin Elmer in fiscal 2007 (See Note 13).

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

Affymetrix also moved to transfer venue of Enzo's action to the Southern District of New York, where other actions commenced by Enzo were pending as well as Affymetrix's subsequently filed action. On January 30, 2004, Affymetrix's motion to transfer was granted. Accordingly, the Enzo and Affymetrix actions are now both pending in the Southern District of New York. Initial pleadings have been completed and discovery has commenced. The Court issued a Markman (claim construction) opinion on July 10, 2006. The Company did not record any revenue from Affymetrix during the fiscal years ended July 31, 2008, 2007 or 2006.

On June 2, 2004, Roche Diagnostic GmbH and Roche Molecular Systems, Inc. (collectively Roche) filed suit in the U.S. District Court of the Southern District of New York against Enzo Biochem, Inc. and Enzo Life Sciences, Inc. (collectively Enzo). The Complaint was filed after Enzo rejected Roche's latest cash offer to settle Enzo's claims for, *inter alia*, alleged breach of contract and misappropriation of Enzo's assets. The Complaint seeks declaratory judgment (i) of patent invalidity with respect to Enzo's 4,994,373 patent (the 373 patent), (ii) of no breach by Roche of its 1994 Distribution and Supply Agreement with Enzo (the 1994 Agreement), (iii) that non-payment by Roche to Enzo for certain sales of Roche products does not constitute a breach of the 1994 Agreement, and (iv) that Enzo's claims of ownership to proprietary inventions, technology and products developed by Roche are without basis. In addition, the suit claims tortious interference and unfair competition. The Company does not believe that the Complaint has merit and intends to vigorously respond to such action with appropriate affirmative defenses and counterclaims. Enzo filed an Answer and Counterclaims on November 3, 2004 alleging multiple breaches of the 1994 Agreement and related infringement of Enzo's 373 patent. Discovery has commenced. The Court issued a Markman opinion on July 10, 2006. The Company did not record any revenue from Roche during the fiscal years ended July 31, 2008, 2007 or 2006. The Roche agreement remains in force to date.

On June 7, 2004, the Company and Enzo Life Sciences, Inc., filed suit in the United States District Court for the District of Connecticut against Applera Corporation and its wholly-owned subsidiary Tropix, Inc. The complaint alleges infringement of six patents (relating to DNA sequencing systems, labeled nucleotide products, and other technology). Yale University is the owner of four of the patents and the Company is the exclusive licensee. These four patents are commonly referred to as the Ward patents. Accordingly, Yale is also a plaintiff in the lawsuit. Yale and Enzo are aligned in protecting the validity and enforceability of the patents. Enzo Life Sciences is the owner of the remaining two patents. The complaint seeks permanent injunction and damages (including treble damages for willful infringement). Defendants answered the complaint on July 29, 2004. The answer pleads affirmative defenses of invalidity, estoppels and laches and asserts counterclaims of non-infringement and invalidity.

A Markman hearing was held on May 25, 2006 and the district court issued a ruling on October 12, 2006. On August 17, 2007, the Company voluntarily dismissed the infringement claims for one of the patents in suit without prejudice. Defendants similarly dismissed their defenses and counterclaims as to that patent. On the same date, the Company conceded a judgment of non-infringement for another of the patents in suit based on the district court's claim construction, reserving the right to appeal their construction. The defendants filed motions for summary judgment for invalidity, laches and non-infringement of the Ward patents on March 5, 2007. The Company and other plaintiff filed a motion for summary judgment on infringement of the Ward patents on March 5, 2007. On August 20, 2007, the district court heard oral arguments on the motions for summary judgment. On September 6, 2007, the court granted defendants' motion for summary judgment of invalidity of three of the remaining Ward patents and entered judgment to that effect. The Company and other plaintiff filed a notice of appeal to the United States Court of Appeals for the Federal Circuit on September 7, 2007. On January 30, 2008, the Court of Appeals for the Federal Circuit granted the Company's alternative motion to dismiss its appeal and remand to the Connecticut Court for further proceedings incident to an entry of a final, appealable judgment. The Company has requested the Connecticut Court to dispose of all outstanding issues (including the Company's claim under the fourth Ward patent and certain counterclaims of Applera's) and enter final judgment. Once the Connecticut Court does this, the Company intends to appeal that judgment. The Company and other plaintiff intend to vigorously pursue this appeal; however, the outcome of the appeal cannot be anticipated at this time. If the appeal is granted, there can be no assurance that the Company will be successful in this litigation. Even if the Company is not successful, management does not believe that there will be a significant adverse monetary impact on the Company.

