

ENZO BIOCHEM INC
Form 10-K
October 15, 2012

**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, 2012

or

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

For the transition period from _____ to _____

Commission File Number 001-09974

ENZO BIOCHEM, INC.

(Exact name of registrant as specified in its charter)

New York

(State or other jurisdiction
of incorporation or organization)

527 Madison Ave.
New York, New York

(Address of principal executive offices)

13-2866202

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

10022

(Zip Code)

(212) 583-0100

(Registrant's telephone number, including area code)

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

(Title of Each Class)

(Name of Each Exchange on Which Registered)

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Common Stock, \$.01 par value

The New York Stock Exchange

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

Yes ☐ No ☒

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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes ☒ No ☐

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

Yes ☒ No ☐

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

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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 \$90,665,000 as of January 31, 2012

The number of shares of the Company's common stock, \$.01 par value, outstanding at October 1, 2012 was 39,278,919.

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 17, 2013 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>	28
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	39
<u>Item 2.</u>	<u>Properties</u>	40
<u>Item 3.</u>	<u>Legal Proceedings</u>	41
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	43
Part II		
<u>Item 5.</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	43
<u>Item 6.</u>	<u>Selected Financial Data</u>	44
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	45
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	60
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	61
<u>Item 9.</u>	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	61
<u>Item 9A.</u>	<u>Controls and Procedures</u>	61
<u>Item 9B.</u>	<u>Other Information</u>	64
Part III		
<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	64
<u>Item 11.</u>	<u>Executive Compensation</u>	64
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	64
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	64
<u>Item 14.</u>	<u>Principal Accountant Fees and Services</u>	64
Part IV		
<u>Item 15.</u>	<u>Exhibits and Financial Statement Schedules</u>	64
	<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 growth-oriented integrated life sciences and biotechnology company focused on harnessing biological processes to develop research tools, diagnostics and therapeutics and serves as a provider of test services, including esoteric tests, to the medical community. Since our founding in 1976, our strategic focus has been on the development of enabling technologies in research, development, manufacture, licensing and marketing of innovative health care products, platforms and services based on molecular and cellular technologies. 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, comprising 107 key issued patents worldwide, and over 300 pending patent applications, along with extensive enabling technologies and platforms.

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 and augmented by the acquisition of a number of related companies. Information concerning sales by geographic area and business segments for the years ended July 31, 2012, 2011 and 2010 is located in Note 15 in the Notes to Consolidated Financial Statements.

Below are brief descriptions of each of our operating segments:

Enzo Clinical Labs is a regional clinical laboratory serving the New York, New Jersey and Eastern Pennsylvania medical communities. The Company believes having clinical diagnostic services allows us to capitalize first hand on our extensive advanced molecular and cytogenetic capabilities and the broader trends in predictive and personalized 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 over 30 patient service centers throughout New York and New Jersey, a stand-alone stat or rapid response laboratory in New York City and a full-service phlebotomy and in-house logistics department.

Enzo Life Sciences manufactures, develops and markets products and tools to life sciences, drug development and clinical research customers world-wide and has amassed a large patent and technology portfolio. Enzo Life Sciences, Inc. is a recognized leader in labeling and detection technologies across research and diagnostic markets. Our strong portfolio of proteins, antibodies, peptides, small molecules, labeling probes, dyes and kits provides life science researchers tools for target identification/validation, high content analysis, gene expression analysis, nucleic acid detection, protein biochemistry and detection, and cellular analysis. We are internationally recognized and acknowledged as a leader in manufacturing, in-licensing, and commercialization of over 7,500 of our own products and in addition distribute over 30,000 products made by over 40 other original manufacturers. Our strategic focus is directed to innovative high quality research reagents and kits in the primary key research areas of genomics, cellular analysis, small molecule chemistry, protein homeostasis epigenetics immunoassays and assay development.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

The segment is an established source for a comprehensive panel of products to scientific experts in the fields of cancer, cardiovascular disease, neurological disorders, diabetes and obesity, endocrine disorders, infectious and autoimmune disease, hepatotoxicity and renal injury.

Enzo Therapeutics is a biopharmaceutical venture 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 45 patents and patent applications.

The Company's primary sources of revenue have historically been from the clinical laboratory services provided to the healthcare community and product revenues and royalty and licensing of Life Sciences' products utilized in life science research. The following table summarizes the sources of revenues for the fiscal years ended July 31, 2012, 2011 and 2010 in \$000's and percentages:

Fiscal year ended July 31,	2012		2011		2010	
Clinical laboratory services	\$ 59,403	58%	\$ 52,762	52%	\$ 44,178	46%
Product revenues	37,722	37	41,830	41	43,111	44
Royalty and license fee income	5,958	5	7,437	7	9,793	10
Total	\$ 103,083	100%	\$ 102,029	100%	\$ 97,082	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 genomic research in both the public and private sectors, including the Human Genome Project. The ongoing challenge of the scientific research community is to determine the function and relevance of each gene, as well as gene to gene and gene/environment interactions. In addition, scientists are looking in detail at the proteins that are expressed by genes, their control and regulation in the cellular environment. 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 a large global demand by biomedical and pharmaceutical researchers for research and diagnostic tools that both facilitate and accelerate the generation of biological information. This demand can be met by gene and protein target based diagnostics for which a variety of formats, or tools, have been developed that enable researchers to study biological pathways. These tools can identify mutations in gene sequences and variations in gene expression levels that can lead to disease, or quantify biomarkers that provide insight to disease and potential therapeutic solutions. These techniques use instruments including DNA sequencing and genotyping instruments, microarrays, fluorescent microscopes, high content screening systems, flow cytometers and plate readers. Common among these instruments is the need for reagents that allow the identification, quantification and characterization, and interactions of specific genes or nucleic acid sequences, proteins, cells and other cellular structures and organelles.

We believe this market will continue to grow as a result of:

long term commitment to research spending by academic, government and private organizations to determine the function and clinical relevance of the gene sequences and proteins 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, immunoassays, genomics, proteomics, gene expression profiling blood banking, and cancer screening assays through histology as well as newer body fluid based approaches. 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 and often its susceptibility to FDA approved drugs.

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 have many advantages over the traditional technologies. Since gene-based diagnostics focus on the identification of diseases at the cellular level, they can identify the presence of the disease at its earliest stage of manifestation in the body. These tests provide results more rapidly, are applicable to a broad spectrum of microorganisms and can easily be automated in a multiplex platform.

Several advances in technology are accelerating the adoption of gene-based diagnostics in clinical laboratories. These advances include high throughput automated formats that minimize labor costs, non-radioactive probes and reagents that are safe to handle, and amplification technologies that improve the sensitivity of such diagnostics.

According to industry sources, the market for molecular diagnostic tools, assays and other products is currently more than \$5 billion per year, and is acknowledged as one of the fastest growing segments in the in-vitro diagnostic industry, growing at more than twice the rate of traditional diagnostics. Contributing to this growth is, 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 or companion diagnostics.

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. 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 over expression 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.

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.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

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, services, and diagnostic technologies used to study and identify disease at the molecular level and to be a provider of therapeutic platforms 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:

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.

Our clinical trial of Optiquel® is a direct result of such research collaboration. We acquired the rights and intellectual property to this candidate drug and technology intended for use in the treatment of autoimmune uveitis. Working with scientists and physicians in the United States and abroad, Enzo continued drug development to the stage of a clinical trial now being conducted in collaboration with the National Eye Institute of the National Institutes of Health in Washington DC.

We have research and clinical collaborations with other institutions including, Hadassah University Medical Center in Jerusalem, Israel relating to our immune regulation technology. Through collaborations such as these 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. There can be no assurance that any of these collaborative projects will be successful.

Enzo Life Sciences maintains large numbers of relationships with academic and commercial groups worldwide in sourcing and commercializing high value reagents developed by leading academics.

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 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 thereby potentially reducing the need for multiple physician visits to obtain additional samples.

Expand marketing and distribution infrastructure

Enzo Life Sciences has developed its sales and marketing infrastructure to more directly service its end users, while simultaneously positioning the Company for targeted product line expansion. Our acquisitions of Axxora in May 2007, Biomol International in May 2008 and Assay Designs in March 2009 expanded our global sales, marketing, manufacturing, product development and distribution infrastructure, and have now been integrated and consolidated into a single global business. Enzo Life Sciences now operates, under its own name, worldwide through wholly owned subsidiaries (in USA, Switzerland, Benelux, Germany, and the UK), a branch office in France 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.

The Company has a license agreement with QIAGEN Gaithersburg Inc. (Qiagen) that began in 2005, whereby the Company earns 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 11 to the Notes to Consolidated Financial Statements.

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, target and signal amplification, and detection technologies and intellectual property to develop diagnostic and monitoring tests for various diseases.

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 2012 we were issued 28 patents and expanded our patent estate in the area of nucleotides, amplification, labeling and 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, (currently), We have also have developed isothermal amplification procedures that can be performed at constant temperatures, unlike polymerase chain reaction (PCR) the most commonly used method of target nucleic acid amplification. These platform technologies could thus potentially lead to assays with advantages over PCR-based tests which require expensive heating and cooling systems or specialized heat-resistant enzymes. Moreover, our AmpiProbe Nucleic Acid Amplification Platform, because of the reduced amount of starting material needed for analysis, may lead to a next-generation of molecular-based diagnostics that can impart higher sensitivity at lower cost than currently available assays.

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 Platform Development

Cell Signaling Pathway

One area of Enzo's therapeutic platform development is related to the development of pharmaceutical agents that affect 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 can 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 continue to explore 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. This platform technology is being developed as a means to manage immune-mediated diseases, such as autoimmune uveitis and Crohn's disease.

We have developed an immunomodulator agent EGS21 as a potential therapeutic for treating immune mediated disorders. EGS 21 is a glycolipid 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.

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.

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 RNA) that we are using as platforms for a portfolio of novel therapeutics.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

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, New Jersey and Eastern Pennsylvania medical communities.

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, through two main channels to market:

Enzo Life Sciences *Scientists enabling Scientists*

Enzo Life Sciences is positioned as a leading manufacturer and supplier of high quality reagents, kits and products supplied to customers in Life Sciences Research, Clinical Research and Drug Development. With direct sales operations in US, Switzerland, Germany, UK, France and Benelux, Enzo Life Sciences also supports its 7,500 products through a global network of dedicated distributors.

Axxora.com *The Reagents Marketplace , Thousands of Reagents, One Marketplace*

Axxora.com is a proven distribution platform for original manufacturers of innovative research reagents. An increasing number of researchers use our unique marketplace to instantly connect with over 40 specialty manufacturers and gain access to over 30,000 products. Purchasing groups from universities, research institutes, biotech and pharmaceutical companies utilize this extensive catalog to source research reagents and conveniently consolidate orders.

The products supplied by Enzo Life Sciences include small molecules, proteins, antibodies, peptides, probes, assay kits and custom services. 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	In Vitro Toxicology
Apoptosis/Cell Death	Kinases/Inhibitors
Biologically Active Peptides	Leukotrienes/Prostaglandins/Thromboxanes
Bone Metabolism	Microarray Labeling
Cancer Research	Multidrug Resistance
Cell Death	Natural Products/Antibiotics
Cell Cycle	Neuroscience
Chemokines/Cytokines	Nitric Oxide Pathway
Cytoskeletal Research	Nuclear Receptors
Dependence Receptors	Oxidative Stress
DNA Fragmentation/Damage/Repair	Protein Aggregation
DNA Regulation	Proteasome/Ubiquitin
Epigenetics	Receptors
FISH	Signal Transduction
Growth Factors/Cytokines	Stem Cell/Cell Differentiation
Hypoxia	Stress Proteins/Heat Shock Proteins
Immunology	Toxicology
Viral Signaling	TNF/TNF Receptor Superfamily
Inflammation/Innate Immunity	Transcription Factors

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Enzo Life Sciences is organized to promote and market its products and brands under its own name, building on a foundation of the brands it has acquired or developed previously:

Enzo The original 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 provides recognition in producing and commercializing innovative high quality reagents and as an established source for a comprehensive panel of products in many key research areas including the fields of cell death, nitric oxide, and obesity/adipogenesis.

Biomol International The Biomol International brand provides global recognition in the cellular biochemistry segment with an emphasis on areas related to protein post-translational modification, be it by ubiquitin or the ubiquitin-like proteins, acetylation, methylation, phosphorylation, sulphation, or glycosylation.

Assay Designs The Assay Designs brand emphasizes our immunoassay development capability in the fields of inflammation, steroids and hormones, and cell signaling.

Stressgen The Stressgen brand is focused exclusively on the fields of the heat shock and cell stress.

Enzo Life Sciences through its selective new product development programs is now entering new markets in the fields of Cellular Analysis and Protein Aggregation detection. As part of this introduction, we established new product lines to increase recognition of our products, such as the CellaStat® range of fluorescent dyes and kits, and ProteoStat® protein aggregation detection line of products. We are also launching certain products, particularly new drug development assays and immunoassay kits developed or acquired through our business collaborators.

In the Fiscal 2012 fourth quarter, in connection with the review of operations and the business strategy the Company created a branding plan that would provide more emphasis around the Enzo Life Sciences brand, which currently encompasses the acquired brands, and over a five (5) year period reduce the emphasis of the acquired brands, Alexis, Biomol International, Assay Designs and Stressgen. The Company intends to maintain the rights to the acquired brands which have long product history. The Company believes the emphasis on the Enzo Life Sciences brand will result in stronger and clearer brand awareness and allow the Company to execute the sale of higher value products and promote more products into the drug development, clinical research and diagnostic markets.

Therapeutic Development Programs

We have a number of therapeutic products in various stages of development that are based on our proprietary platform technologies. Our therapeutic programs are described below.

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.

Enzo acquired the 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.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Based on the results from the German study, we entered into a Cooperative Research and Development Agreement (CRADA) with the National Eye Institute (NEI), part of the National Institutes of Health (NIH), for further development of our candidate compound Optiquel® for the treatment of autoimmune uveitis. In October 2010, we announced the initiation of a human clinical trial. Currently, patients are being enrolled and treated. Under the terms of the CRADA, the NEI and Enzo will share the development costs of the studies and Enzo will supply its proprietary compound, Optiquel. The agreement additionally includes non clinical research focusing on the use of various compounds that may serve to enhance the immune mediated oral tolerance response to specific antigens. Such research may be applicable across the entire spectrum of the Company's immune regulation platform. The clinical trial is currently ongoing at the NEI to assess the safety and efficacy of Optiquel®. The study is designed as a randomized, double-masked, placebo-controlled proof-of-concept study with a long-term follow-up.

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

Inflammatory bowel diseases. We believe Alequel, Enzo's proprietary candidate drug based on 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 extracted during a routine colonoscopy. The Enzo protein extract is administered to the patient orally. Clinical results indicated that the study met its primary and secondary endpoints. Although not statistically significant, the results 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. No treatment-related adverse events were noted. Thus, we conclude that Alequel may be a safe and effective method for treatment of patients with moderate to severe Crohn's disease.

Osteoporosis (and certain bone disorders) and Diabetes

We have a number of 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.

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.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

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.

Clinical Laboratory Services

We operate a regional clinical laboratory that offers extensive diagnostic services to the New York, New Jersey and Eastern Pennsylvania medical communities. 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 offer a comprehensive and broad range 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 levels, or search for an otherwise undiagnosed condition.

Our full service clinical laboratory in Farmingdale, New York contains an infrastructure that includes comprehensive information technology applications, logistics, client service and billing departments. Also, we have a network of over thirty strategically located patient service centers and a full service phlebotomy department. Patient service centers collect from patients 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 primarily 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 in most instances utilizing EnzoDirect, our proprietary computer-based ordering and results delivery system. Once the information is entered into the laboratory computer system the tests are performed on the corresponding laboratory testing instrumentation and the results are delivered primarily through an interface from the laboratory testing instrumentation 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 reported electronically via our 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 by our customer service personnel.

For fiscal years ended July 31, 2012, 2011 and 2010, respectively, approximately 58%, 52% and 46% of the Company's revenues were derived from the clinical laboratory. At July 31, 2012 and 2011, respectively, approximately 55% and 51% 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 third party payers that insure individuals.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

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.

Revenues, net of contractual adjustment, from direct billings under the Federal Medicare program during the years ended July 31, 2012 and 2010 were approximately 21%, 22% and 25%, 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 self-payers, 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, and 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 approximately 21%, 22% and 25% of the Clinical Labs segment's net revenue for the fiscal year ended July 31, 2012, 2011 and 2010, respectively. Another third party provider represents 13% and 11% of the Clinical Labs segment's net revenue for the fiscal year end July 31, 2012 and 2011, respectively. 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 both New York and New Jersey, 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 inaccurate billing information on requisitions received from the ordering physician. In addition, the bad debts 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. We perform the requested tests and report test results regardless of whether the billing or diagnostic coding information is inaccurate or missing. We subsequently attempt to contact the ordering physician to obtain and rectify incorrect billing information.

Missing or inaccurate information on the requisitions adds complexity to and may slow the billing process, creates backlogs of unbilled requisitions, and generally decreases the collectability and increases the aging of accounts receivable. When all issues relating to the missing or inaccurate information are not resolved in a timely manner, the related receivables are fully reserved to the allowance for doubtful accounts or allowances for contractual adjustments 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 and stringent federal and state regulations including those relating to coverage, billing and reimbursements. Future changes in regulations could further complicate our billing and increase our billing expenses.

