

ENZO BIOCHEM INC  
Form 10-K  
October 14, 2010

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**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, 2010

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)

\_\_\_\_\_  
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

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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 \$165,991,000 as of January 31, 2010

The number of shares of the Company's common stock, \$.01 par value, outstanding at October 1, 2010 was approximately 38,160,000.

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 14, 2011 are incorporated by reference into Part III of this annual report.

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**PART I**

Item 1. Business

**Overview**

Enzo Biochem, Inc. (the Company 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 71 key issued patents worldwide, and over 200 pending patent applications, along with extensive enabling technologies and platforms.

**Recent Events**

In September 2010, we announced that we had streamlined our operations, which is expected to result in a reduction in annualized operating expenses beginning in the fiscal 2011 first quarter. These initiatives are also expected to result in increased gross margins. The operating cost reductions affect all of our operating businesses as well as corporate overhead. The overall improvements are primarily a result of streamlining operations at Enzo Life Sciences, where we completed a series of acquisitions over the past three years, and Enzo Clinical Labs, where we have invested significantly over the past year in technology and process improvements.

At Enzo Clinical Labs, we expect gross margin improvements and expense reductions, primarily through selective work force rationalization and process improvements, including customer service and billing designed to reduce processing and collection costs of receivables, improved laboratory service operations and lower reagent costs. At Enzo Life Sciences, as a result of the acquisitions that we have completed, certain operations have become redundant, which provided opportunities to reduce costs through realignment or centralization of R&D, customer service and manufacturing activities. Enzo Life Sciences has also undertaken a repositioning of its product offerings, refocusing its marketing efforts on higher-margin, higher volume products. As a result, we recorded a charge in the fiscal 2010 fourth quarter of \$1.3 million as certain low-volume products were rationalized. We expect the benefits of the operational improvements to occur commencing with our fiscal 2011 first quarter ending October 31, 2010. In connection with the streamlining, we also recorded a one-time charge of approximately \$500,000 in its fiscal 2010 fourth quarter to reflect severance payments to terminated employees.

**Operating Segments**

We are comprised of three operating segments, of which the Therapeutics and Life Sciences segments have evolved out of our core competencies: the use of nucleic acids as informational molecules and the use of compounds for immune modulation. Information concerning sales by geographic area and business segments for the years ended July 31, 2010, 2009 and 2008 is located in Note 17 in the Notes to Consolidated Financial Statements.

Below are brief descriptions of each of our operating segments:

**Enzo Life Sciences** manufactures, develops and markets functional biology and cellular biochemistry products and tools to research and pharmaceutical 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 9,000 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 protein homeostasis, epigenetics, live cell analysis, molecular biology and immunoassays.



The segment is an established source for a comprehensive panel of products to scientific experts in the fields of Natural Products/Antibiotics, Autophagy, Cancer, Cell Cycle, Cell Death, Cell Signaling, Cellular Analysis, Endocrinology/Hormones, DNA regulation, Compound Screening, Genomics/Molecular Biology, GPCRs, Immunology, Inflammation, Metabolism, Neuroscience, Nitric Oxide pathway, Obesity/Adipokines, Oxidative Stress, Proteases, Proteosomes, Protein Expression and modification, Signal Transduction, Stress/Heat Shock proteins and Ubiquitin/Ubl signaling.

**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 approximately 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 logistics department.

**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 40 patents and patent applications.

The Company's primary sources of revenue have historically been from product revenues and royalty and licensing of Life Sciences' products utilized in life science research and from the clinical laboratory services provided to the healthcare community. The following table summarizes the sources of revenues for the fiscal years ended July 31, 2010, 2009 and 2008, (in \$000's and percentages):

Fiscal year ended July 31,	2010		2009		2008	
Product revenues	\$ 43,111	44%	\$ 40,592	45%	\$ 28,087	36%
Royalty and license fee income	9,793	10	9,376	11	7,630	10
Clinical laboratory services	44,178	46	39,604	44	42,078	54
Total	\$ 97,082	100%	\$ 89,572	100%	\$ 77,795	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 an increasing 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-based diagnostics for which a variety of formats, or tools, have been developed that enable researchers to study biological pathways and to identify mutations in gene sequences and variations in gene expression levels that can lead to disease. These tools include DNA sequencing and genotyping instruments, microarrays, fluorescent microscopes, high content screening systems, flow cytometers and plate readers. Common among these formats 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.

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

research spending by academic, government and private organizations to determine the function and clinical relevance of the gene sequences 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 it s 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. 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.

### **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.

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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.

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.

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

We have research collaborations with other institutions including, Hadassah University Hospital in Jerusalem, Israel relating to our immune regulation technology. Through other collaborations we are developing our candidate drug Optiquel for autoimmune uveitis. There can be no assurance that any of these collaborative projects will be successful.

Similarly, we seek to fully exploit the commercial value of our technology by partnering with for-profit enterprises in specific areas in order to act on opportunities that can be accretive to our efforts in accelerating our development program.