In January 2006, the Company was named along with certain of its officers and directors among others, in several complaints titled Francis Scott Hunt, et al. v. Enzo Biochem Inc., et al., Index No. 06-CV-00170 (SAS) and Ken Roberts v. Enzo Biochem, Inc. et al., Index No. 06-CV-00213 (SAS), and Paul Lewicki v. Enzo Biochem Inc., et al., Index No. 06-CV-06347 (SAS) based only upon a claim for common law fraud. These three consolidated actions were all filed in the United States District Court for the Southern District of New York. In their amended complaints, plaintiffs collectively seek more than \$8.0 million in damages. Limited discovery has occurred to date. The actions are all based on allegations of a fraudulent scheme to pump and dump Enzo securities as was initially set forth in a previous action (filed by the same attorney) which was dismissed by the Eastern District of Virginia and such dismissal was affirmed by the Fourth Circuit Court of Appeals and is now final since the U.S. Supreme Court denied a petition for certiorari. The Company and the other defendants likewise moved to dismiss all of the Complaints in these actions and that motion was granted by U.S. District Court. As a result, some of the Plaintiffs were no longer able to pursue their claims or choose not to pursue them further. Other Plaintiffs amended their Complaints and the Company and the other defendants moved again to dismiss those Amended Complaints. The Court recently granted in part and denied in part those motions. As a result of the Court's latest decision, however, certain of the defendants, including Enzo Biochem, Inc. are proceeding with discovery. The Company believes that the latest Complaints in these actions have no merit, and intends to move for summary judgment and otherwise to defend these actions vigorously.

The Company is party to other claims, legal actions and complaints that arise in the ordinary course of business. The Company believes that any liability that may ultimately result from the resolution of these matters will not, individually or in the aggregate, have a material adverse effect on its financial position or results of operations.

Note 17 Segment reporting

The Company has three reportable segments: Life Sciences, Therapeutics and Clinical Labs. The Company's Life Sciences segment develops, manufactures, and markets products to research and pharmaceutical customers. The Company's Therapeutic segment conducts research and development activities for therapeutic drug candidates. The Clinical Labs segment provides diagnostic services to the health care community. The Company evaluates segment performance based on segment income (loss) before taxes. Costs excluded from segment income (loss) before taxes and reported as other consist of corporate general and administrative costs which are not allocable to the three reportable segments.

Management of the Company assesses assets on a consolidated basis only and therefore, assets by reportable segment have not been included in the reportable segments below. The accounting policies of the reportable segments are the same as those described in the summary of significant accounting policies.

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2008 and 2007

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

Year ended July 31, 2008

Revenues:	Life Sciences	Therapeutics	Clinical Labs	Other	Consolidated
Product revenues	\$ 28,087				\$ 28,087
Royalty income and license fee income	7,630				7,630
Clinical laboratory services			\$ 42,078		42,078
	<u>35,717</u>		<u>42,078</u>		<u>77,795</u>
Cost and expenses and other (income):					
Cost of product revenues	19,159				19,159
Cost of clinical laboratory services			21,063		21,063
Research and development	3,473	\$ 5,164			8,637
Provision for uncollectible accounts			3,716		3,716
Selling, general and administrative and legal	9,779		15,495	\$ 14,732	40,006
Interest income			(239)	(3,457)	(3,696)
Other income	(98)	(100)			(198)
Income (loss) before income taxes	<u>\$ 3,404</u>	<u>\$ (5,064)</u>	<u>\$ 2,043</u>	<u>\$ (11,275)</u>	<u>\$ (10,892)</u>
Depreciation and amortization included above	<u>\$ 1,138</u>	<u>\$ 35</u>	<u>\$ 853</u>	<u>\$ 120</u>	<u>\$ 2,146</u>
Share - based compensation included in					
Cost of products	\$ 8		\$ 6		\$ 14
Research and development	34	\$ 63			97
Selling, general and administrative and legal	129		247	\$ 1,079	1,455
Total	<u>\$ 171</u>	<u>\$ 63</u>	<u>\$ 253</u>	<u>\$ 1,079</u>	<u>\$ 1,566</u>
Capital expenditures	<u>\$ 2,308</u>	<u>\$ 63</u>	<u>\$ 797</u>	<u>\$ 63</u>	<u>\$ 3,231</u>