These additional costs include those related to: (1) complexity added to our billing processes and change our reimbursements; (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 established Medicare reimbursement rate for clinical laboratory services has been reduced by the Federal government in a number of instances over the past several years. In March 2010, U.S. federal legislation was enacted to reform healthcare. The legislation provides for reductions in the Medicare clinical laboratory fee schedule of 1.9% for five years beginning in 2010 and also includes a productivity adjustment which reduces the Consumer Price Index (CPI) market basket update beginning in 2011. The legislation imposes an excise tax on the seller for the sale of certain medical devices in the United States, including those purchased and used by laboratories, beginning in 2013. The legislation establishes the Independent Payment Advisory Board (IPAB), which will be responsible, beginning in 2014, annually to submit proposals aimed at slowing Medicare cost growth while preserving quality.

If the projected growth in per capita Medicare costs exceeds a specified target level, the IPAB must submit proposals to reduce or eliminate the difference. For 2015 – 2019, the target growth rate is the average of the increases in the consumer price index and the medical consumer price index; for 2020 and thereafter, the target growth rate is the rate of increase in gross domestic product per capita plus one percent point. If it is necessary for the IPAB to submit proposals, they will automatically be implemented unless Congress enacts alternative proposals that achieve the same savings targets. We could experience a significant decrease in revenue from Medicare as a result of this legislation, which could have a material adverse effect on us.

Research and Development

Our principal research and development efforts are directed toward developing innovative new clinical research and diagnostic platforms, and selective expansion of our research product lines, given our increased manufacturing, distribution capability following the acquisitions of Axxora, Biomol International, and Assay Designs. We have developed our core research expertise in the life science field as a result of over 30 years of dedicated focus in this area. We conduct our research and other product development efforts through internal research and collaborative relationships.

In the fiscal years ended July 31, 2012, 2011 and 2010, the Company has trimmed cost in line with the business structure, and has incurred costs of approximately \$6.3 million, \$7.8 million and \$9.7 million, respectively, for research and development activities.

Internal Research Programs

Our professional staff, including 65 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 large numbers of collaborative relationships with prominent companies and leading-edge research institutions in order to maximize the application of our technology in areas where we believe such relationship will benefit the development of our technology.

Sales and Marketing

Our sales and marketing strategy for Enzo Life Sciences is to sell our life science products through: (i) direct sales to end-users under the Enzo Life Sciences name, with direct recognition to our acquired brands (ii) direct sales to end users under the Axxora electronic market place name (iii) supply agreements with manufacturers and (iv) 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 who recognize the brands (Alexis, Assay Designs, Biomol, Enzo and Stressgen) now receive products directly from Enzo Life Sciences where we are recognized for innovative high quality products, supported directly by our qualified technical staff. We sell the same products through our Axxora electronic market place which is also the source for life science research reagents from over 40 original manufacturers. Our direct marketing and sales network includes fully-owned subsidiaries (USA, Switzerland, Germany, Benelux, and UK), a branch office in France 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 a broad range of ordering physicians in the metro New York, New Jersey and Eastern Pennsylvania region through our direct sales force who are supported by customer service and patient service representatives. We monitor and where appropriate, we change the service levels and terminate ordering physician 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 and are consistently looking to add higher value molecular and esoteric testing to our menu to assist sales in new account penetration as well as to improve our level of service to existing clients

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 in certain market places.

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, offer innovative products at the forefront of technological development to targeted market segments, 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, and local entities, some of which are larger than we are and have greater financial resources than we do. Our laboratory competes primarily on the basis of the quality and specialized nature of its testing, reporting and information services, its reputation in the medical community, 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 2012 we owned or licensed over 100 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 their sugar and phosphate sites. The claims contained in these patents cover products that incorporate a signaling moiety into a nucleic acid attached to a sugar or phosphate for the purpose of nucleic acid detection or quantification, including sequencing and real time nucleic acid amplification. Enzo also has patents directed to proprietary dyes that may be used to label the sugar, base or phosphate positions of nucleic acids.

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.

REGULATION AFFECTING OUR BUSINESSES

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

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

Clinical laboratories also are subject to state regulation. CLIA provides that a state may adopt different or more stringent regulations than Federal law, and permits states to apply for exemption from CLIA if HHS determines that the state's laboratory laws are equivalent to, or more stringent than, CLIA. The State of New York's clinical laboratory regulations contain provisions that are more stringent than Federal law, and New York has received exemption from CLIA.

Therefore, as long as New York maintains its CLIA-exempt status, laboratories in New York, including our laboratory, are regulated under New York law rather than CLIA. Our laboratory is licensed in New York and has continuing programs to ensure that its operations meet all applicable regulatory requirements.

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

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.

Under federal health care reform legislation enacted in March 2010, the annual updates for clinical laboratory services through 2015, which are based on the Consumer Price Index for All Urban Consumers (CPI-U), are reduced by a multi-factor productivity adjustment and then by 1.75 percentage points. Based on these calculations, the Medicare Fee Schedule was reduced in calendar year 2010 by 1.9%, reduced in calendar year 2011 by 1.75% and increased in calendar year 2012 by .65%. Future reductions/increases may occur depending on percentage changes in the CPI-U. (See Item 1A Risk Factors).

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. 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.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

In February 1997, the OIG released a model voluntary 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 federal health care reform legislation adopted in March, 2010, contains provisions requiring providers to establish compliance programs as a condition of Medicare, Medicaid and State Children's Health Insurance Program enrollment. No implementing regulations or guidance has been issued yet by the Centers for Medicare and Medicaid Services, nor have they issued any timeline for provider implementation. In addition, New York State has adopted mandatory compliance program requirements for certain specified providers, including those who directly or indirectly receive more than \$500,000 annually in Medicaid payments.

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. Although the Company does not meet the New York State threshold for mandatory compliance programs, in order to address these various Federal and state laws, the Company has nevertheless 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 team 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 included 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. Regulations have been adopted for electronic transaction, privacy and security standards and include the requirement to use a National Provider Identifier in electronic health care transactions. These provisions have very broad applicability and they specifically apply to health care providers, which include physicians and clinical laboratories. The National Provider Identifier is an identifier that replaced all other identifiers that are currently used for healthcare transactions (e.g., UPIN, Medicaid provider numbers; identifiers assigned by commercial insurers).

The electronic transaction standards regulations created 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 established standard data content and format for submitting electronic claims and other administrative health transactions. Health care providers and health plans are required to use standard formats when transmitting claims, referrals, authorizations, and certain other transactions electronically. The Company believes it is in compliance with these standards.

Privacy regulations and 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 the HIPAA privacy and security requirements. Furthermore, we need to continuously ensure that there are 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 also 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. 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 requires significant effort and expense for virtually all entities that conduct health care transactions electronically and handle patient health information.

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. We use outside vendors to dispose of 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 U.S. 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 in the United States and internationally 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.

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 twelve months, but it can last longer. The process of obtaining PMA approval is much more costly, lengthy and uncertain. It generally takes from one to three years or even longer. We cannot be sure that 510(k) clearance or PMA approval will ever be obtained for any product we propose to market.

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

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

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

Although clinical investigations of most devices are subject to the investigational device exemption (IDE) requirements, clinical investigations of in vitro diagnostic (IVDs) tests are exempt from the IDE requirements, including the need to obtain the FDA's prior approval, provided the testing is noninvasive, does not require an invasive sampling procedure that presents a significant risk, does not introduce energy into the subject, and is not used as a diagnostic procedure without confirmation by another medically established test or procedure.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

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.

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.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

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.

Manufacturing and Research Facilities

Our internal integrated laboratory and scientific efforts for our three segments take place primarily at our two adjacent facilities in Farmingdale, New York. A major part of one facility is utilized by Life Science as its global headquarters, and also for research and manufacturing with special handling capabilities and clean rooms suitable for our operations. The Life Sciences segment has centered its US logistics, reagent and kit manufacturing at its facility in Ann Arbor, Michigan, and has European logistics operations in Lausen, Switzerland. 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, 2012, we employed 467 full-time and 64 part-time employees. Of the full-time employees, 121 were engaged in research, development, manufacturing, and marketing of research products, 5 in therapeutics research, 360 in performing testing, marketing and billing our clinical laboratories services and 45 in finance, legal, administrative and executive functions. Our scientific staff, including 65 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 we have established good relationships with our employees.

Information Systems

Information systems are used extensively in virtually all aspects of our businesses. In our clinical laboratory business, our information systems are critical with respect to laboratory testing, billing, accounts receivable, 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 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.

In addition to our own internal quality control programs, our laboratory participates in numerous externally administered, blind quality surveillance programs, including on-site evaluation by the College of American Pathologies (CAP) proficiency testing program and the New York State survey program. The blind programs supplement all other quality assurance procedures and give our management the opportunity to review our technical and service performance from the client's perspective.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

The CAP accreditation program involves both on-site inspections of our laboratory and participation in the CAP's proficiency testing program for all categories in which our laboratory is accredited by the CAP. The CAP is an independent nongovernmental organization of board certified pathologists, which offers an accreditation program to which laboratories can voluntarily subscribe. A laboratory's receipt of accreditation by the CAP satisfies the Medicare requirement for participation in proficiency testing programs administered by an external source. Our clinical laboratory facilities are accredited by the CAP.

FORWARD - LOOKING AND CAUTIONARY STATEMENTS

This Annual Report contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact, including, without limitation, the statements under Management's Discussion and Analysis of Financial Condition and Results of Operations are forward-looking statements. Forward-looking statements may include the words believes, expects, plans, intends, anticipates, continues or other similar expressions. These statements are based on the Company's current expectations of future events and are subject to a number of risks and uncertainties that may cause the Company's actual results to differ materially from those described in the forward-looking statements. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, estimated or projected. The Company assumes no obligation to revise or update any forward-looking statements for any reason, except as required by law.

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 five fiscal years and quarter to quarter over such periods and our losses have resulted in the use of cash in operations. If such losses and cash uses continue the value of your investment could decline significantly.

We incurred net losses of \$39.3 million, inclusive of a non-cash impairment charge of \$22.4 million net of tax of \$2.1 million (See Note 2), \$12.9 million and \$22.2 million for the fiscal years ended July 31, 2012, 2011 and 2010, 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 and use cash in operations which could have an adverse effect on our business and adversely affect your investment in our Company.

We may need additional capital to fund growth, which may not be available on acceptable terms or at all, and could result in our business plan being limited and our business being harmed.

Our ability to increase revenue and improve profitability and liquidity will depend in part on our ability to grow the Enzo Life Science business with higher margin products and increase our market share and continue to grow the Enzo Clinical Lab business with new tests with higher reimbursements and increase our service volume which may require significant additional capital that may not be available to us. We may need additional financing due to future developments, changes in our business plan or failure of our current business plan to succeed, which could result from increased marketing, distribution or research and development costs. Our actual funding requirements could vary materially from our current estimates. If additional financing is needed, we may not be able to raise sufficient funds on favorable terms or at all. If we issue common stock or securities convertible into common stock in the future, such issuance will result in the then-existing stockholders sustaining dilution to their relative proportion of our outstanding equity. If we fail to obtain any necessary financing on a timely basis, then our ability to execute our current business plan may be limited, and our business, liquidity and financial condition could be harmed.

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;

health care reform regulations affecting providers and plan sponsors;

changes in reimbursement policies from third party payers

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 offerings, add new technology or add presence in a market;

expenses associated with defending our intellectual property portfolio;

customer demand for our products due to changes in purchasing requirements and research needs;

general worldwide economic conditions affecting funding of research and;

seasonal fluctuations affected by weather and holiday periods.

Consequently, results for any interim period may not necessarily be indicative of results in subsequent periods.

A significant proportion of our sales are to academic centers, funded by government grants in our major markets globally.

Governments around the world have been reviewing long term public funding of life science research in response to the problems arising from global financial pressures. As a result, the available funds for discretionary purchases from market to market have been capped or reduced based on available National budgets. Reduced grants for researchers could impact our business, in the amount, price and type of products bought and used by customers.

A significant proportion of our sales are to customers in Pharmaceutical and Biotech companies.

Globally, pharmaceutical companies are challenging internal budgets, and the return of investment from their R&D spend. This could impact our business, in the amount, price and type of products bought and used by customers.

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, state-wide agency 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 five fiscal years we have made significant acquisitions in our Life Sciences segment. Our strategy envisions that a part of our future growth will come from acquiring and integrating similar operations and/or product lines. 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 a marketing program designed to more directly service its end users, while simultaneously promoting the Enzo Life Science brand, with reference to our acquired brands. We will continue to reach out to our customers using our direct field sales force, in house business team, the on-going enhancement of our interactive websites, continued attendance at top industry trade meetings, and publications to customers and in leading scientific journals. In addition to our direct sales, we operate worldwide through wholly-owned subsidiaries (in USA, Switzerland, Belgium, Germany, and the UK), a branch office in France and a network of third-party distributors in most other significant markets. If we are unable to successfully continue 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 professionals.

These competitive conditions could, among other things:

Require us to reduce our prices to retain market share;

Require us to increase our marketing efforts which could reduce our profit margins;

Increase our cost of labor to attract qualified personnel;

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, and own brand products from large numbers of suppliers. 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 governmental 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.

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 ASC 350, Intangibles, Goodwill and Other (ASC 350) 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.

During the fiscal 2012 fourth quarter we recorded impairments on our indefinite-lived intangibles of \$5.7 million and our goodwill of \$18.8 million. The aggregate non-cash charge of \$24.5 million did not impact the Company's consolidated cash flows, liquidity and capital resources (See Note 2 to the Consolidated Financial Statements). As of July 31, 2012, goodwill and other intangible assets with indefinite lives represented approximately 11% 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.

U.S. healthcare reform legislation may result in significant change and our business could be adversely impacted if we fail to adapt.

Government oversight of and attention to the healthcare industry in the United States is significant and increasing. In March 2010, U.S. federal legislation was enacted to reform healthcare. The annual updates for clinical laboratory services through 2015, which are based on the Consumer Price Index for All Urban Consumers (CPI-U), are reduced by a multi-factor productivity adjustment and then by 1.75 percentage points. Based on these calculations, the Medicare Fee Schedule was reduced in calendar year 2010 by 1.9%, reduced in calendar year 2011 by 1.75% and increased in calendar year 2012 by .65%. Future reductions/increases may occur depending on percentage changes in the CPI-U. In 2012, 2011, and 2010 approximately 21%, 22% and 25% of our Clinical Lab's segment revenues were reimbursed by Medicare under the clinical laboratory fee schedule. The legislation imposes an excise tax on the seller for the sale of certain medical devices in the United States, including those purchased and used by laboratories, beginning in 2013. The legislation establishes the Independent Payment Advisory Board, which will be responsible, beginning in 2014, annually to submit proposals aimed at reducing Medicare cost growth while preserving quality. These proposals automatically will be implemented unless Congress enacts alternative proposals that achieve the same savings targets.

Further, the legislation calls for a Center for Medicare and Medicaid Innovation that will examine alternative payment methodologies and conduct demonstration programs. The legislation provides for extensive health insurance reforms, including the elimination of pre-existing condition exclusions and other limitations on coverage, fixed percentages on medical loss ratios, expansion in Medicaid and other programs, employer mandates, individual mandates, creation of state and regional health insurance exchanges, and tax subsidies for individuals to help cover the cost of individual insurance coverage. The legislation also permits the establishment of accountable care organizations, a new healthcare delivery model. While the ultimate impact of the legislation on the healthcare industry is unknown, it is likely to be extensive and may result in significant change. Our failure to adapt to these changes could have a material adverse effect on our business.

Changes in provider mix, including 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, impacts of the economy on patient traffic at our customers 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, reduced patient traffic, 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. 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 established 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.

If we fail to maintain or monitor our information systems our businesses could be adversely affected.

We depend on information systems throughout our Company to control our Life Science manufacturing, inventory, 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 paying 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 we have successfully recruited and hired qualified key employees. 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 15% of total revenues in fiscal 2012. 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;

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;
- the carrying value of our goodwill and intangible assets;
- 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.

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:

Location	Primary use	Segments	Leased / owned	Square footage
Farmingdale, NY (Note 1)	Clinical laboratory and research	Clinical Labs	Leased	43,000
Farmingdale, NY	Manufacturing, research, sales and administrative office	Life Sciences, Therapeutics	Owned	22,000
New York, NY (Note 2)	Corporate headquarters	Other	Leased	11,300
Lausen, Switzerland (Note 3)	Operational headquarters in Europe, including sales and distribution	Life Sciences	Leased	18,829
Ann Arbor, Michigan (Note 4)	Manufacturing, research, and distribution	Life Sciences	Leased	26,820

Note 1 In March 2005, the Company amended and extended the lease for its Farmingdale laboratory for a period of 12 years (See Note 13 to the Consolidated Financial Statements).

Note 2 In February 2010, the lease, which includes 4,100 square feet under a sublease rental agreement through December 31, 2013, was extended through May 2020.

Note 3 The lease for this property was acquired in connection with the Axxora acquisition in May 2007 and was amended and extended through July 2016.

Note 4 The lease for this property was acquired in connection with the Assay Designs acquisition in March 2009 and was amended and extended through April 2016.

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. On September 24, 2012, the court ruled on Defendants' motion for summary judgment of non-infringement. The Defendants' motion was granted in part and denied in part. The parties were further directed to submit a joint letter by October 19, 2012 setting forth each party's respective positions on how the case should proceed on remaining issues.