***Apply our biomedical research technology to the clinical diagnostics market***

We intend to develop our proprietary research technology for use in the clinical diagnostics market. We currently offer over 25 gene-based tests for the research market, for the identification of such viruses as human papillomavirus, *cytomegalovirus*, and Epstein-Barr virus.

We also have an extensive library of probes for the detection of various diseases. We have developed a standardized testing format that can permit multiple diagnoses to be performed on the same specimen.

***Expand marketing and distribution infrastructure***

Enzo Life Sciences continues to develop its sales and marketing infrastructure to more directly service its end users, while simultaneously positioning the Company for product line expansion. Our acquisitions of Axxora in May 2007, Biomol International in May 2008 and Assay Designs in March 2009 have expanded our global sales, marketing, manufacturing, product development and distribution infrastructure. Enzo Life Sciences now operates worldwide through wholly owned subsidiaries (in USA, Switzerland, Benelux, Germany, and the UK) and a network of third party distributors in most other significant markets worldwide.

***Expand our collaborations with major life sciences companies***

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

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

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 13 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, 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 2010, we were awarded eleven 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, unlike PCR (currently the most commonly used method of amplification), we have developed isothermal amplification procedures that can be performed at constant temperatures and thus do not require expensive heating and cooling systems or specialized heat-resistant enzymes.

**Non-radioactive labeling and detection.** Traditionally, nucleic acid probes were labeled with radioactive isotopes. However, radioactively labeled probes have a number of shortcomings. They are unstable and consequently have a limited shelf life. They are potentially hazardous, resulting in restrictive licensing requirements and safety precautions for preparation, use and disposal. Finally, radioactive components are expensive. Our technologies permit gene analysis without the problems associated with radioactively labeled probes and are adaptable to a wide variety of formats.

**Formats.** There are various processes, or formats, for performing probe-based tests. In certain formats, the probe is introduced to a target sample affixed to a solid matrix; in others the probe is combined with the sample in solution (homogeneous assay). Solid matrix assays include: *in situ* assays in which the probe reaction takes place directly on a microscope slide; dot blot assays in which the target DNA is fixed to a membrane; and microplate and microarray assays in which the DNA is fixed on a solid surface, and the reaction can be quantified by instrumentation.

***Therapeutic Platform Development***

**Cell Signaling Pathway**

Our newest therapeutic platform development project involves the development of pharmaceutical agents that affect with protein-protein interactions. Over the past several years, our scientists and collaborators have unlocked the secrets of a major cell signaling pathway thus producing a means to modify biologic activity in a number of physiological systems.

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Further investigation into the design and control of this system has allowed our scientists and their collaborators to determine the structure of key regulatory proteins and to identify active sites that then become targets for Enzo s

proprietary technology generating system. Our technology is capable of generating active compounds that range from orally delivered small molecules to peptides, oligonucleotides or antibodies. We have performed pioneering work on the structure and function of LRP and its ligands, developed a screening technology to identify active compounds, and have synthesized proprietary molecules capable of producing biological effects in cell-based systems and animal models of disease. Specifically, this system allows the Company to successfully:

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

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

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

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

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

### **Immune Regulation**

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

### **Gene Regulation**

We have developed an approach to gene regulation known as genetic antisense or antisense RNA. Our technology involves the introduction into cellular DNA of a gene that codes for an RNA molecule that binds to, and thus deactivates, RNA produced by a specific gene. To deliver our antisense gene to the target cell, in a process called transduction, we have developed proprietary vector technology.

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

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



nuclear localization.

In summary, we have developed proprietary technologies in the areas of cell signaling, immune modulation and gene regulation (genetic antisense or antisense RNA) that we are using as platforms for a portfolio of novel therapeutics. There can be no assurance that we will be able to secure patents or that these programs will be successful. The potential therapeutics we are developing could be used, if successful, for the treatment of a variety of diseases, including

osteoporosis, osteonecrosis and other bone pathologies, diabetes, autoimmune uveitis, and inflammatory bowel disease, including Crohn's Disease and ulcerative colitis, among others.

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

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

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

### **Products and Services**

We are applying our core technologies to develop novel therapeutics as well as research tools for the life sciences and clinical diagnostics markets. In addition, we provide clinical laboratory services to physicians and other health care providers in the New York, 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    Enabling Discovery in Life Sciences***

Enzo Life Sciences is positioned as a leading manufacturer and supplier of high quality reagents, kits and products supplied to scientific researchers in academia, clinical research and drug discovery. With direct sales operations in US, Switzerland, Germany, UK, France and Benelux, Enzo Life Sciences also supports its 9,000 products through a global network of dedicated distributors.

#### ***Axxora.com    the Innovative Research Reagents 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.

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The products supplied by Enzo Life Sciences include small molecules, proteins, antibodies, peptides, 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	TNF/TNF Receptor Superfamily
Inflammation/Innate Immunity	Transcription Factors
	Viral Signaling

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 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 are establishing new product lines to increase recognition of our products, such as the Celestial® range of fluorescent dyes and kits, and ProteoStat® protein aggregation detection line of products.