Year ended July 31, 2007

Revenues:	Life Sciences	Therapeutics	Clinical Labs	Other	Consolidated
Product revenues	\$ 6,658				\$ 6,658
Royalty and license fee income	5,820				5,820
Clinical laboratory services			\$ 40,430		40,430
	<u>12,478</u>		<u>40,430</u>		<u>52,908</u>
Cost and expenses and other (income):					
Cost of product revenues	5,034				5,034
Cost of clinical laboratory services			18,199		18,199
Research and development	3,349	\$ 6,044			9,393

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Provision for uncollectible accounts			4,653		4,653
Selling, general and administrative and legal	2,772		14,403	\$ 19,420	36,595
Interest income			(99)	(4,993)	(5,092)
Other income	(2,699)				(2,699)
Income (loss) before income taxes	\$ 4,022	\$ (6,044)	\$ 3,274	\$ (14,427)	\$ (13,175)
Depreciation and amortization included above	\$ 288	\$ 16	\$ 838	\$ 47	\$ 1,189
Share - based compensation included in					
Cost of products	\$ 10				\$ 10
Research and development	51	\$ 111			162
Selling, general and administrative and legal	66		\$ 358	\$ 881	1,305
Total	\$ 127	\$ 111	\$ 358	\$ 881	\$ 1,477
Capital expenditures	\$ 106	\$ 82	\$ 698	\$ 562	\$ 1,448

F-29

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2008 and 2007

Year ended July 31, 2006

<u>Revenues:</u>	<u>Life Sciences</u>	<u>Therapeutics</u>	<u>Clinical Labs</u>	<u>Other</u>	<u>Consolidated</u>
Product revenues	\$ 4,750				\$ 4,750
Royalty income	3,150				3,150
Clinical laboratory services			\$ 31,926		31,926
	<u>7,900</u>		<u>31,926</u>		<u>39,826</u>
Cost and expenses and other (income):					
Cost of product revenues	2,400				2,400
Cost of clinical laboratory services			13,917		13,917
Research and development	3,659	\$ 4,237			7,896
Provision for uncollectible accounts			3,633		3,633
Selling, general and administrative and legal	2,034		14,322	\$ 15,777	32,133
Interest income				(3,144)	(3,144)
	<u>\$ (193)</u>	<u>\$ (4,237)</u>	<u>\$ 54</u>	<u>\$ (12,633)</u>	<u>\$ (17,009)</u>
(Loss) income before income taxes					
Depreciation and amortization included above	\$ 180	\$ 12	\$ 897	\$ 35	\$ 1,124
	<u>\$ 21</u>	<u>\$ 143</u>	<u>\$ 539</u>	<u>\$ 867</u>	<u>\$ 1,493</u>
Share - based compensation included in					
Cost of products	\$ 21				\$ 21
Research and development	106	\$ 143			249
Selling, general and administrative and legal	87		\$ 539	\$ 867	1,493
Total	<u>\$ 214</u>	<u>\$ 143</u>	<u>\$ 539</u>	<u>\$ 867</u>	<u>\$ 1,763</u>
Capital expenditures	\$ 3,332	\$ 6	\$ 860	\$ 29	\$ 4,227

Geographic financial information is as follows (in thousands):

Net sales to unaffiliated customers:	<u>2008</u>	<u>2007</u>	<u>2006</u>
United States	\$ 62,243	\$ 50,051	\$ 38,287
Switzerland	9,142	945	
United Kingdom	2,127	272	
Other international countries	4,283	1,640	1,539
Total	<u>\$ 77,795</u>	<u>\$ 52,908</u>	<u>\$ 39,826</u>
Long-lived assets at July 31,	<u>2008</u>	<u>2007</u>	<u>2006</u>
United States	\$ 34,202	\$ 21,438	\$ 14,557
Switzerland	7,437	6,652	
United Kingdom	4,193		