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. On August 26, 2011, the court allowed Affymetrix to renew its motion for previous summary judgment related only to alleged non-infringement of one patent in suit. Affymetrix's initial brief was filed on October 11, 2011, and all briefing was completed on January 13, 2012. On September 24, 2012, the court ruled on Defendants' motion for summary judgment of non-infringement. The Defendants' motion was granted in part and denied in part. The parties were further directed to submit a joint letter by October 19, 2012 setting forth each party's respective positions on how the case should proceed on remaining issues.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

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 patents. On August 26, 2011, the court allowed Roche to renew its motion for summary judgment related only to alleged non-infringement of some of the patents in suit. Roche's initial brief was filed on October 11, 2011, and all briefing was completed on January 13, 2012. On September 24, 2012, the court ruled on Defendants' motion for summary judgment of non-infringement. The Defendants' motion was granted in part and denied in part. The parties were further directed to submit a joint letter by October 19, 2012 setting forth each party's respective positions on how the case should proceed on remaining issues.

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." The Company's claim for infringement of one of the four Ward patents is set for trial on October 15, 2012. The Company's claims for infringement of the other five patents have been dismissed. 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, three actions were filed against the Company and certain of its officers and directors by Francis Scott Hunt and others. These actions were filed by the same attorney who had previously filed a virtually identical claim against the Company and certain of its officers and directors in the Eastern District of Virginia. On June 15, 2009, the Court granted the remaining defendants' motion for summary judgment and dismissed the complaints. The remaining Plaintiffs then filed a notice of appeal to the Second Circuit Court of Appeals. On August 30, 2011, the Second Circuit denied the appeal. The remaining Plaintiffs then moved for a rehearing and that motion was also denied. No further appeal was taken. Accordingly, the dismissal is final and the action is concluded.

On or about September 22, 2010, Mayflower Partners, L.P. f/k/a Biomol International, L.P. ("Mayflower") filed an action against Enzo Biochem, Inc. and Enzo Life Sciences, Inc. (together "Enzo") in the United States District Court for the Southern District of New York, alleging breach of the stock and asset purchase agreement dated as of May 8, 2008 between Enzo and Mayflower (the "Agreement"). On November 3, 2011, the Company and Mayflower entered into an Earn-Out Dispute Settlement Agreement in which the Company paid \$1.1 million in cash in full settlement of the second and final earn-out under the Agreement. The settlement, which was accrued for at July 31, 2011, was recorded in Goodwill as additional purchase price consideration.

The Company is party to other claims, legal actions, complaints, and contractual disputes 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. Mine Safety Disclosures

Not Applicable

Part IIItem 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.

2012 Fiscal Year (August 1, 2011 to July 31, 2012):

	High	Low
1st Quarter	\$ 3.93	\$ 2.05
2nd Quarter	\$ 2.85	\$ 1.98
3rd Quarter	\$ 3.15	\$ 2.13
4th Quarter	\$ 2.80	\$ 1.43

2011 Fiscal Year (August 1, 2010 to July 31, 2011):

	High	Low
1st Quarter	\$ 4.62	\$ 3.37
2nd Quarter	\$ 5.80	\$ 4.16
3rd Quarter	\$ 5.09	\$ 3.46
4th Quarter	\$ 4.74	\$ 3.52

As of September 30, 2012, the Company had approximately 923 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.

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 2008 through 2012 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.

For the fiscal year ended July 31, (In thousands, except per share amounts)					
Operating Results	2012	2011	2010	(1) 2009	(2) 2008
Revenues	\$ 103,083	\$ 102,029	\$ 97,082	\$ 89,572	\$ 77,795
Impairment charges (3)	\$ (24,540)				
Operating loss	\$ (40,479)	\$ (12,928)	\$ (22,058)	\$ (23,407)	\$ (14,786)
Net loss	\$ (39,269)	\$ (12,960)	\$ (22,233)	\$ (23,564)	\$ (10,653)
Basic and diluted net loss per common share:	\$ (1.01)	\$ (0.34)	\$ (0.59)	\$ (0.63)	\$ (0.29)

July 31, (in thousands)					
Financial Position	2012	2011	2010	2009	2008
Working capital	\$ 21,412	\$ 33,670	\$ 42,181	\$ 60,518	\$ 92,392
Total assets (3)	\$ 69,123	\$ 109,474	\$ 115,245	\$ 133,128	\$ 154,522
Stockholders' equity (3)	\$ 49,101	\$ 88,715	\$ 97,016	\$ 116,781	\$ 138,289

Notes to Selected Financial Data:

- (1) On March 12, 2009, Enzo Life Sciences Inc. acquired Assay Designs, Inc. (ADI). As such, the operating results of ADI are included in the consolidated operating results beginning March 12, 2009.
- (2) On May 8, 2008, Enzo Life Sciences Inc. acquired Biomol International, LP. (Biomol). As such, the operating results of Biomol are included in the consolidated operating results beginning May 8, 2008.
- (3) In the fourth quarter of fiscal 2012, the Company recorded an impairment charge on goodwill and indefinite lived intangible assets (See Item 7, Management Discussion and Analysis of Financial Conditions and Results of Operations and Note 2 to the Consolidated Financial Statements),

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

The Company's Enzo Clinical Labs and Enzo Life Sciences operating units, as described below, are affected by different US and global economic conditions which are included in Item 1A, Risk Factors.

The Clinical Lab reporting unit is impacted by various risk factors, including among others, reduced reimbursements from third party payers for testing performed and from recent health care legislation. Despite the growth we have experienced there can be no assurance future growth can be achieved. The introduction of new molecular and esoteric tests is expected to increase our revenue per test and could offset impacts from the above factors. The Company anticipates improved profitability with increased service volume. Clinical Labs experienced year over year growth in fiscal 2012 of 13%.

During Fiscal 2012, the Life Science reporting unit experienced a decline in revenues of 10%. As a global provider of product and tools we were directly affected by global economic conditions that affected the funding for research and in addition we experienced a decline attributed to certain distributed products for certain customer types and the impact of reduced demand from the academia and pharmaceutical sectors. Despite the fact that we have completed a review of our business in the fiscal 2012 fourth quarter, completed the integration of acquired businesses and have reduced our product offerings to focus on selling higher margin products there is no assurance past results can be achieved.

See Recent Actions below and the Liquidity and Capital Resources section for further information on the plan to reduce cash expenditures and improve liquidity.

Recent Actions

In the fourth quarter of fiscal 2012, the Company completed a strategic review of its global operations, including its corporate office. As a result of the review the Company initiated a plan to reduce operating expenses by approximately \$6.0 million in Fiscal 2013, without impacting current operations or business expansion plans at the Clinical Lab or Life Sciences reporting units. The review which was completed by September 1, 2012 included, among other items, a realignment of our workforce, final integration of the acquired businesses at Life Sciences, rationalization of low margin products, a refocus of our research and development program toward higher value diagnostic platforms and the reduction in outside consulting costs.

In connection with the annual assessment of indefinite-lived intangibles as of May 1, 2012, the Company determined the estimated fair value of trademarks, relating to the Enzo Life Sciences reporting unit, were less than their carrying value by \$5.7 million primarily due to declines in projected revenues and in connection with future plans resulting from the aforementioned strategic review. As a result of this impairment, which included the change in the future branding strategy, the useful life of the trademarks were reassessed and determined to have an estimated economic life of 5 years. A non-cash impairment charge of \$5.7 million, (\$4.4 million net of related taxes) was recorded for the trademark impairment in the fourth quarter.

As a result of decline in the Company's market capitalization relating to the decline in our stock price of 44% from May 1 to July 31, 2012 declining results in the fourth quarter of the Life Sciences reporting unit, and the completion of the refocusing of the Enzo Life Sciences reporting unit, the Company completed an interim impairment test as of July 31, 2012. The results of the step-two impairment analysis for the Enzo Life Sciences reporting unit as of July 31, 2012 indicated that the goodwill was fully impaired. As a result of the analysis, the Company recognized a total non-cash goodwill impairment charge of \$18.8 million in the fiscal 2012 fourth quarter. The fair value of the Enzo Clinical Lab reporting unit was higher than its carrying value and a step-two analysis was not required.

The aggregate impairment charges of \$24.5 million, prior to a tax benefit of \$2.1 million, did not impact the Company's consolidated cash flows, liquidity and capital resources. (See Note 2 to the Consolidated Financial Statements)

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

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 15 in the Notes to Consolidated Financial Statements):

Enzo Clinical Labs is a regional clinical laboratory serving the greater New York, New Jersey and Eastern Pennsylvania medical communities. The Company believes having clinical diagnostic services allows us to capitalize firsthand on our extensive advanced molecular and cytogenetic capabilities and the broader trends in predictive and personalized 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 approximately 30 patient service centers throughout greater New York, New Jersey and Eastern Pennsylvania, a standalone stat or rapid response laboratory in New York City, and a full-service phlebotomy and an in-house logistics department. Payments for clinical laboratory testing services are made by the Medicare program, healthcare insurers and patients.

Enzo Life Sciences manufactures, develops and markets products and tools to life sciences, drug development and clinical research customers world-wide and has amassed a large patent and technology portfolio. Enzo Life Sciences, Inc. is a recognized leader in labeling and detection technologies across research and diagnostic markets. Our strong portfolio of proteins, antibodies, peptides, small molecules, labeling probes, dyes and kits provides life science researchers tools for target identification/validation, high content analysis, gene expression analysis, nucleic acid detection, protein biochemistry and detection, and cellular analysis. We are internationally recognized and acknowledged as a leader in manufacturing, in-licensing, and commercialization of over 7,500 of our own products and in addition distribute over 30,000 products made by over 40 other original manufacturers. Our strategic focus is directed to innovative high quality research reagents and kits in the primary key research areas of genomics, cellular analysis, small molecule chemistry, protein homeostasis and epigenetics and immunoassays and assay development.

The segment is an established source for a comprehensive panel of products to scientific experts in the fields of cancer, cardiovascular disease, neurological disorders, diabetes and obesity, endocrine disorders, infectious and autoimmune disease, hepatotoxicity and renal injury.

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 445 patents and patent applications.

The following table summarizes the sources of revenues for the fiscal years ended July 31, 2012, 2011 and 2010, (in \$000 s and percentages):

Fiscal year ended July 31,

	2012		2011		2010	
Clinical laboratory services	\$ 59,403	58%	\$ 52,762	52%	\$ 44,178	46%
Product revenues	37,722	37	41,830	41	43,111	44
Royalty and license fee income	5,958	5	7,437	7	9,793	10
Total	\$ 103,083	100%	\$ 102,029	100%	\$ 97,082	100%

Results of Operations
Fiscal year ended July 31, 2012 as compared to July 31, 2011

Comparative Financial Data for the Fiscal year Ended July 31,

	2012	2011	Increase (Decrease)	% Change
Revenues:				
Clinical laboratory services	\$ 59,403	\$ 52,762	\$ 6,641	13%
Product revenues	37,722	41,830	(4,108)	(10)
Royalty and license fee income	5,958	7,437	(1,479)	(20)
Total revenues	103,083	102,029	1,054	1
Operating expenses:				
Cost of clinical laboratory services	36,305	31,682	4,623	15
Cost of product revenues	19,668	22,137	(2,469)	(11)
Research and development	6,293	7,806	(1,513)	(19)
Selling, general, and administrative	47,928	45,191	2,737	6
Provision for uncollectible accounts receivable	5,104	4,431	673	15
Legal	3,724	3,710	14	
Impairment charges	24,540		24,540	
Total operating expenses	143,562	114,957	28,605	25
Operating loss	(40,479)	(12,928)	(27,551)	213
Other income (expense):				
Interest	21	11	10	91
Other	77	45	32	71
Foreign currency (loss) gain	(540)	49	(589)	
Loss before income taxes	\$ (40,921)	\$ (12,823)	\$ (28,098)	219

Consolidated Results:

The 2012 period and the 2011 period refer to the Fiscal year ended July 31, 2012 and 2011, respectively.

Clinical laboratory services revenue during the 2012 period were \$59.4 million compared to \$52.8 million in the 2011 period. The 2012 period's increase over the 2011 period was \$6.6 million or 13% due to organic growth.

Product revenues decreased by \$4.1 million or 10% in the 2012 period to \$37.7 million as compared to \$41.8 million in the 2011 period due to a decline in organic sales. During the 2012 period we experienced a decline attributed to certain distributed products for certain customer types and declines in resale products due to market softness in research reagent products.

Royalty and license fee income during the 2012 period was \$6.0 million compared to \$7.5 million in the 2011 period, a decrease of \$1.5 million or 20%. Royalties were primarily earned from the reported sales of Qiagen products subject to a license agreement. During the 2012 period the Qiagen royalties decreased by \$0.8 million as compared to the 2011 period, to \$5.9 million as a result of lower reported sales from Qiagen. The 2012 period decrease is also due to Abbott's notification in the 2011 period that they had made a final payment under a license agreement, which aggregated \$0.5 million, since they were not aware of any non-expired patents covered under the license agreement. Other royalties declined \$0.1 million. There are no direct expenses relating to royalty and licensing income.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

The cost of clinical laboratory services during the 2012 period was \$36.3 million as compared to \$31.7 million in the 2011 period, an increase of \$4.6 million or 15%. The Company incurred increased costs in the 2012 period due to higher reagent costs and supplies of \$1.7 million, higher laboratory personnel costs and related costs of \$1.1 million, higher outside reference lab costs of \$1.1 million and other lab costs of \$0.7 million, all attributed to the increased service volume and higher employee benefit costs. In the 2012 period the gross profit margin decreased to 39% from 40% in the 2011 period due to the increased costs.

The cost of product revenues during the 2012 period was \$19.6 million compared to \$22.1 million in the 2011 period, a decrease of \$2.5 million or 11%. The decrease is primarily due to lower revenues and decreases to manufacturing costs.

Research and development expenses were approximately \$6.3 million during the 2012 period, compared to \$7.8 million in the 2011 period, a decrease of \$1.5 million or 19%. The decrease was attributed to lower costs of \$1.5 million at Enzo Life Sciences principally due to lower payroll of \$0.9 million, overhead costs of \$0.4 million due to integration of facilities and lower patent related costs of \$0.2 million. Research and development for the Clinical Labs segment, which commenced in the 2012 period, was \$0.3 million. The Therapeutics segment expense decreased by \$0.3 million as compared to the 2011 period primarily due the recognition of deferred revenue from a research grant.

Selling, general and administrative expenses were approximately \$48.0 million during the 2012 period as compared to \$45.2 million in the 2011 period, an increase of \$2.7 million or 6%. The Clinical Lab segment's selling general and administrative increased by \$2.4 million primarily due to an increase in sales commissions of \$0.5 million, an increase in other expenses of \$1.9 million, including among others payroll and related benefits, severance costs, rent and repairs and maintenance for patient collection centers, phones, and billing support, all related to the increased revenue volume. The Life Sciences segment selling general and administrative increased by \$0.4 million due to a \$0.5 million increase in compensation costs for existing personnel and for new hires of senior level marketing personnel in the latter half of fiscal 2011, and an increase in overhead costs of approximating \$0.3 million, partially offset by a decrease of \$0.4 million in compensation costs for administrative personnel due to headcount reduction. The Other selling general and administrative decreased by \$0.1 million, primarily due to decreases in compensation and related costs and other employee benefit costs of \$0.5 million offset by increases in professional fees of \$0.4 million.

The provision for uncollectible accounts receivable, primarily relating to the Clinical Labs segment, was \$5.1 million for the 2012 period as compared to \$4.4 million in the 2011 period primarily due to the increase in service volume. As a percentage of revenues the provision for uncollectible accounts receivable for the Clinical Labs segment approximated 8.4% in both periods.

Legal expense was \$3.7 million during the 2012 and 2011 periods relating to general legal services, patent and litigation related matters.

During the 2012 period, the Company recorded pre-tax non-cash impairment charges of \$24.5 million related to US and foreign goodwill and trademarks carried in the Life Sciences segment. The charges resulted in a deferred tax benefit of approximately \$2.1 million, bringing the impact of the charges, net of the tax benefit, to \$22.4 million (See Note 2 to the Consolidated Financial Statements).

During the 2012 period, the loss on foreign currency transactions was \$0.5 million compared to income of \$0.1 million in the 2011 period. The loss in the 2012 period was due to the weakening of foreign currencies relative to the US dollar and the impact that had principally on intercompany loans denominated in foreign currencies.

Segment Results

Clinical Labs

The Clinical Labs segment's loss before taxes was \$3.3 million for the 2012 period as compared to a loss of \$2.1 million in the 2011 period, an increase of \$1.2 million. The revenue from laboratory services increased in the 2012 period by \$6.6 million or 13% due to organic growth. The 2012 period gross profit of \$23.1 million increased over the 2011 period by \$2.0 million or 10% due to increases in service revenues and cost of lab services. Selling, general and administrative expense increased by approximately \$2.4 million primarily due to increases in sales commissions directly the result of increased service revenues and other costs associated with the increased volume. The provision for uncollectible accounts receivables increased by \$0.6 million as compared to the 2011 period due to the increase in service volume but as a percentage of revenues was approximately 8.4% in both the 2012 and 2011 periods. Research and development, which commenced in the 2012 period, was \$0.3 million.

Life Sciences

The Life Sciences segment's (loss) income before taxes was (\$24.3) million for the 2012 period, which includes a non-cash impairment charge of \$ 24.5 million related to goodwill and trademarks, as compared to income before taxes of \$2.8 million for the 2011 period. Company product revenues decreased by \$4.1 million or 10% in the 2012 period primarily due to a decline in sales of certain distributed products for certain customer types and declines in resale products due to market softness in research reagent products. Further, royalty and license fee income decreased by \$1.5 million in the 2012 period attributed to a decrease in royalties of \$0.8 million from the reported sales of Qiagen products subject to a license agreement, as previously discussed, and in addition, no royalty payments were received under another license agreement after the first quarter of the 2011 period. The segment's gross profit of \$24.0 million in the 2012 period, as compared \$27.1 million in the 2011 period, was negatively impacted by the previously discussed changes in revenues. The segment's gross profit percentage was 55% in the 2012 and 2011 periods. The segment's other operating expenses, including selling, general and administrative, legal and research and development, decreased by approximately \$1.2 million during the 2012 period primarily due to reduced research and development costs of \$1.4 million and decreased legal cost of \$0.2 million, offset by higher compensation of \$0.1 million and higher overhead of \$0.3 million.