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Other international countries	<u>2,198</u>	<u>1,545</u>	<u></u>
Total	<u>\$ 48,030</u>	<u>\$ 29,635</u>	<u>\$ 14,557</u>

F-30

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2008 and 2007

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

In 000 s	2008	2007	2006
United States	\$ 20,165	\$ 9,621	\$ 6,361
Foreign countries	15,552	2,857	1,539
	<u>\$ 35,717</u>	<u>\$ 12,478</u>	<u>\$ 7,900</u>

Note 18 Summary of Selected Quarterly Financial Data (unaudited)

The following table contains statement of operations information for each quarter of the years ended July 31, 2008 and 2007. The Company believes that the following information reflects all normal recurring adjustments necessary for a fair presentation of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

Unaudited quarterly financial data (in thousands, except per share amounts) for fiscal 2008 and 2007 is summarized as follows:

	Quarter Ended			
	October 31, 2007	January 31, 2008	April 30, 2008	July 31, 2008
Fiscal 2008				
Total revenues	\$ 19,447	\$ 18,224	\$ 18,948	\$ 21,176
Gross profit	9,882	9,045	9,336	9,310
Loss before income taxes	(1,347)	(4,013)	(1,940)	(3,592)
Net loss	(1,232)	(4,055)	(2,107)	(3,259)
Basic loss per common share	\$ (0.03)	\$ (0.11)	\$ (0.06)	\$ (0.09)
Diluted loss per common share	\$ (0.03)	\$ (0.11)	\$ (0.06)	\$ (0.09)

	Quarter Ended			
	October 31, 2006	January 31, 2007	April 30, 2007	July 31, 2007
Fiscal 2007				
Total revenues	\$ 10,442	\$ 10,594	\$ 13,960	\$ 17,912
Gross profit	6,391	6,157	7,934	9,193
Loss before income taxes	(1,201)	(4,777)	(3,754)	(3,443)
Net loss	(1,246)	(4,852)	(3,833)	(3,329)
Basic loss per common share	\$ (0.04)	\$ (0.14)	\$ (0.10)	\$ (0.09)
Diluted loss per common share	\$ (0.04)	\$ (0.14)	\$ (0.10)	\$ (0.09)

ENZO BIOCHEM, INC
SCHEDULE II
VALUATION AND QUALIFYING ACCOUNTS
Years ended July 31, 2008, 2007 and 2006
(in thousands)

Year ended July 31,	Description	Balance at Beginning of period	Charged (credited) to costs and expenses	Charged to other accounts	Deductions	Balance at end of period
2008	Allowance for doubtful accounts receivable	1,404	3,716		4,234 (1)	886
2007	Allowance for doubtful accounts receivable	1,033	4,653		4,282 (1)	1,404
2006	Allowance for doubtful accounts receivable	2,292	3,633		4,892 (1)	1,033
2008	Deferred tax valuation allowance	9,385	3,580			12,965
2007	Deferred tax valuation allowance	4,856	5,220		691 (2)	9,385
2006	Deferred tax valuation allowance	129	4,727			4,856
2008	Reserve for obsolete inventory	379	283		25 (3)	637
2007	Reserve for obsolete inventory	238	337		196 (3)	379
2006	Reserve for obsolete inventory		596		358 (3)	238

(1) Write-off of uncollectible accounts receivable net of recoveries.

(2) Utilization of deferred tax assets

(3) Write-off of obsolete inventory

S-1

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-3 No. 333-138417, 333-15533, 33-58736, 33-60229, 33-78760, 33-72170, and 33-68542) of Enzo Biochem, Inc., and
- (2) Registration Statement (Form S-8 No. 33-45348, 33-75466, 33-88826, 333-87153, 333-89308 and 333-123712) pertaining to the 2005 Equity Compensation Incentive Plan, 1999 Stock Option Plan and 1994 Stock Option Plan of Enzo Biochem, Inc.;

of our report dated October 14, 2008, with respect to the consolidated financial statements and schedule of Enzo Biochem, Inc., and our report dated October 14, 2008, with respect to the effectiveness of internal control over financial reporting of Enzo Biochem, Inc., included in this Annual Report (Form 10-K) of Enzo Biochem, Inc.

/s/ Ernst & Young LLP

Melville, New York
October 14, 2008