Therapeutics

The Therapeutics segment's loss before income taxes was approximately \$1.7 million in the 2012 and \$2.0 in 2011 period. The decline was due to the recognition of deferred revenue from a research grant of \$0.4 million offset by other increases of \$0.1 million.

Other

The Other loss before taxes for the 2012 period was approximately \$11.7 million as compared to \$11.5 million the 2011 period. In the 2012 period, legal expenses increased by \$0.3 million, and general and administrative costs relating to compensation costs and other employee benefit costs decreased by \$0.5 million offset by an increase in professional fees of \$0.4 million.

Results of Operations

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

	<u>2011</u>	<u>2010</u>	<u>Increase (Decrease)</u>	<u>% Change</u>
<u>Revenues:</u>				
Clinical laboratory services	\$ 52,762	\$ 44,178	\$ 8,584	19
Product revenues	41,830	43,111	(1,281)	(3)
Royalty and license fee income	7,437	9,793	(2,356)	(24)
	<u>102,029</u>	<u>97,082</u>	<u>4,947</u>	<u>5</u>
<u>Operating expenses:</u>				
Cost of clinical laboratory services	31,682	29,570	2,112	7
Cost of product revenues	22,137	22,547	(410)	(2)
Research and development	7,806	9,704	(1,898)	(20)
Selling, general, and administrative	45,191	48,395	(3,204)	(7)
Provision for uncollectible accounts receivable	4,431	3,480	951	27
Legal	3,710	1,746	1,964	112
Litigation settlement and related legal costs		3,698	(3,698)	(100)
	<u>114,957</u>	<u>119,140</u>	<u>(4,183)</u>	<u>(4)</u>
Operating loss	(12,928)	(22,058)	9,130	41
<u>Other income (expense):</u>				
Interest	11	19	(8)	(42)
Other	45	44	1	2
Foreign exchange gain (loss)	49	(266)	315	118
	<u>\$ (12,823)</u>	<u>\$ (22,261)</u>	<u>\$ 9,438</u>	<u>42</u>

Consolidated Results:

The 2011 period and the 2010 period refer to the fiscal year ended July 31, 2011 and 2010, respectively.

Clinical laboratory services revenue during the 2011 period were \$52.8 million compared to \$44.2 million in the 2010 period. The 2011 period's increase over the 2010 period was \$8.6 million or 19% due to organic growth of 11% and an increase of 8% in revenue related to a new payer contract with Empire Blue Cross of New York.

Product revenues were \$41.8 million in the 2011 period compared to \$43.1 million in the 2010 period, a decrease of \$1.3 million or 3% due to a decline of \$1.5 million or 3.5% in organic sales. The decline is attributed to the ongoing strategy to increase direct sales and rationalize certain distribution business and negative impact from the Japanese market. The decline is offset by a 0.5% positive impact from foreign currency transactions.

Royalty and license fee income was \$7.4 million in the 2011 period compared to \$9.8 million in the 2010 period, a decrease of \$2.4 million or 24%. Royalties are primarily earned from the reported sales of Qiagen products subject to a license agreement. During both the 2011 and 2010 periods, the Company recognized royalties of approximately \$6.8 million from Qiagen. The 2011 period decrease is due to Abbott's notification that they had made a final payment under a license agreement since they are not aware of any non-expired patents covered under the license agreement. Abbott and the Company are in communication as to patents covered under the license agreement which remains in full force.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

During the 2011 period, the Company recognized royalties and license fees from the Abbott agreement of approximately \$0.4 compared to \$3.0 million in the 2010 period. There are no direct expenses relating to royalty and licensing income.

The cost of clinical laboratory services during the 2011 period was \$31.7 million as compared to \$29.6 million in the 2010 period, an increase of \$2.1 million or 7%. The Company incurred increased costs due to higher reagent costs and supplies of \$1.7 million, primarily due to increased service volume and reagent costs for certain tests that were previously sent to outside reference labs, higher laboratory personnel and related costs of \$0.2 million primarily due to incremental increases in service volume and increases in the other lab operating costs of \$0.3 million offset by a decrease of outside reference lab costs of \$0.1 million. In the 2011 period the gross profit margin improved from 33% to 40% due to increased revenues, process improvements and the positive impact of greater service volume on fixed costs coverage.

The cost of product revenues during the 2011 period was \$22.1 million compared to \$22.5 million in the 2010 period, a decrease of \$0.4 million or approximately 2%. Although product sales declined during the 2011 period, cost of product revenues was negatively impacted by compensation costs, foreign exchange, other inventory adjustments and changes in cost allocations to the cost of production of \$1.7 million, offset by a charge in the prior year for excess and obsolete inventory that arose primarily from the strategic realignment of marketing efforts for core products of \$1.3 million.

Research and development expenses were approximately \$7.8 million during the 2011 period, compared to \$9.7 million in the 2010 period, a decrease of \$1.9 million or 20%. The decrease was principally attributed to lower costs of \$1.4 million at Enzo Life Sciences primarily due the realignment of the R&D workforce that occurred in July 2010. There was a \$0.2 million decline in clinical trial and related activities and \$0.3 million in payroll costs at the Therapeutics segment.

Selling, general and administrative expenses were approximately \$45.2 million during the 2011 period as compared to \$48.4 million in the 2010 period, a decrease of \$3.2 million or 7%. The Enzo Life Sciences segment decreased by \$1.9 million principally comprised of a decline of approximately \$1.1 million of discretionary marketing costs due to refocused spending and decreases of \$1.0 million related to reallocation and realignment of personnel offset by increases in payroll and related costs of \$0.2 million. The Clinical Lab segment's selling general and administrative decreased by \$0.1 million primarily due to a decline in payroll and related benefits of \$0.8 million offset by an increase in sales commission of \$0.5 million as a result of increased service revenues and an increase in other expenses of \$0.2 million. The Other segment's selling general and administrative decreased by \$1.2 million, primarily due to decreases in outside consulting costs of \$0.8 million, professional fees of \$0.4 million and other operating expenses of \$0.1 million, directly related to planned cost reductions effective August 1, 2010 and other expense improvements, offset by increases of \$0.1 million in payroll and payroll related costs.

The provision for uncollectible accounts receivable, primarily relating to the Clinical Labs segment was \$4.4 million for the 2011 period as compared to \$3.5 million in the 2010 period, an increase of \$0.9 million attributed to an increase in patient service revenue. As a percentage of Clinical Lab revenues, bad debts approximated 8% in both the 2011 and 2010 periods.

Legal expense was \$3.7 million during the 2011 period compared to \$1.7 million in the 2010 period, an increase of \$2.0 million due to overall increases in legal services in the 2011 period for general, litigation and proxy related matters of \$1.0 million and the impact of \$0.5 million in insurance reimbursements and \$0.5 million in negotiation and settlement adjustments in the 2010 period.

During the 2010 period, in connection with the litigation settlement with Mr. Shahram K. Rabbani to settle all of his claims against the Company, and certain of its executive officers, the Company agreed to pay a lump sum payment of \$2.7 million. The Company recorded a settlement expense of approximately \$3.7 million, consisting of the lump sum payment of \$2.7 million and approximately \$1.0 million of legal expenses incurred in connection with the claims.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

The 2011 period foreign exchange benefit was approximately \$0.1 million compared to a loss of \$0.2 million in the 2010 period. The foreign exchange benefit or loss is determined on two factors, an intercompany loan denominated in British pounds sterling and transactions denominated in foreign currencies other than the functional currency.

Segment Results

The Clinical Labs segment's loss before taxes was \$2.1 million for the 2011 period as compared to \$7.5 million in the 2010 period an improvement of \$5.4 million arising from revenue growth, process improvements and cost containment. The revenue from laboratory services increased in the 2011 period by \$8.6 million due to organic growth of 11% and the 8% increase in revenue due to the new payer contract with Empire Blue Cross of New York. The 2011 period gross profit of \$21.1 million improved the gross profit margin from 33% to 40% over the 2010 period due to the previously discussed changes in service revenues and favorable impacts on costs from process improvements and benefits resulting from greater service volume on fixed costs coverage. Selling, general and administrative expense decreased by approximately \$0.1 million primarily due to decreases in benefits and other costs, partially offset by increases in sales commissions directly the result of increased service revenues. The provision for uncollectible accounts receivables increased by \$1.0 million as compared to the 2010 period due to the increase in patient service volume.

The Life Sciences segment's income before taxes was \$2.8 million for the 2011 period as compared to \$2.9 million for the 2010 period with the positive impact of the on-going integration of our businesses and related operational improvements and cost reductions offset by a decline in revenues. Product revenues decreased by \$1.3 million or 3% in the 2011 period primarily due to a decline of organic sales of 3.5% partially attributed to the on-going strategy to increase direct sales and rationalize certain distribution business and softness in the Japan market offset by a positive impact of foreign exchange of 0.5%. Further, royalty and license fee income decreased by \$2.4 million in the 2011 period principally attributed to no royalty payments received under the Abbott license agreement after the first quarter of the 2011 period. The segment's gross profit of \$27.1 million in the 2011 period was negatively impacted by the previously discussed changes in revenues and cost of product revenues. The segment's other operating expenses, including selling, general and administrative, legal and research and development, decreased by approximately \$2.8 million during the 2011 period primarily due to the lower marketing and selling expenses attributed to refocused and lower planned spending, a decline in payroll and payroll related costs, changes in expense allocations and reduced research and development expenses principally due to the realignment of research and development workforce that occurred in July 2010 offset by increased legal of \$0.6 million.

The Therapeutics segment's loss before income taxes was approximately \$2.0 million for the 2011 period as compared to a loss of \$2.5 million for the 2010 period. The decrease in the segment loss of \$0.5 million was primarily due to decreases in clinical trial activities, impacted by timing of activities, of \$0.2 million and a \$0.3 million decrease in payroll related expenses.

The Other segment's loss before taxes for the 2011 period was approximately \$11.5 million as compared to \$15.1 million in the 2010 period, a decrease of \$3.6 million. During the 2011 period, a decrease of \$1.2 million in selling, general and administrative primarily due to lower consulting costs and professional fees, partially attributed to the July 2010 planned cost reductions was offset by an increase of \$1.2 million in legal fees for general, litigation and proxy related costs and the impact of the recording \$0.5 million in insurance reimbursements and \$0.5 million in negotiation and settlement adjustments in the 2010 period. Further, the 2010 period loss included a litigation settlement and related legal costs of \$3.7 million.

Liquidity and Capital Resources

At July 31, 2012, the Company had cash and cash equivalents of \$15.1 million of which \$2.5 million was in foreign accounts, as compared to cash and cash equivalents and short term investments of \$24.2 million, of which \$1.7 million was in foreign accounts at July 31, 2011. It is the Company's current intent to permanently reinvest these funds outside of the United States, and its current plans do not demonstrate a need to repatriate them to fund its United States operations. The Company had working capital of \$21.4 million at July 31, 2012 compared to \$33.7 million at July 31, 2011. The decrease in working capital of \$12.3 million was primarily the result of the net loss, net of non-cash impairment charges during the fiscal 2012 period, funding capital expenditures and the settlement of the final earn-out under a prior acquisition offset by changes in net operating assets and liabilities.

Net cash used in operating activities for the year ended July 31, 2012 was approximately \$6.0 million as compared to \$8.3 million for the year ended July 31, 2011. The decrease in net cash used in operating activities in the 2012 period over the 2011 period of approximately \$2.3 million was primarily due to an increase in the net loss net of non-cash charges of \$3.0 million, offset by changes in operating assets and liabilities of \$5.3 million, relating primarily to increases in accounts receivable, inventory and increases in current liabilities.

Net cash provided by investing activities was approximately \$7.4 million as compared to cash provided of \$13.5 million in the year ago period. The decrease in 2012 of \$6.1 million is primarily due to the decrease in the maturities of short-term investments over 2011 of \$4.8 million, by an increase in cash used for capital expenditures in 2012 of \$0.2 million and the use of cash for an earn-out payment of approximately \$1.1 million in the 2012 period in connection with a prior acquisition.

Net cash used in financing activities in 2012 was \$0.2 million and \$0.1 million in 2011. The increase was attributed to increased installment loan payments for transportation equipment.

As previously noted, in the fourth quarter of fiscal 2012, the Company completed a review of all operating units and expects to reduce annual cash expenditures by \$6.0 million in fiscal 2013 based on actions completed by September 1, 2012 which included, among other items, a realignment of our workforce, final integration of the acquired businesses at Life Sciences, rationalization of low margin products, a refocus of our research and development program toward higher value diagnostic platforms and the reduction in outside consulting costs. The Company anticipates a reduction in cash used as a result of the aforementioned actions taken. In addition, the Company anticipates, but there can be no assurance, that it will be able to increase its revenue in the Life Sciences reporting unit and that it will continue to see growth in its Clinical Lab reporting unit. Further, despite the challenging global economic environment, declining revenues in the Life Sciences reporting unit in fiscal 2012 and impacts of healthcare reform regulations affecting providers and plan sponsors and the funding of research, the Company believes that its current cash and cash equivalents level is sufficient for its foreseeable liquidity and capital resource needs over the next twelve (12) months, although there can be no assurance that future events will not alter such view. Although there can be no assurances in the event additional capital is required, the Company believes it has the ability to raise funds through equity offerings, secure asset-based borrowings, or other sources of funds. Our liquidity plans are subject to a number of risks and uncertainties, including those described in the Item 1A. Risk Factors section of this Form 10-K, some of which are outside our control. Macroeconomic conditions could limit our ability to successfully execute our business plans and therefore adversely affect our liquidity plans.

Effect of New Accounting Pronouncements

In May 2011, the FASB issued Accounting Standards Update No. 2011-04 Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS. This standard results in a common requirement between the FASB and the International Accounting Standards Board (IASB) for measuring fair value and for disclosing information about fair value measurements. This amendment was effective prospectively for the Company's interim reporting period ended April 30, 2012. The adoption of this standard did not have a material impact on the Company's consolidated financial position or results of operations.

In June 2011, the FASB issued Accounting Standards Update No. 2011-05, Presentation of Comprehensive Income (ASU No. 2011-05), which improves the comparability, consistency, and transparency of financial reporting and increases the prominence of items reported in other comprehensive income (OCI) by eliminating the option to present components of OCI as part of the statement of changes in stockholders' equity. The amendments in this standard require that all non-owner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. Subsequently in December 2011, the FASB issued Accounting Standards Update No. 2011-12, Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income (ASU No. 2011-12), which indefinitely defers the requirement in ASU No. 2011-05 to present on the face of the financial statements reclassification adjustments for items that are reclassified from OCI to net income in the statement(s) where the components of net income and the components of OCI are presented.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

The amendments in these standards do not change the items that must be reported in OCI, when an item of OCI must be reclassified to net income, or change the option for an entity to present components of OCI gross or net of the effect of income taxes. The amendments in ASU No. 2011-05 and ASU No. 2011-12 are effective for interim and annual periods beginning with the first quarter of the Company's fiscal year beginning on August 1, 2012 and are to be applied retrospectively. The adoption of the provisions of ASU No. 2011-05 and ASU No. 2011-12 will not have a material impact on the Company's consolidated financial position or results of operations.

In July 2011, the FASB issued ASU No. 2011-07 Health Care Entities (Topic 954) - Presentation and Disclosure of Patient Service Revenue, Provision for Bad Debts, and the Allowance for Doubtful Accounts for Certain Health Care Entities. This update was issued to provide greater transparency relating to accounting practices used for net patient service revenue and related bad debt allowances by health care entities. Some health care entities recognize patient service revenue at the time the services are rendered regardless of whether the entity expects to collect that amount or has assessed the patient's ability to pay. These prior accounting practices used by some health care entities resulted in a gross-up of patient service revenue and the provision for bad debts, causing difficulty for users of financial statements to make accurate comparisons and analyses of financial statements among entities. ASU No. 2011-07 requires certain healthcare entities to change the presentation of the statement of operations, reclassifying the provision for bad debts associated with patient service revenue from an operating expense to a deduction from patient service revenue and also requires enhanced quantitative and qualitative disclosures relevant to the entity's policies for recognizing revenue and assessing bad debts. This update is not designed to change and will not change the net income reported by healthcare entities. This update is effective for fiscal years beginning after December 15, 2011 with early adoption permitted. The Company will adopt this update in the fiscal year beginning August 1, 2012. The adoption of the provisions of ASU No. 2011-07 will not have a material impact on the Company's consolidated financial position or results of operations.

In September 2011, the FASB issued Accounting Standards Update No. 2011-08 Testing Goodwill for Impairment (ASU No. 2011-08) which is intended to reduce the complexity and costs to test goodwill for impairment. The amendment allows an entity the option to make a qualitative evaluation about the likelihood of goodwill impairment to determine whether it is necessary to perform the two-step quantitative goodwill impairment test. An entity will no longer be required to calculate the fair value of a reporting unit unless the entity determines, based on its qualitative assessment, that it is more likely than not that the fair value of the reporting unit is less than its carrying amount. The ASU also expands upon the examples of events and circumstances that an entity should consider between annual impairment tests in determining whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. The amendment becomes effective for annual and interim goodwill impairment tests performed for the Company's fiscal year beginning August 1, 2012. The Company does not expect the adoption of ASU 2011-08 to have a material impact on its consolidated financial statements.

In September 2011, the FASB issued Accounting Standards Update No. 2011-09 Compensation - Retirement Benefits - Multiemployer Plans (Subtopic 715-80): Disclosures about an Employer's Participation in a Multiemployer Plan (ASU 2011-09), which requires additional quantitative and qualitative disclosures for employers who participate in multiemployer pension plans. ASU 2011-09 was adopted by the Company during the year ended July 31, 2012. ASU 2011-09 requires additional disclosures, but otherwise did not have a material impact on the Company's consolidated financial position, annual results of operations or cash.

In July 2012, the FASB issued ASU 2012-02, Intangibles - Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment (ASU 2012-02), which permits an entity to make a qualitative assessment of whether it is more likely than not that the fair value of a reporting unit's indefinite-lived intangible asset is less than the asset's carrying value before applying the two-step goodwill impairment model that is currently in place. If it is determined through the qualitative assessment that the fair value of a reporting unit's indefinite-lived intangible asset is more likely than not greater than the asset's carrying value, the remaining impairment steps would be unnecessary. The qualitative assessment is optional, allowing companies to go directly to the quantitative assessment. ASU 2012-02 is effective for the Company for annual and interim indefinite-lived intangible asset impairment tests performed beginning August 1, 2013, however early adoption is permitted. The Company is currently evaluating the impact ASU 2012-02 will have on its consolidated financial statements.

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 13 to the Consolidated Financial Statements for a further description of these various leases.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

The following is a summary of future payments under the Company's contractual obligations as of July 31, 2012:

Payments Due by Period

In 000's	Total	Less than 1 year	1-3 years	4-5 years	Over 5 years
Real estate and equipment leases	\$ 20,155	\$ 3,966	\$ 7,541	\$ 4,518	\$ 4,130
Employment agreements	1,135	1,048	87		
Total contractual cash obligations	\$ 21,290	\$ 5,014	\$ 7,628	\$ 4,518	\$ 4,130

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.

Off-Balance Sheet Arrangements

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.

Royalties

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

Revenues - Clinical laboratory services

Revenues from the Clinical Labs segment 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 table represents the clinical laboratory segment's net revenues and percentages by revenue category:

Revenue category	Year ended July 31 2012		Year ended July 31 2011		Year ended July 31 2010	
	(In 000 \$)	(in %)	(In 000 \$)	(in %)	(In 000 \$)	(in %)
Medicare	\$ 12,658	21	\$ 11,856	22	\$ 11,158	25
Third-party payers	29,616	50	24,335	46	19,534	44
Patient self-pay	11,895	20	11,554	22	8,758	20
HMO's	5,234	9	5,017	10	4,728	11
Total	\$ 59,403	100%	\$ 52,762	100%	\$ 44,178	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 payers and Health Maintenance Organizations (HMO's) categories represent approximately 21%, 22% and 25% of the Clinical Labs segment net revenue for the years ended July 31, 2012, 2011 and 2010 respectively. Another third party provider represents 13% and 11% of the Clinical Labs segment's net revenue for the fiscal year end July 31, 2012 and 2011 respectively.

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 and 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.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

During the years ended July 31, 2012, 2011 and 2010, the contractual adjustment percentages, determined using current and historical reimbursement statistics, were approximately 85%, 84% and 83% respectively, of gross billings. The Company believes a decline in reimbursement rates or a shift to managed care, 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 \$3.8 million, \$3.2 million, and \$2.6 million, for the years ended July 31, 2012, 2011, and 2010, respectively, and a change in the net accounts receivable of approximately \$0.5 million and \$0.5 million as of July 31, 2012 and 2011, respectively.

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 monthly 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 statistics 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, 2012 and 2011, approximately 55% and 51%, respectively, of the Company's net accounts receivable relates to its Clinical Labs business, which operates in the New York, New Jersey and Eastern Pennsylvania medical communities. The Life Sciences segment's accounts receivable, of which \$2.3 million or 36% and \$2.5 million or 33% represents foreign receivables as of July 31, 2012 and 2011 respectively, includes royalty receivables of \$1.7 million and \$2.0 million, respectively, from Qiagen Corporation.

Net accounts receivable

Billing category	July 31, 2012		July 31, 2011	
	(In 000 s)	(in %)	(In 000 s)	(in %)
Clinical Labs				
Medicare	\$ 1,270	16	\$ 1,434	19
Third party payers	3,478	45	3,087	40
Patient self-pay	2,655	35	2,865	37
HMO s	330	4	314	4
Total Clinical Labs	7,733	100%	7,700	100%
Total Life Sciences	6,402		7,545	
Total accounts receivable	\$ 14,135		\$ 15,245	

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

In 000 s	July 31, 2012	July 31, 2011
Beginning balance	\$ 3,488	\$ 2,839
Provision for doubtful accounts	5,104	4,431
Write-offs, net	(5,319)	(3,782)
Ending balance	\$ 3,273	\$ 3,488

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

The allowance for doubtful accounts includes the balances, after receipt of the approved settlements from third party payers for the insufficient diagnosis information received from the ordering physician, which result in denials of payment and the uncollectible portion of receivables from self payers, including deductibles and copayments, which are subject to credit risk and patients' ability to pay. During the years ended July 31, 2012 and 2011, 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 collectability of its receivables is directly linked to the quality of its billing processes, most notably, those related to obtaining the accurate 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.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

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 table indicates the Clinical Labs aged gross receivables by payer group (in thousands), 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, 2012	Total Amount	%	Medicare Amount	%	Third Party Payers Amount	%	Self-pay Amount	%	HMO s Amount	%
1-30 days	\$ 27,092	54%	\$ 5,246	56%	\$ 14,529	52%	\$ 3,337	39%	\$ 3,980	89%
31-60 days	8,282	17%	475	5%	4,566	17%	3,092	36%	149	3%
61-90 days	4,922	9%	964	10%	2,561	9%	1,257	15%	140	3%
91-120 days	3,758	8%	512	6%	2,124	8%	977	10%	145	3%
121-150 days	2,301	5%	515	6%	1,733	6%		0%	53	1%
Greater than 150 days*	3,701	7%	1,589	17%	2,072	8%		0%	40	1%
Totals	\$ 50,056	100%	\$ 9,301	100%	\$ 27,585	100%	\$ 8,663	100%	\$ 4,507	100%

As of July 31, 2011	Total Amount	%	Medicare Amount	%	Third Party Payers Amount	%	Self-pay Amount	%	HMO s Amount	%
1-30 days	\$ 29,880	60%	\$ 5,843	60%	\$ 13,851	56%	\$ 6,173	55%	\$ 4,013	95%
31-60 days	7,013	14%	791	8%	3,441	14%	2,687	24%	93	2%
61-90 days	4,029	8%	566	6%	2,522	10%	890	8%	51	1%
91-120 days	3,826	8%	917	9%	1,819	7%	1,046	9%	44	1%
121-150 days	2,084	4%	375	4%	1,385	6%	288	3%	37	1%
Greater than 150 days**	3,050	6%	1,234	13%	1,717	7%	94	1%	5	0%
Totals	\$ 49,882	100%	\$ 9,726	100%	\$ 24,735	100%	\$ 11,178	100%	\$ 4,243	100%

* Total includes \$1,178 fully reserved over 210 days as of July 31, 2012.

** Total includes \$800 fully reserved over 210 days as of July 31, 2011.

Income Taxes

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

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

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. To the extent the

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

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.

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. Write downs of inventories to market value are based on a review of inventory quantities on hand and estimated sales forecasts based on sales history and anticipated future demand. Unanticipated changes in demand could have a significant impact on the value of our inventory and require additional write downs of inventory which would impact our results of operations.

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.

Goodwill and Indefinite-Lived Intangibles

Goodwill represents the excess of the cost on an acquisition over the fair value of the net assets acquired. The Company tests goodwill and other indefinite lived intangibles for impairment annually as of the first day of the fourth quarter, or more frequently if indicators of potential impairment exist. Goodwill is reviewed for impairment utilizing a two-step process. The first step of the impairment test requires the identification of the reporting units and comparison of the fair value of each of these reporting units to their respective carrying value. If the carrying value of the reporting unit is less than its fair value, no impairment exists and the second step is not performed. If the carrying value of the reporting unit is higher than its fair value, the second step must be performed to compute the amount of the goodwill impairment, if any. In the second step, the impairment is computed by comparing the implied fair value of the reporting unit goodwill with the carrying amount of that goodwill. If the carrying amount of the reporting unit goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized for the excess. In the fiscal 2012 fourth quarter the Company recorded a non-cash goodwill impairment charge relating to the Life Sciences reporting unit of \$18.8 million after completing an interim impairment assessment as of July 31, 2012. The interim impairment test as of July 31, 2012 was required due to a decline in market capitalization of 44% from May 1 to July 31, 2012 and declining revenues experienced in the fourth quarter of fiscal 2012.

In connection with the annual assessment of indefinite-lived intangibles as of May 1, 2012, the Company determined the estimated fair value of trademarks, relating to the Enzo Life Sciences reporting unit, were less than their carrying value by \$5.7 million primarily due to declines in projected revenues and in connection with future plans resulting from the strategic review. As a result of this impairment, which included a change in the future branding strategy, the useful life of the trademarks were reassessed and determined to have an estimated economic life of 5 years. A non-cash impairment charge of \$5.7 million, (\$4.4 million net of related taxes) was recorded for the trademark impairment in the fourth quarter. As a result of the reclassification of trademarks from indefinite lived to a 5 year life, annual amortization of trademarks is estimated to be \$0.6 million per year.

Intangible Assets

Intangible assets (exclusive of patents), arose primarily from acquisitions 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. The Company has capitalized 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.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk from changes in foreign currency exchange rates resulting from acquisitions with foreign locations (See Item 1A. Risk Factors and Note 2 in the Notes to Consolidated Financial Statements) that could impact our results of operations and financial position. We do not currently engage in any hedging or market risk management tools.

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 decline of 10% in the exchange rates of foreign currencies against the U.S. dollar at July 31, 2012, our assets and liabilities would decrease by \$1.9 million and \$0.8 million, respectively, and our net sales and net earnings (loss) would decrease by \$1.6 million and \$0.1 million, 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 increase of 10% in the exchange rates of foreign currencies against the U.S. dollar at July 31, 2012, our pre-tax earnings (loss) would be unfavorably impacted by approximately \$0.3 million on an annual basis.

Interest Rate Risk

Our excess cash is invested in highly liquid money market accounts and U.S. Treasury bills. Changes in interest rates may affect the investment income we earn on these funds which are classified as cash equivalents and therefore affect our cash flows and results of operations. As of July 31, 2012, we were exposed to interest rate change market risk with respect to our cash equivalents of \$8.5 million. The cash equivalents bear interest rates ranging from 0% to 0.05%. As of July 31, 2012, based on the cash equivalents held, it is determined we have no material interest rate risk.

As of July 31, 2012, we have fixed interest rate financing on transportation and equipment leases.

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

None.

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, 2012. 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, 2012, 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, 2012 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).

Based on its assessment, management concluded that we maintained effective internal control over financial reporting as of July 31, 2012.

Ernst & Young LLP, our independent registered public accounting firm, has audited the effectiveness of the Company's internal control over financial reporting as of July 31, 2012, as stated in their report, which is included herein.

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, 2012, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). The Company'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.

In our opinion, Enzo Biochem, Inc. maintained, in all material respects, effective internal control over financial reporting as of July 31, 2012 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, 2012 and 2011 and the related consolidated statements of operations, stockholders' equity and comprehensive income (loss) and cash flows for each of the three years in the period ended July 31, 2012 of Enzo Biochem, Inc. and our report dated October 15, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Jericho, New York
October 15, 2012

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, 2012 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, 2012 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, 2012 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, 2012 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, 2012 and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

- (a) (1) Consolidated Financial Statements
 - Consolidated Balance Sheets - July 31, 2012 and 2011
 - Consolidated Statements of Operations- Years ended July 31, 2012, 2011 and 2010
 - Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss) - Years ended July 31, 2012, 2011 and 2010
 - Consolidated Statements of Cash Flows - Years ended July 31, 2012, 2011 and 2010
 - 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:

Exhibit No.	Description
3(a)	Certificate of Incorporation (1)
3(b)	Certificate of Incorporation, as amended on March 17, 1980. (1)
3(c)	Certificate of Amendment of the Certificate of Incorporation as amended on June 16, 1981. (2)
3(d)	Certificate of Amendment to the Certificate of Incorporation as of July 22, 1988. (3)
3(e)	Amended and restated Bylaws. (4)
10(a)	1994 Stock Option Plan. (5)
10 (b)	1999 Stock Option Plan. (6)
10 (c)	2005 Equity Compensation Incentive Plan (7)
10 (d)	2011 Incentive Plan (8)
10 (e)	Lease agreement with Pari Management (9)
10 (f)	Settlement and Release Agreement between the Company and Sigma Aldrich (10)
10 (g)	Stock Purchase Agreement By and Among Enzo Life Sciences, Inc., Axxora Life Sciences Inc., and the Stock holders, Option holders and Warrant holders (12)
10 (h)	Stock Asset Purchase Agreement By and Among Buyer Parties and Seller Parties with respect to the Biomol International and affiliate acquisition (13)
10 (i)	Asset Purchase Agreement By and Among Enzo Life Sciences, Acquisition, Inc. and Assay Designs, Inc.(14)
10 (j)	Amended and Restated Employment Agreement with Elazar Rabbani (15)
10(k)	Amended and Restated Employment Agreement with Barry Weiner (15)
14 (a)	Code of Ethics (11)
21*	List of subsidiaries of the Company
23*	Consent of Independent Registered Public Accounting Firm
31 (a)*	Certification of CEO Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31 (b)*	Certification of CFO Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32 (a)*	Certification of CEO Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32 (b)*	Certification of CFO Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

101. INS** XBRL Instance Document

101.SCH** XBRL Taxonomy Extension Schema Document

101.CAL** XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF** XBRL Taxonomy Extension Definitions Linkbase Document

101.LAB** XBRL Taxonomy Extension Label Linkbase Document

101.PRE** XBRL Taxonomy Extension Presentation Linkbase Document

**Notes to
exhibits**

* Filed herewith

** XBRL (Extensible Business Reporting Language) information is being furnished and not filed for purposes of Sections 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934.

- (1) The exhibits were filed as exhibits to the Company's Registration Statement on Form S-18 (File No. 2-67359) and are incorporated herein by reference.
- (2) This exhibit was filed as an exhibit to the Company's Form 10-K for the year ended July 31, 1981 and is incorporated herein by reference.
- (3) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 1989 and is incorporated herein by reference.
- (4) This exhibit was filed with the Company's Current Report on Form 8-K May 8, 2008 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, 1995 and is incorporated herein by reference.
- (6) This exhibit was filed with the Company's Registration Statement on Form S-8 (333-87153) and is incorporated herein by reference.
- (7) This exhibit was filed as an exhibit to the Company's Proxy Statement of Schedule 14A filed on January 19, 2006 and is incorporated herein by reference.
- (8) This exhibit was filed as appendix B to the Company's Definitive Proxy Statement on Schedule 14A, which was filed with the Securities and Exchange Commission on November 16, 2010 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, 2006 and is incorporated herein by reference.
- (10) This exhibit was filed with the Company's Current Report on Form 8-K on September 21, 2006 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, 2003 and is incorporated here by reference.
- (12) This exhibit was filed with the Company's Current Report on Form 8-K May 30, 2007 and is incorporated herein by reference.
- (13) This exhibit was filed with the Company's Current Report on Form 8-K May 8, 2008 and is incorporated herein by reference.
- (14) This exhibit was filed with the Company's Current Report on Form 8-K March 13, 2009 and is incorporated herein by reference.
- (15) This exhibit was filed with the Company's Current Annual Report on Form 10-K for the year ended July 31, 2010 and is incorporated herein by reference.

- (16) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 2011 and is incorporated herein by reference.

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 15, 2012

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 15, 2012

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

By: /s/ Barry W. Weiner

October 15, 2012

Barry W. Weiner,
President, Chief Financial Officer, Principal Accounting Officer, Treasurer and Director

By: /s/ Stephen B. H. Kent Ph.D.

October 15, 2012

Stephen B. H. Kent, Director

By: /s/ Bernard L. Kasten MD

October 15, 2012

Bernard Kasten, Director

By: /s/ Gregory M. Bortz

October 15, 2012

Gregory M. Bortz, Director

By: /s/ Dov Perlysky

October 15, 2012

Dov Perlysky, 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, 2012 and 2011</u>	F-3
<u>Consolidated Statements of Operations Years ended July 31, 2012, 2011 and 2010</u>	F-4
<u>Consolidated Statements of Stockholders Equity and Comprehensive Income (Loss) Years ended July 31, 2012, 2011 and 2010</u>	F-5
<u>Consolidated Statements of Cash Flows Years ended July 31, 2012, 2011 and 2010</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7
<u>Schedule II - Valuation and Qualifying Accounts Years ended July 31, 2012, 2011 and 2010</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, 2012 and 2011, and the related consolidated statements of operations, stockholders' equity and comprehensive income (loss), and cash flows for each of the three years in the period ended July 31, 2012. 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, 2012 and 2011, and the consolidated results of their operations and their cash flows for each of the three years in the period ended July 31, 2012, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, present fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Enzo Biochem Inc.'s internal control over financial reporting as of July 31, 2012, 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 15, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Jericho, New York
October 15, 2012

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

	July 31, 2012	July 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 15,076	\$ 14,161
Short term investments		10,000
Accounts receivable, net of allowance for doubtful accounts of \$3,273 in 2012 and \$3,488 in 2011	14,135	15,245
Inventories	8,800	9,260
Prepaid expenses	2,357	2,733
Total current assets	40,368	51,399
Property, plant, and equipment, net	9,116	10,335
Goodwill	7,452	27,373
Intangible assets, net	11,780	19,985
Other	407	382
Total assets	\$ 69,123	\$ 109,474
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable - trade	\$ 9,020	\$ 7,858
Accrued liabilities	9,818	8,188
Other current liabilities	118	1,683
Total current liabilities	18,956	17,729
Deferred taxes	938	2,934
Other liabilities	128	96
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: 39,495,475 at July 31, 2012 and 39,045,837 at July 31, 2011	395	390
Additional paid-in capital	304,358	305,833
Less treasury stock at cost: 216,556 shares at July 31, 2012 and 450,014 shares at July 31, 2011	(3,074)	(6,387)
Accumulated deficit	(254,183)	(214,914)
Accumulated other comprehensive income	1,605	3,793
Total stockholders' equity	49,101	88,715
Total liabilities and stockholders' equity	\$ 69,123	\$ 109,474

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

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

	Years ended July 31,		
	2012	2011	2010
Revenues:			
Clinical laboratory services	\$ 59,403	\$ 52,762	\$ 44,178
Product revenues	37,722	41,830	43,111
Royalty and license fee income	5,958	7,437	9,793
Total revenues	103,083	102,029	97,082
Operating expenses:			
Cost of clinical laboratory services	36,305	31,682	29,570
Cost of product revenues	19,668	22,137	22,547
Research and development	6,293	7,806	9,704
Selling, general, and administrative	47,928	45,191	48,395
Provision for uncollectible accounts receivable	5,104	4,431	3,480
Legal	3,724	3,710	1,746
Litigation settlement and related costs			3,698
Impairment charges	24,540		
Total operating expenses	143,562	114,957	119,140
Operating loss	(40,479)	(12,928)	(22,058)
Other income (expense):			
Interest	21	11	19
Other	77	45	44
Foreign exchange (loss) gain	(540)	49	(266)
Loss before income taxes	(40,921)	(12,823)	(22,261)
Benefit (provision) for income taxes	1,652	(137)	28
Net loss	(\$ 39,269)	(\$ 12,960)	(\$ 22,233)
Net loss per common share:			
Basic and diluted	(\$ 1.01)	(\$ 0.34)	(\$ 0.59)
Weighted average common shares outstanding:			
Basic and diluted	38,798	38,357	38,001

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, 2012, 2011, and 2010
(In thousands, except share data)

	Common Stock Shares	Treasury Stock Shares	Common Stock Amount	Additional Paid-in Capital	Treasury Stock Amount	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity	Comprehensive loss
Balance at July 31, 2009	38,589,880	735,554	\$ 386	\$ 306,280	(\$ 10,440)	(\$ 179,721)	\$ 276	\$ 116,781	
Net (loss) for the year ended July 31, 2010						(22,233)		(22,233)	\$ (22,233)
Vesting of restricted stock	192,845		2					2	
Stock based compensation charges				1,170				1,170	
Issuance of stock for employee 401(k) plan match		(111,706)		(889)	1,586			697	
Foreign currency translation adjustments							599	599	599
Comprehensive loss									(21,634)
Balance at July 31, 2010	38,782,725	623,848	388	306,561	(8,854)	(201,954)	875	97,016	
Net (loss) for the year ended July 31, 2011						(12,960)		(12,960)	(12,960)
Vesting of restricted stock	263,112		2					2	
Stock based compensation charges				1,049				1,049	
Issuance of treasury stock for employee 401(k) plan match		(173,834)		(1,777)	2,467			690	
Foreign currency translation adjustments							2,918	2,918	2,918
Comprehensive loss									(10,042)
Balance at July 31, 2011	39,045,837	450,014	390	305,833	(6,387)	(214,914)	3,793	88,715	

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Net (loss) for the year ended July 31, 2012					(39,269)		(39,269)	(39,269)
Vesting of restricted stock	174,638	2					2	
Stock based compensation charges				719			719	
Issuance of treasury stock for employee 401(k) plan match	(233,458)		(2,664)	3,313			649	
Issuance of common stock for services	275,000	3	470				473	
Foreign currency translation adjustments					(2,188)	(2,188)	(2,188)	
Comprehensive loss							\$	(41,457)
Balance at July 31, 2012	39,495,475	216,556	\$ 395	\$ 304,358	\$ (3,074)	\$ (254,183)	\$ 1,605	\$ 49,101

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,		
	2012	2011	2010
Cash flows from operating activities:			
Net loss	(\$ 39,269)	(\$ 12,960)	(\$ 22,233)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of property, plant and equipment	2,817	2,962	2,727
Amortization of intangible assets	1,660	1,507	1,542
Provision for uncollectible accounts receivable	5,104	4,431	3,480
Deferred income tax (benefit) provision	(1,762)	17	(45)
Share based compensation charges	719	1,049	1,170
Share based 401(k) employer match expense	649	690	1,115
Deferred revenue recognized	(400)	(38)	(450)
Foreign exchange loss (gain)	538	(131)	45
Impairment charges	24,540		
Changes in operating assets and liabilities:			
Accounts receivable	(4,210)	(6,537)	(3,844)
Inventories	199	(178)	681
Prepaid expenses	356	(432)	220
Accounts payable trade	1,031	1,462	2,348
Accrued liabilities, other current liabilities and other liabilities	2,056	(168)	(220)
Total adjustments	33,297	4,634	8,769
Net cash used in operating activities	(5,972)	(8,326)	(13,464)
Cash flows from investing activities:			
Capital expenditures	(1,364)	(1,223)	(3,251)
Maturities of short term investments	58,497	182,453	232,140
Purchases of short term investments	(48,497)	(167,646)	(213,643)
(Increase) decrease in security deposits and other	(25)	(45)	81
Earn-out payment	(1,150)		
Net cash provided by investing activities	7,461	13,539	15,327
Cash flows from financing activities:			
Installment loan payments	(154)	(68)	
Net cash used in financing activities	(154)	(68)	
Effect of exchange rate changes on cash and cash equivalents	(420)	257	(33)
Increase in cash and cash equivalents	915	5,402	1,830
Cash and cash equivalents - beginning of year	14,161	8,759	6,929
Cash and cash equivalents - end of year	\$ 15,076	\$ 14,161	\$ 8,759

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

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2012 and 2011
(Dollars in thousands except share data)

Note 1 - Summary of significant accounting policies

Nature of business

Enzo Biochem, Inc. (the Company) is an integrated life science and biotechnology company 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 in the New York, New Jersey and Eastern Pennsylvania medical communities. The Company operates in three segments (see Note 15).

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 the 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 amounts reported in the financial statements and accompanying footnotes. Actual results could differ from those estimates.

Foreign Currency Translation/Transactions

The Company has determined that the functional currency for its foreign subsidiaries is the local currency. For financial reporting purposes, 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. Gains or losses resulting from transactions entered into in other than the functional currency are recorded as foreign exchange gains and losses in the consolidated statements of operations.

Cash and cash equivalents

Cash and cash equivalents consist of demand deposits with banks, highly liquid money market funds, and highly liquid U.S. Government instruments with maturities of less than ninety days.

Short term investments

Short term investments are highly liquid U.S. Government instruments with maturities greater than ninety days.

Fair Values of Financial Instruments

The recorded amounts of the Company's cash and equivalents, short-term investments, receivables, accounts payable and accrued liabilities approximate their fair values principally because of the short-term nature of these items. The fair value of short term investments is based on quoted market prices where available.

Concentration of credit risk

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of cash and cash equivalents, short term investments, and accounts receivable. The Company's short term investments are invested in highly liquid US Government instruments.

F-7

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2012 and 2011
(Dollars in thousands except share data)

The Company believes the fair value of the aforementioned financial instruments approximates the cost 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 third party payers that insure individuals. 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.

Accrual for Self-Funded Medical

Accruals for self-funded medical insurance are determined based on a number of assumptions and factors, including historical payment trends, claims history and current estimates. These estimated liabilities are not discounted. If actual trends differ from these estimates, the financial results could be impacted.

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.

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.

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2012 and 2011
(Dollars in thousands except share data)

Clinical laboratory services

Revenues from the Clinical Labs segment 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 tables of the Clinical Lab segment's net revenues and revenue percentages by revenue category:

Revenue category	2012		Years ended July 31, 2011		2010	
		(in %)		(in %)		(in %)
Medicare	\$ 12,658	21	\$ 11,856	22	\$ 11,158	25
Third-party payers	29,616	50	24,335	46	19,534	44
Patient self-pay	11,895	20	11,554	22	8,758	20
HMO s	5,234	9	5,017	10	4,728	11
Total	\$ 59,403	100%	\$ 52,762	100%	\$ 44,178	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 payers and Health Maintenance Organizations (HMO s) categories represent approximately 21%, 22% and 25% of the Clinical Labs segment net revenue for the years ended July 31, 2012, 2011 and 2010 respectively. Another third party provider represents 13% and 11% of the Clinical Labs segment's net revenue for the years ended July 31, 2012 and 2011, respectively.

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, 2012, 2011 and 2010, the contractual adjustment percentages, determined using current and historical reimbursement statistics, were approximately 85%, 84% and 83%, respectively, of gross billings.

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2012 and 2011
(Dollars in thousands except share data)

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, payer mix and other relevant factors.

During the years ended July 31, 2012 and 2011, 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 collectability 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 Clinical Labs segment's net receivables are detailed by billing category and as a percent to its total net receivables. At July 31, 2012 and 2011, approximately 55% and 51%, respectively, of the Company's net accounts receivable relates to its Clinical Labs business, which operates in the New York, New Jersey, and Eastern Pennsylvania medical communities.

The Life Sciences segment's accounts receivable includes royalties receivable of \$1.7 million and \$2.0 million, as of July 31, 2012 and 2011, respectively, due from QIAGEN Gaithersburg Inc. (Qiagen) (see Note 11).

The following is a table of the Company's net accounts receivable by segment.

	July 31, 2012		July 31, 2011	
Net accounts receivable by segment		(in %)		(in %)
Clinical Labs (by billing category)				
Medicare	\$ 1,270	16	\$ 1,434	19
Third party payers	3,478	45	3,087	40
Patient self-pay	2,655	35	2,865	37
HMO's	330	4	314	4
Total Clinical Labs	7,733	100%	7,700	100%
Total Life Sciences	6,402		7,545	
Total accounts receivable	\$ 14,135		\$ 15,245	

F-10

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2012 and 2011
(Dollars in thousands except share data)

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

	<u>July 31, 2012</u>	<u>July 31, 2011</u>
Beginning balance	\$ 3,488	\$ 2,839
Provision for doubtful accounts	5,104	4,431
Write-offs	(5,319)	(3,782)
	<u> </u>	<u> </u>
Ending balance	<u>\$ 3,273</u>	<u>\$ 3,488</u>

Inventories

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. Write downs of inventories to market value are based on a review of inventory quantities on hand and estimated sales forecasts based on sales history and anticipated future demand. Unanticipated changes in demand could have a significant impact on the value of our inventory and require additional write downs of inventory which would impact our results of operations.

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 which range 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. The Company reviewed long-lived assets for impairment at July 31, 2012 in conjunction with the step two test performed on goodwill as part of the interim impairment testing. This test did not result in any impairment of long-lived assets. There were no impairments in 2011 or 2010.

Goodwill and Indefinite-Lived Intangibles

Goodwill represents the excess of the cost on an acquisition over the fair value of the net assets acquired. The company tests goodwill and other indefinite lived intangibles for impairment annually as of the first day of the fourth quarter, or more frequently if indicators of potential impairment exist. Goodwill is reviewed for impairment utilizing a two-step process. The first step of the impairment test requires the identification of the reporting units and comparison of the fair value of each of these reporting units to their respective carrying value. If the carrying value of the reporting unit is less than its fair value, no impairment exists and the second step is not performed. If the carrying value of the reporting unit is higher than its fair value, the second step must be performed to compute the amount of the goodwill impairment, if any. In the second step, the impairment is computed by comparing the implied fair value of the reporting unit goodwill with the carrying amount of that goodwill. If the carrying amount of the reporting unit goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized for the excess.

Intangible Assets

Intangible assets (exclusive of patents), arose primarily from acquisitions, and primarily consist of customer relationships, trademarks, licenses, 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, 2012 and 2011
(Dollars in thousands except share data)

The Company has capitalized 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 loss

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. Accumulated other comprehensive income is a separate component of stockholders' equity and consists of foreign currency translation adjustments.

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 \$237, \$235 and \$375 for the years ended July 31, 2012, 2011 and 2010, 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, 2012, 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.

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2012 and 2011
(Dollars in thousands except share data)

Segment Reporting

The Company follows accounting pronouncements which establish 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 15).

Net income (loss) 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. Diluted weighted average shares outstanding for fiscal 2012, 2011 and 2010 do not include the potential common shares from stock options and unvested restricted stock because to do so would have been antidilutive and as such is the same as basic weighted average shares outstanding. 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, 2012, 2011, and 2010 was 0, 27,000, and 51,000, respectively.

For the years ended July 31, 2012, 2011 and 2010, the effect of approximately 736,000, 785,000 and 1,132,000 respectively, of outstanding out of the money options to purchase common shares were excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. The following table sets forth the computation of basic and diluted net loss per share for the years ended July 31:

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Numerator:			
Net loss	\$ (39,269)	\$ (12,960)	\$ (22,233)
Denominator:			
Weighted-average common shares outstanding- Basic	38,798	38,357	38,001
Add: effect of dilutive stock options and restricted stock			
Weighted-average common shares outstanding - Diluted	38,798	38,357	38,001
Net loss per share			
Basic and diluted	\$ (1.01)	\$ (0.34)	\$ (0.59)

Share-Based Compensation

The Company records compensation expense associated with stock options and restricted stock based upon the fair value of stock based awards as measured at the grant date. The expense is recorded by amortizing the fair values on a straight line basis over the vesting period, adjusted for estimated forfeitures.

For the years ended July 31, 2012, 2011 and 2010, share-based compensation expense relating to the fair value of restricted shares and restricted stock units was approximately \$719, \$1,049, and \$1,170, respectively (see Note 9). No excess tax benefits were recognized for the year ended July 31, 2012, 2011 and 2010.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

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:

	2012	2011	2010
	<u> </u>	<u> </u>	<u> </u>
Cost of clinical laboratory services	\$ 10	\$ 10	\$ 12
Research and development	4	14	14
Selling, general and administrative	705	1,025	1,144
	<u> </u>	<u> </u>	<u> </u>
	\$ 719	\$ 1,049	\$ 1,170
	<u> </u>	<u> </u>	<u> </u>

F-13

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2012 and 2011
(Dollars in thousands except share data)

As of July 31, 2012, there was \$657 of total unrecognized compensation cost related to nonvested share-based payment arrangements granted under the Company's incentive stock plans, which will be recognized over a weighted average remaining life of approximately fifteen months.

Subsequent events

In accordance with authoritative guidance, the Company evaluates subsequent events through the date of filing.

Effect of new accounting pronouncements

In May 2011, the FASB issued Accounting Standards Update No. 2011-04 Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS. This standard results in a common requirement between the FASB and the International Accounting Standards Board (IASB) for measuring fair value and for disclosing information about fair value measurements. This amendment was effective prospectively for the Company's interim reporting period ended April 30, 2012. The adoption of this standard did not have a material impact on the Company's consolidated financial position or results of operations.

In June 2011, the FASB issued Accounting Standards Update No. 2011-05, Presentation of Comprehensive Income (ASU No. 2011-05), which improves the comparability, consistency, and transparency of financial reporting and increases the prominence of items reported in other comprehensive income (OCI) by eliminating the option to present components of OCI as part of the statement of changes in stockholders' equity. The amendments in this standard require that all non-owner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. Subsequently in December 2011, the FASB issued Accounting Standards Update No. 2011-12, Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income (ASU No. 2011-12), which indefinitely defers the requirement in ASU No. 2011-05 to present on the face of the financial statements reclassification adjustments for items that are reclassified from OCI to net income in the statement(s) where the components of net income and the components of OCI are presented. The amendments in these standards do not change the items that must be reported in OCI, when an item of OCI must be reclassified to net income, or change the option for an entity to present components of OCI gross or net of the effect of income taxes. The amendments in ASU No. 2011-05 and ASU No. 2011-12 are effective for interim and annual periods beginning with the first quarter of the Company's fiscal year beginning on August 1, 2012 and are to be applied retrospectively. The adoption of the provisions of ASU No. 2011-05 and ASU No. 2011-12 will not have a material impact on the Company's consolidated financial position or results of operations.

In July 2011, the FASB issued ASU No. 2011-07 Health Care Entities (Topic 954) - Presentation and Disclosure of Patient Service Revenue, Provision for Bad Debts, and the Allowance for Doubtful Accounts for Certain Health Care Entities. This update was issued to provide greater transparency relating to accounting practices used for net patient service revenue and related bad debt allowances by health care entities. Some health care entities recognize patient service revenue at the time the services are rendered regardless of whether the entity expects to collect that amount or has assessed the patient's ability to pay. These prior accounting practices used by some health care entities resulted in a gross-up of patient service revenue and the provision for bad debts, causing difficulty for users of financial statements to make accurate comparisons and analyses of financial statements among entities. ASU No. 2011-07 requires certain healthcare entities to change the presentation of the statement of operations, reclassifying the provision for bad debts associated with patient service revenue from an operating expense to a deduction from patient service revenue and also requires enhanced quantitative and qualitative disclosures relevant to the entity's policies for recognizing revenue and assessing bad debts. This update is not designed to change and will not change the net income reported by healthcare entities. This update is effective for fiscal years beginning after December 15, 2011 with early adoption permitted. The Company will adopt this update in the fiscal year beginning August 1, 2012. The adoption of the provisions of ASU No. 2011-07 will not have a material impact on the Company's consolidated financial position or results of operations.

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2012 and 2011
(Dollars in thousands except share data)

In September 2011, the FASB issued Accounting Standards Update No. 2011-08 "Testing Goodwill for Impairment" (ASU No. 2011-08) which is intended to reduce the complexity and costs to test goodwill for impairment. The amendment allows an entity the option to make a qualitative evaluation about the likelihood of goodwill impairment to determine whether it is necessary to perform the two-step quantitative goodwill impairment test. An entity will no longer be required to calculate the fair value of a reporting unit unless the entity determines, based on its qualitative assessment, that it is more likely than not that the fair value of the reporting unit is less than its carrying amount. The ASU also expands upon the examples of events and circumstances that an entity should consider between annual impairment tests in determining whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. The amendment becomes effective for annual and interim goodwill impairment tests performed for the Company's fiscal year beginning August 1, 2012. The Company does not expect the adoption of ASU 2011-08 to have a material impact on its consolidated financial statements.

In September 2011, the FASB issued Accounting Standards Update No. 2011-09 "Compensation - Retirement Benefits - Multiemployer Plans (Subtopic 715-80): Disclosures about an Employer's Participation in a Multiemployer Plan" (ASU 2011-09), which requires additional quantitative and qualitative disclosures for employers who participate in multiemployer pension plans. ASU 2011-09 was adopted by the Company during the year ended July 31, 2012. ASU 2011-09 requires additional disclosures, but otherwise did not have a material impact on the Company's consolidated financial position, annual results of operations or cash.

In July 2012, the FASB issued ASU 2012-02, "Intangibles - Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment" (ASU 2012-02), which permits an entity to make a qualitative assessment of whether it is more likely than not that the fair value of a reporting unit's indefinite-lived intangible asset is less than the asset's carrying value before applying the two-step goodwill impairment model that is currently in place. If it is determined through the qualitative assessment that the fair value of a reporting unit's indefinite-lived intangible asset is more likely than not greater than the asset's carrying value, the remaining impairment steps would be unnecessary. The qualitative assessment is optional, allowing companies to go directly to the quantitative assessment. ASU 2012-02 is effective for the Company for annual and interim indefinite-lived intangible asset impairment tests performed beginning August 1, 2013, however early adoption is permitted. The Company is currently evaluating the impact ASU 2012-02 will have on its consolidated financial statements.

Note 2 Goodwill and intangible assets

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

	Enzo Life Sciences	Enzo Clinical Labs	Total
August 1, 2010	\$ 17,491	\$ 7,452	\$ 24,943
Additional purchase price consideration	1,150		1,150
Foreign currency translation	1,280		1,280
July 31, 2011	19,921	7,452	27,373
Foreign currency translation	(1,083)		(1,083)
Impairment charge	(18,838)		(18,838)
July 31, 2012	\$	\$ 7,452	\$ 7,452

Goodwill represents the excess of the cost of an acquisition over the fair value of the net assets acquired. The Company tests goodwill and other indefinite lived intangibles for impairment annually as of the first day of the fourth quarter, or more frequently if indicators of potential impairment exist. Goodwill is reviewed for impairment utilizing a two-step process. The first step of the impairment test requires the identification of the reporting units and comparison of the fair value of each of these reporting units to their respective carrying value. If the carrying value of the reporting unit is less than its fair value, no impairment exists and the second step is not performed. If the carrying value of the reporting unit is higher than its fair value, the second step must be performed to compute the amount of the goodwill impairment, if any. In the second step, the impairment is computed by comparing the implied fair value of the reporting unit goodwill with the carrying amount of that goodwill. If the carrying amount of the reporting

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

unit goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized for the excess.

The Company estimates the fair value of a reporting unit using a forward-looking discounted cash flow methodology. The assumptions included in the discounted cash flow methodology included among others; forecasted revenues based on historical and recent revenue trends, gross profit margins, operating income margins, working capital cash flow, perpetual growth rates, and long-term discount rates, all of which require significant judgments by management. As of the first day of the fourth quarter of 2012, the annual assessment date, the Company's test did not indicate impairment at any of the Company's reporting units.

F-15

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2012 and 2011
(Dollars in thousands except share data)

As a result of decline in the Company's market capitalization, relating to the decline in the Company's stock price of 44% from May 1 to July 31, 2012, declining results in the fourth quarter and results from the completion of the refocusing of the Enzo Life Sciences reporting unit, the Company determined that these impairment factors required the completion of an interim impairment test as of July 31, 2012. Based upon the results of the interim impairment test as of July 31, 2012, the carrying value of the Enzo Life Sciences reporting unit was determined to be higher than its fair value and, accordingly, the Company performed a step two impairment analysis. The results of the step-two impairment analysis for the Enzo life Sciences reporting unit indicated that goodwill was fully impaired. As a result of the analysis the Company recognized a total non-cash impairment charge of \$18.8 million (\$18.0 net of related taxes) as of July 31, 2012. The impairment charge did not impact the Company's consolidated cash flows, liquidity, and capital resources. The fair value of the Enzo Clinical Lab reporting unit was higher than its carrying value and therefore a step-two analysis was not required.

Intangible assets

The Company's change in the net carrying amount of intangible assets, all in the Life Sciences segment is as follows:

	Gross	Accumulated Amortization	Net
August 1, 2010	\$ 33,940	(13,572)	20,368
Amortization expense		(1,507)	(1,507)
Foreign currency translation	898	226	1,124
July 31, 2011	34,838	(14,853)	19,985
Amortization expense		(1,660)	(1,660)
Foreign currency translation	(1,232)	389	(843)
Trademark impairment charge	(5,702)		(5,702)
July 31, 2012	\$ 27,904	\$ (16,124)	\$ 11,780

Intangible assets consist of the following:

	July 31, 2012			July 31, 2011		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Finite-lived intangible assets:						
Patents	\$ 11,027	\$ (10,439)	\$ 588	\$ 11,027	\$ (10,278)	\$ 749
Customer relationships	12,304	(4,356)	7,948	12,789	(3,472)	9,317
Website and acquired content	1,019	(874)	145	1,063	(748)	315
Licensed technology and other	485	(300)	185	649	(355)	294
Trademarks, gives effect for impairment charge and reclassification to finite-lived as of May 1, 2012	3,069	(155)	2,914	9,310		9,310
Total	\$ 27,904	\$ (16,124)	\$ 11,780	\$ 34,838	\$ (14,853)	\$ 19,985

At July 31, 2012 information with respect to the intangibles acquired is as follows:

Useful life assigned	Weighted average remaining useful life
---------------------------------	---

At July 31, 2012, the weighted average useful lives of amortizable intangible assets were approximately seven years.

F-16

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2012 and 2011
(Dollars in thousands except share data)

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

2013	\$ 1,911
2014	1,796
2015	1,755
2016	1,729
2017	1,515

Amortization expense for the years ended July 31, 2012, 2011, and 2010 was \$1,660, \$1,507, and \$1,542, respectively.

In connection with the annual assessment of indefinite-lived intangibles as of May 1, 2012, the Company determined the estimated fair value of trademarks, relating to the Enzo Life Science reporting unit, were less than their carrying value by \$5.7 million primarily due to declines in projected revenues and in connection with future plans resulting from the aforementioned strategic review. As a result of this impairment, which included a change in the future branding strategy, the useful life of the trademarks were reassessed and determined to have an estimated economic life of 5 years. A non-cash impairment charge of \$5.7 million, (\$4.4 million net of related taxes) was recorded for the trademark impairment in the fourth quarter. As a result of the reclassification of trademarks from indefinite lived to a 5 year life, annual amortization of trademarks is estimated to \$0.6 million per year.

The aggregate goodwill and indefinite lived-intangible impairment charge recorded in the fiscal 2012 fourth quarter was \$24.5 million, (\$22.4 million net of related taxes). These charges did not affect consolidated cash flows, current liquidity or capital resources.

Note 3- Supplemental disclosure for statement of cash flows

In the years ended July 31, 2012, 2011, and 2010, income taxes paid by the Company approximated \$70, \$107, and \$186 respectively.

Note 4 Short term investments

At July 31, 2012, the Company had no short term investments. At July 31, 2011 the Company's short-term investments, whose fair value approximates cost, were in U.S. Treasury bills, which are purchased at discounts with remaining maturities greater than ninety days.

The authoritative guidance for fair value measurements establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurements) and the lowest priority to unobservable inputs (level 3 measurements). The three levels of the fair value hierarchy under the guidance are described below:

- Level 1:* Valuations based on quoted market prices in active markets for identical assets or liabilities.
- Level 2:* Valuations based on quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable data for substantially the full term of the assets or liabilities
- Level 3:* Valuations based on inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2012 and 2011
(Dollars in thousands except share data)

Note 5 - Inventories

Inventories consisted of the following at July 31:

	2012	2011
	<u> </u>	<u> </u>
Raw materials	\$ 1,283	\$ 1,063
Work in process	2,821	2,517
Finished products	4,696	5,680
	<u> </u>	<u> </u>
	\$ 8,800	\$ 9,260
	<u> </u>	<u> </u>

Note 6 Property, plant, and equipment

At July 31, 2012 and 2011 property, plant, and equipment consist of:

	2012	2011
	<u> </u>	<u> </u>
Building and building improvements	\$ 4,751	\$ 4,320
Machinery and equipment	6,760	6,916
Office furniture and computer equipment	14,879	14,551
Leasehold improvements	4,498	4,694
	<u> </u>	<u> </u>
	30,888	30,481
Accumulated depreciation and amortization	(22,484)	(20,858)
	<u> </u>	<u> </u>
	8,404	9,623
Land and land improvements	712	712
	<u> </u>	<u> </u>
	\$ 9,116	\$ 10,335
	<u> </u>	<u> </u>

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2012 and 2011
(Dollars in thousands except share data)

Note 7 - Income taxes

The benefit (provision) for income taxes for fiscal years ended July 31 is as follows:

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Current (provision) benefit:			
Federal	\$	\$ 8	\$ 119
State and local	(49)	(161)	(75)
Foreign	(61)	33	(61)
Deferred (provision) benefit	1,762	(17)	45
	<u></u>	<u></u>	<u></u>
Benefit (provision) for income taxes	\$ 1,652	\$ (137)	\$ 28
	<u></u>	<u></u>	<u></u>

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 are as follows:

	<u>2012</u>	<u>2011</u>
Deferred tax assets:		
Federal tax carryforward losses	\$ 29,531	\$ 25,504
Provision for uncollectible accounts receivable	1,263	1,340
State and local tax carry forward losses	2,914	2,419
Accrued royalties	143	143
Stock compensation	450	1,218
Depreciation	445	
Research and development and other tax credit carryforwards	795	633
Foreign tax carryforward losses	108	381
Intangibles	2,903	
Inventory	1,630	1,515
Accrued expenses	909	736
Other, net	15	23
	<u></u>	<u></u>
Deferred tax assets	41,106	33,912
	<u></u>	<u></u>
Deferred tax liabilities:		
Deferred patent costs	(139)	(170)
Intangibles		(2,983)
Depreciation		(27)
Prepaid expenses	(613)	(691)
Other, net	(31)	(55)
	<u></u>	<u></u>
Deferred tax liabilities	(783)	(3,926)
	<u></u>	<u></u>
Net deferred tax assets (liabilities) before valuation allowance	40,323	29,986
Less: valuation allowance	(41,261)	(32,920)
	<u></u>	<u></u>
Net deferred tax liabilities	\$ (938)	\$ (2,934)
	<u></u>	<u></u>

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2012 and 2011
(Dollars in thousands except share data)

At July 31, 2012, the Company had net deferred tax liabilities of approximately \$0.9 million which consists primarily of identifiable intangible assets and cumulative tax deductions in excess of book expenses recognized by foreign subsidiaries.

Net deferred tax liabilities are included in the consolidated balance sheets as of July 31 as follows:

	2012	2011
Deferred taxes:		
Current	\$	\$
Non-current	938	2,934
	<u>\$ 938</u>	<u>\$ 2,934</u>

The Company recorded a valuation allowance during the year ended July 31, 2012 and 2011 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, 2012, the Company had U.S. federal net operating loss carryforwards of approximately \$86.9 million. The U.S. federal tax loss carryforwards, if not fully utilized, expire between 2013 and 2032. Utilization is dependent on generating sufficient taxable income prior to expiration of the tax loss carryforwards. In addition, the Company has research and development tax credit carryforwards of approximately \$0.7 million which expire between 2025 and 2032. As of July 31, 2012, the Company had foreign loss carryforwards of approximately \$0.4 million.

As a result of certain acquisitions approximately \$1.1 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 before income taxes consisted of the following for the years ended July 31:

	2012	2011	2010
United States operations	\$ (31,817)	\$ (12,284)	\$ (19,642)
International operations	(9,104)	(539)	(2,619)
Loss before taxes	<u>\$ (40,921)</u>	<u>\$ (12,823)</u>	<u>\$ (22,261)</u>

The benefit (provision) for income taxes were at rates different from U.S. federal statutory rates for the following reasons for the years ended July 31:

	2012	2011	2010
Federal statutory rate	34.0%	34.0%	34.0%
Expenses not deductible for income tax return purposes	(0.5)	(2.3)	(1.5)
State income taxes, net of (benefit) of federal tax deduction	0.9	1.0	0.1
Change in valuation allowance	(23.2)	(34.6)	(32.3)
Impairment of goodwill	(7.1)		
Reversal of tax reserve		0.1	0.5

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Other	(0.1)	0.7	(0.7)
	<u>4.0%</u>	<u>(1.1)%</u>	<u>0.1%</u>

U.S. federal income taxes have not been provided on approximately \$164 of undistributed earnings at the Company's foreign subsidiaries at July 31, 2012, because it is the Company's intent to keep the earnings reinvested. As of July 31, 2012, the Company has no liabilities for uncertain tax positions. It is the Company's policy to record interest and penalties as a component of tax expense. 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 years July 31, 2009 through 2011.

F-20

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2012 and 2011
(Dollars in thousands except share data)

Note 8 Accrued Liabilities, Other Current Liabilities and Other Liabilities

At July 31 accrued liabilities consist of:

	2012	2011
Legal	\$ 1,475	\$ 610
Payroll, benefits, severance and commissions	5,125	4,286
Research and development	696	709
Professional fees	901	782
Other	1,621	1,801
	\$ 9,818	\$ 8,188

At July 31 other current liabilities consist of:

	2012	2011
Liability for purchase price consideration	\$	\$ 1,150
Deferred revenue		396
Other	118	137
	\$ 118	\$ 1,683

Self-Insured Medical Plan

During Fiscal 2010, the Company began self-funding medical insurance coverage for certain of its U.S. based employees. The risk to the Company is being limited through the use of individual and aggregate stop loss insurance. As of July 31, 2012 and 2011, the Company has established a reserve of \$0.4 million and \$0.4 million which is included in accrued liabilities, for claims that have been reported but not paid and incurred but not reported. The reserve is based upon the Company's historical payment trends, claim history and current estimates.

Installment Loans

The Company has installment loans outstanding for transportation and lab equipment aggregating \$0.2 million at July 31, 2012, which bear interest at interest rates ranging from 0% to 4.82% per annum, and are secured by the underlying assets. The principal payments under the installment loans are as follows: 2013 - \$0.1 million, included in Other Current Liabilities, and 2014 - \$0.1 million and 2015 - \$0.03 million totaling \$0.2 million, included in Other Liabilities.

Note 9 Stockholders' equity*Common stock*

In June 2012, the Company issued 275,000 shares of common stock at a fair value of \$0.5 million for services performed.

Treasury stock

In fiscal 2012, the Company issued 233,458 shares from treasury stock to match its employees' 401(k) contributions. The Company recorded an expense of \$649 for the match, reducing treasury stock by \$3,313 for the average acquisition cost of such shares and adjusting additional paid in capital by \$2,664.

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2012 and 2011
(Dollars in thousands except share data)

In fiscal 2011, the Company issued 173,834 shares from treasury stock for its employees' 401(k) matched contributions obligation. The Company recorded an expense of \$690 for the match, reducing treasury stock by \$2,467 for the average acquisition cost of such shares and adjusting additional paid in capital by \$1,777.

In fiscal 2010, the Company issued 111,706 shares from treasury stock for its employees' 401(k) matched contributions obligation. The Company recorded an expense of \$697 for the match, reducing treasury stock by \$1,586 for the average acquisition cost of such shares and adjusting additional paid in capital by \$889.

Incentive stock plans

The Company has an incentive stock option plan (the 1999 Plan) and an incentive stock option and restricted stock award plan (the 2005 Plan), under which the Company may grant 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. On January 14, 2011, the Company's stockholders approved the adoption of the 2011 Incentive Plan (the 2011 Plan) which provides for the issuance of equity awards, including among others, options, restricted stock and restricted stock units for up to 3,000,000 Common Shares. No additional awards may be granted under the 1999 or 2005 Plans. The exercise price of options granted under the 2011 Plan, and consistent with other Plans, is equal to or greater than fair market value of the Common Stock on the date of grant. Unless terminated earlier by the Board of Directors the 2011 Plan will terminate at the earliest of; (a) such time as no shares of Common Stock remain available for issuance under the 2011 Plan or (b) tenth anniversary of the effective date of the 2011 Plan. Awards outstanding upon expiration of the 2011 Plan shall remain in effect until they have been exercised, terminated, or have expired. As of July 31, 2012, there were approximately 2,686,000 shares available for grant under the 2011 Plan.

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 2011 Plan provides for the issuance of restricted stock and restricted stock unit awards which generally vest over a two to four year period.

A summary of the information pursuant to the Company's stock option plans for the years ended July 31, 2012, 2011, and 2010 is as follows:

	2012		2011		2010	
	Options	Weighted - Average Exercise Price	Options	Weighted - Average Exercise Price	Options	Weighted - Average Exercise Price
Outstanding at beginning of year	785,124	\$ 14.53	1,132,450	\$ 14.30	1,191,519	\$ 14.41
Exercised		\$		\$		\$
Cancelled	(48,634)	\$ 15.05	(347,326)	\$ 13.78	(59,069)	\$ 16.14
Outstanding at end of year	736,490	\$ 14.50	785,124	\$ 14.53	1,132,450	\$ 14.30
Exercisable at end of year	736,490	\$ 14.50	785,124	\$ 14.53	1,132,450	\$ 14.30
Weighted average fair value of options granted during year		\$		\$		

There is no aggregate intrinsic value of options both outstanding and exercisable at July 31, 2012.

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2012 and 2011
(Dollars in thousands except share data)

The following table summarizes information for stock options outstanding at July 31, 2012:

Range of Exercise prices	Options outstanding and exercisable		
	Shares	Weighted- Average Remaining Contractual Life in years	Weighted- Average Exercise Price
\$10.45-12.25	355,874	.46	\$ 11.82
\$12.99-17.66	380,616	1.94	\$ 17.01
	<u>736,490</u>		

Restricted Stock Awards

During fiscal 2012, 2011 and 2010, the compensation committee of the Company's board of directors approved grants of restricted stock and restricted stock unit awards (the "Awards"), respectively, to the Company's directors, certain officers and certain employees under the 2012 and 2005 Plans. 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 based on the fair value of the award as measured on the grant date and 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 Plans' terms. The Awards settle in shares of the Company's common stock on a one-for-one basis.

A summary of the information pursuant to the Company's Restricted Stock Awards for the years ended July 31, 2012, 2011 and 2010 is as follows:

	2012		2011		2010	
	Awards	Weighted - Average Award Price	Awards	Weighted - Average Award Price	Awards	Weighted - Average Award Price
Outstanding at beginning of year	311,952	\$ 4.84	417,578	\$ 5.50	377,400	\$ 6.05
Awarded	144,143	\$ 2.51	181,643	\$ 3.78	241,610	\$ 5.54
Vested	(174,638)	\$ (4.85)	(263,112)	\$ 5.11	(192,845)	\$ 6.46
Forfeited	(23,874)	\$ (4.30)	(24,157)	\$ 5.27	(8,587)	\$ 9.29
Outstanding at end of year	<u>257,583</u>	<u>\$ 3.58</u>	<u>311,952</u>	<u>\$ 4.84</u>	<u>417,578</u>	<u>\$ 5.50</u>
Weighted average market value of awards granted during year		<u>\$ 2.51</u>		<u>\$ 3.78</u>		<u>\$ 5.54</u>

Note 10 - 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, 2012, 2011, and 2010, 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 share-based 401(k) employer matched contribution was approximately \$649,

\$690, and \$1,115 in fiscal years 2012, 2011, and 2010, respectively.

F-23

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2012 and 2011
(Dollars in thousands except share data)

The Company's Swiss operations provide a pension plan named the Enzo Life Sciences (ELS) AG Vertrag - Nr. 601013, (the Swiss Plan) under the Swiss government's social security system for Swiss employees. The current required minimum contribution is 8% and minimum annual investment return is 2%. 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. The status of the Swiss Plan, which is substantially funded as of December 31, 2011, the latest plan year end, is as follows:

As of December 31,	2011	2010	2009
Total Assets	\$ 3,247,099	\$ 3,080,281	\$ 2,802,496
Accumulated Benefit Obligation	\$ 3,224,370	\$ 3,083,361	\$ 2,754,853
Funded status	99.30%	100.1%	98.3%
Fiscal Year ended July 31,			
Contributions	\$ 483,000	\$ 480,000	\$ 408,000

The Swiss Plan's contract expires December 31, 2014 and currently the Company has no plans to change the current funding or plan design. No events have occurred that would impact the Swiss Plan status.

Note 11 Royalty and other income

The Company has a license agreement with Qiagen that began in 2005, whereby the Company earns quarterly running royalties on the net sales of Qiagen products subject to the license until the expiration of the patent on April 24, 2018. During the years ended July 31, 2012, 2011 and 2010, the Company recorded royalty income under the agreement of approximately \$5,900, \$6,800 and \$6,800, respectively, which is included in the Life Sciences segment.

Note 12 - 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 required each party to pay royalties, as defined through the lives of the related non-expired patents. During the years ended July 31, 2011 and 2010, the Company recorded approximately \$400 and \$3,000, respectively, in royalties and license fee income under the Licensing Agreement. In January 2011, Abbott notified the Company that they have made a final royalty payment because they are unaware of any non-expired patents.

Note 13 Commitments

Leases

The Company leases equipment, office and laboratory space under several non-cancelable operating leases that expire between August 2011 and May 2020. 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, approximated \$1,556, \$1,509, and \$1,470 during fiscal years 2012, 2011 and 2010, respectively.

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Total rent expense incurred by the Company during fiscal 2012, 2011 and 2010 was approximately \$4,378, \$4,023, and \$4,076, respectively. Minimum future annual rentals under non-cancelable operating leases, net of sublease rental income of \$424 as of July 31, 2012, are as follows:

Years ended July 31,	
2013	\$ 3,966
2014	3,849
2015	3,692
2016	3,313
2017	1,205
Thereafter	4,130
	<hr/>
	\$ 20,155

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 September 2013. Aggregate minimum compensation commitments, exclusive of any severance provisions as of July 31, 2012 is \$1,135.

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2012 and 2011
(Dollars in thousands except share data)

Note 14 Contingencies

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. On September 24, 2012, the court ruled on Defendants' motion for summary judgment of non-infringement. The Defendants' motion was granted in part and denied in part. The parties were further directed to submit a joint letter by October 19, 2012 setting forth each party's respective positions on how the case should proceed on remaining issues.

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. On August 26, 2011, the court allowed Affymetrix to renew its motion for previous summary judgment related only to alleged non-infringement of one patent in suit. Affymetrix's initial brief was filed on October 11, 2011, and all briefing was completed on January 13, 2012. On September 24, 2012, the court ruled on Defendants' motion for summary judgment of non-infringement. The Defendants' motion was granted in part and denied in part. The parties were further directed to submit a joint letter by October 19, 2012 setting forth each party's respective positions on how the case should proceed on remaining issues.

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 patents.

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2012 and 2011
(Dollars in thousands except share data)

On August 26, 2011, the court allowed Roche to renew its motion for summary judgment related only to alleged non-infringement of some of the patents in suit. Roche's initial brief was filed on October 11, 2011, and all briefing was completed on January 13, 2012. On September 24, 2012, the court ruled on Defendants' motion for summary judgment of non-infringement. The Defendants' motion was granted in part and denied in part. The parties were further directed to submit a joint letter by October 19, 2012 setting forth each party's respective positions on how the case should proceed on remaining issues.

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. The Company's claim for infringement of one of the four Ward patents is set for trial on October 15, 2012. The Company's claims for infringement of the other five patents have been dismissed. 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, three actions were filed against the Company and certain of its officers and directors by Francis Scott Hunt and others. These actions were filed by the same attorney who had previously filed a virtually identical claim against the Company and certain of its officers and directors in the Eastern District of Virginia. On June 15, 2009, the Court granted the remaining defendants' motion for summary judgment and dismissed the complaints. The remaining Plaintiffs then filed a notice of appeal to the Second Circuit Court of Appeals. On August 30, 2011, the Second Circuit denied the appeal. The remaining Plaintiffs then moved for a rehearing and that motion was also denied. No further appeal was taken. Accordingly, the dismissal is final and the action is concluded.

On or about September 22, 2010, Mayflower Partners, L.P. f/k/a Biomol International, L.P. (Mayflower) filed an action against Enzo Biochem, Inc. and Enzo Life Sciences, Inc. (together Enzo) in the United States District Court for the Southern District of New York, alleging breach of the stock and asset purchase agreement dated as of May 8, 2008 between Enzo and Mayflower (the Agreement). On November 3, 2011, the Company and Mayflower entered into an Earn-Out Dispute Settlement Agreement in which the Company paid \$1.1 million in cash in full settlement of the second and final earn-out under the Agreement. The settlement, which was accrued for at July 31, 2011, was recorded in Goodwill as additional purchase price consideration.

The Company is party to other claims, legal actions, complaints, and contractual disputes 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 15 Segment reporting

The Company has three reportable segments: Life Sciences, Clinical Labs and Therapeutics. The Company's Life Sciences segment develops, manufactures, and markets products to research and pharmaceutical customers. The Clinical Labs segment provides diagnostic services to the health care community. The Company's Therapeutics segment conducts research and development activities for therapeutic drug candidates. 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, 2012 and 2011
(Dollars in thousands except share data)

The following financial information represents the operating results of the reportable segments of the Company:

Year ended July 31, 2012

	Clinical Labs	Life Sciences	Therapeutics	Other	Consolidated
<u>Revenues:</u>					
Clinical laboratory services	\$ 59,403				\$ 59,403
Product revenues		\$ 37,722			37,722
Royalty and license fee income		5,958			5,958
Total revenues	59,403	43,680			103,083
<u>Operating expenses:</u>					
Cost of clinical laboratory services	36,305				36,305
Cost of product revenues		19,668			19,668
Research and development	299	4,308	\$ 1,686		6,293
Selling, general and administrative	20,856	18,305		\$ 8,767	47,928
Provision for uncollectible accounts receivable	4,987	117			5,104
Legal	262	536		2,926	3,724
Impairment charges		24,540			24,540
Total operating expenses	62,709	67,474	1,686	11,693	143,562
Operating loss	(3,306)	(23,794)	(1,686)	(11,693)	(40,479)
<u>Other income (expense)</u>					
Interest	(5)	23		3	21
Other	28	27		22	77
Foreign exchange loss		(540)			(540)
Loss before income taxes	\$ (3,283)	\$ (24,284)	\$ (1,686)	\$ (11,668)	\$ (40,921)
Depreciation and amortization included above	\$ 1,092	\$ 3,217	\$ 43	\$ 125	\$ 4,477
<u>Share-based compensation included in above:</u>					
Cost of clinical laboratory services	\$ 10				\$ 10
Research and development		\$ 4			4
Selling, general and administrative	49	59		\$ 597	705
Total	\$ 59	\$ 63		\$ 597	\$ 719

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Capital expenditures	\$ 921	\$ 443	\$	\$ 1,364
	<u> </u>	<u> </u>	<u> </u>	<u> </u>

F-27

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2012 and 2011
(Dollars in thousands except share data)

Year ended July 31, 2011

	<u>Clinical Labs</u>	<u>Life Sciences</u>	<u>Therapeutics</u>	<u>Other</u>	<u>Consolidated</u>
<u>Revenues:</u>					
Clinical laboratory services	\$ 52,762				\$ 52,762
Product revenues		\$ 41,830			41,830
Royalty and license fee income		7,437			7,437
	<u>52,762</u>	<u>49,267</u>			<u>102,029</u>
<u>Operating expenses:</u>					
Cost of clinical laboratory services	31,682				31,682
Cost of product revenues		22,137			22,137
Research and development		5,784	\$ 2,022		7,806
Selling, general and administrative	18,426	17,855		\$ 8,910	45,191
Provision for uncollectible accounts receivable	4,415	16			4,431
Legal	387	726		2,597	3,710
	<u>54,910</u>	<u>46,518</u>	<u>2,022</u>	<u>11,507</u>	<u>114,957</u>
Operating (loss) income	(2,148)	2,749	(2,022)	(11,507)	(12,928)
<u>Other income (expense)</u>					
Interest	(5)	2		14	11
Other	30	(3)		18	45
Foreign exchange gain		49			49
	<u>(2,123)</u>	<u>2,797</u>	<u>(2,022)</u>	<u>\$ (11,475)</u>	<u>\$ (12,823)</u>
Depreciation and amortization included above	\$ 1,012	\$ 3,282	\$ 47	\$ 128	\$ 4,469
<u>Share-based compensation included in above:</u>					
Cost of clinical laboratory services	\$ 10		\$		\$ 10
Research and development		\$ 14			14
Selling, general and administrative and legal	61	84		\$ 880	1,025
	<u>71</u>	<u>98</u>	<u>\$</u>	<u>\$ 880</u>	<u>\$ 1,049</u>
Capital expenditures	\$ 834	\$ 389	\$	\$	\$ 1,223

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2012 and 2011
(Dollars in thousands except share data)

Year ended July 31, 2010

	<u>Clinical Labs</u>	<u>Life Sciences</u>	<u>Therapeutics</u>	<u>Other</u>	<u>Consolidated</u>
<u>Revenues:</u>					
Clinical laboratory services	\$ 44,178				44,178
Product revenues		\$ 43,111			\$ 43,111
Royalty and license fee income		9,793			9,793
Total revenues	44,178	52,904			97,082
<u>Operating expenses:</u>					
Cost of clinical laboratory services	29,570				29,570
Cost of product revenues		22,547			22,547
Research and development		7,202	\$ 2,502		9,704
Selling, general and administrative	18,503	19,800		\$ 10,092	48,395
Provision for uncollectible accounts receivable	3,432	48			3,480
Legal	222	145		1,379	1,746
Litigation settlement				3,698	3,698
Total operating expenses	51,727	49,742	2,502	15,169	119,140
Operating (loss) income	(7,549)	3,162	(2,502)	(15,169)	(22,058)
<u>Other income (expense)</u>					
Interest		(5)		24	19
Other	46	(8)		6	44
Foreign exchange loss		(266)			(266)
(Loss) income before income taxes	\$ (7,503)	\$ 2,883	\$ (2,502)	\$ (15,139)	\$ (22,261)
Depreciation and amortization included above	\$ 982	\$ 3,110	\$ 52	\$ 125	\$ 4,269
<u>Share-based compensation included in above:</u>					
Cost of clinical laboratory services	\$ 12		\$		\$ 12
Research and development		\$ 14			14
Selling, general and administrative and legal	78	114		\$ 952	1,144
Total	\$ 90	\$ 128	\$	\$ 952	\$ 1,170
Capital expenditures	\$ 1,728	\$ 1,450	\$ 11	\$ 62	\$ 3,251

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2012 and 2011
(Dollars in thousands except share data)

Geographic financial information is as follows:

Net sales to unaffiliated customers:	2012	2011	2010
United States	\$ 87,776	\$ 85,691	\$ 82,873
Switzerland	6,802	8,508	7,037
United Kingdom	2,728	2,825	2,507
Other international countries	5,777	5,005	4,665
Total	\$ 103,083	\$ 102,029	\$ 97,082

Long-lived assets at July 31,	2012	2011	2010
United States	\$ 25,081	\$ 44,028	\$ 45,439
Switzerland	2,223	8,958	7,063
United Kingdom	618	2,857	2,944
Other international countries	426	1,850	1,723
Total	\$ 28,348	\$ 57,693	\$ 57,169

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 there. 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:

	2012	2011	2010
United States	\$ 28,372	\$ 32,928	\$ 38,695
Foreign countries	15,308	16,339	14,209
	\$ 43,680	\$ 49,267	\$ 52,904

Note 16 Summary of Selected Quarterly Financial Data (unaudited)

The following table contains statement of operations information for each quarter of the years ended July 31, 2012 and 2011. 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 for fiscal 2012 and 2011 is summarized as follows:

	Quarter Ended			
Fiscal 2012	October 31, 2011	January 31, 2012	April 30, 2012	July 31, 2012

Edgar Filing: ENZO BIOCHEM INC - Form 10-K

Total revenues	\$	25,753	\$	24,973	\$	25,949	\$	26,408
Gross profit		11,802		11,579		12,056		11,673
Loss before income taxes		(4,326)		(4,076)		(3,445)		(29,074)
Net loss		(4,494)		(4,221)		(3,411)		(27,143)
Basic and diluted loss per common share	\$	(0.12)	\$	(0.11)	\$	(0.09)	\$	(0.69)

Quarter Ended

		October 31, 2010	January 31, 2011	April 30, 2011	July 31, 2011			
Fiscal 2011								
Total revenues	\$	25,652	\$	23,734	\$	25,827	\$	26,816
Gross profit		13,473		10,331		12,364		12,042
Loss before income taxes		(1,060)		(5,562)		(2,002)		(4,199)
Net loss		(1,122)		(5,708)		(2,110)		(4,020)
Basic and diluted loss per common share	\$	(0.03)	\$	(0.15)	\$	(0.05)	\$	(0.11)

F-30

ENZO BIOCHEM, INC
SCHEDULE II
VALUATION AND QUALIFYING ACCOUNTS
Years ended July 31, 2012, 2011 and 2010
(in thousands)

Year ended July 31,	Description	Balance at Beginning of period	Charged to costs and expenses	Charged to other accounts	Deductions	Balance at end of period
2012	Allowance for doubtful accounts receivable	3,488	5,104		5,319(1)	3,273
2011	Allowance for doubtful accounts receivable	2,839	4,431		3,782(1)	3,488
2010	Allowance for doubtful accounts receivable	4,786	3,480		5,427(1)	2,839
2012	Deferred tax valuation allowance	32,920	8,341			41,261
2011	Deferred tax valuation allowance	28,901	4,019			32,920
2010	Deferred tax valuation allowance	21,716	7,185			28,901

(1) Write-off of uncollectible accounts receivable.

S-1