### Therapeutic Development Programs

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

**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.

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While there are steps that can be taken to preserve sight and slow the progress of vision loss, individuals with uveitis also are at increased risk of developing cataracts, glaucoma or retinal detachment.

In 2005, we acquired rights and intellectual property to a candidate drug and technology intended for use in the treatment of uveitis. The drug is the result of a discovery by scientists at the eye clinic of the Ludwig Maximilians University in Munich, Germany, who found a small peptide that when fed to rats with experimental allergic uveitis promoted their recovery. Based on favorable preclinical studies, the developers conducted an open, pilot Phase I clinical trial in Germany with encouraging results.

In September of 2009, we entered into a Cooperative Research and Development Agreement (CRADA) with the National Eye Institute, part of the National Institute of Health (NIH), for further study of our candidate compound Optiquel for the treatment of autoimmune uveitis. In October 2010, we announced the initiation of a human clinical trial to be conducted at the NIH. Under the terms of the CRADA, the NIH and Enzo will share the development costs of the studies and Enzo will supply its proprietary compound, Optiquel. The clinical trial will be conducted to assess the safety and efficacy of Optiquel in a proof-of-concept clinical trial designed as a randomized, double-masked, placebo-controlled study with a long-term follow-up. 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.

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 our immune regulation technology may be used to treat inflammatory bowel disease (IBD), including ulcerative colitis and Crohn's Disease. According to the Crohn's and Colitis Foundation, approximately one million persons in the United States suffer from IBD. Although the cause of these disorders remains unknown, various features suggest immune system involvement in their pathogenesis.

Patients are managed during short-term episodes through the use of anti-inflammatory medications, or immunosuppressants, which provide symptomatic relief over short periods of time, but do not provide a cure. These drugs are all based on a generalized suppression of the immune response and are non-specific. As such, they have considerable side effects and may make the body more prone to infection, lymphoma, or other diseases.

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

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

An expanded double-blind, placebo-controlled study to broaden the diversity of the patient population was completed at Hadassah Hospital in Jerusalem. The data was presented at the 2009 annual Digestive Disease Week conference. The study met its primary and secondary endpoints.

### **Osteoporosis (and certain bone disorders) and Diabetes**

We have a number of new compounds in preclinical development that could provide therapy for treating bone disorders including osteoporosis, bone loss, fractures, abnormalities, diseases, and other applications. These candidate compounds were identified through an innovative approach, combining structural biology, computational screening, mutational analyses and biological in vitro assays, followed by validation in animal model systems.

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



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

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

### **Non-Alcoholic SteatoHepatitis (NASH)**

We have completed a double-blind, placebo-controlled study at Hadassah Hospital in Jerusalem designed to investigate the effects of EGS-21, a glycolipid, as an immune modulator for the alleviation of NASH. We presented results at the 2009 American Association for Liver Disease Meeting. The study concluded that oral administration of EGS21 appears to be safe and biologically active in patients with insulin resistance and NASH, leading to decreased hepatic steatosis, and improved insulin resistance.

### **Human Immunodeficiency Virus (HIV-1)**

Based on Phase I trial results demonstrating long-term survival and functioning of antisense RNA in white blood cells, including CD4+ cells, we initiated a Phase I/II study at University of California San Francisco (UCSF), the site of the Phase I study. This study focuses on a strategy designed to increase the percentage of engineered CD4+ cells that contain the anti-HIV-1 antisense genes. The first patient has undergone treatment and we are continuing to monitor the progress. We have no plans at the present time to expand this trial.

### **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 menu of routine and esoteric clinical laboratory tests or procedures. These tests are frequently used in general patient care by physicians to establish or support a diagnosis, to monitor treatment or medication levels, or search for an otherwise undiagnosed condition.

Our full service clinical laboratory in Farmingdale, NY contains infrastructure that includes comprehensive information technology applications, logistics, client service and billing departments. Also, we have a network of approximately thirty strategically located patient service centers and a full service phlebotomy department. Patient service centers collect the specimens as requested by physicians. We also operate a fully equipped STAT laboratory in New York City. A STAT lab is a laboratory that has the ability to perform certain routine tests quickly and report results to the physician immediately.

Patient specimens are delivered to our laboratory facilities 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 certain laboratory testing equipment and the results are delivered primarily through an interface from the laboratory testing equipment or in some instances, manually into the laboratory computer system. Most routine testing is completed by early the next morning, and test results are reported to the ordering physician.





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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, 2010, 2009 and 2008, respectively, 46%, 44% and 54% of the Company's revenues were derived from the clinical laboratory. At July 31, 2010 and 2009, respectively, approximately 45% and 40%, of the Company's net accounts receivable were derived from its clinical laboratory business. The Company believes that the concentration of credit risk with respect to the Clinical Labs accounts receivable is mitigated by the diversity of its numerous third party payers and individual patient accounts, and is limited to certain large payers that insure individuals that utilize the Clinical Labs services. To reduce risk, the Company routinely assesses the financial strength of these payers and, consequently, believes that its accounts receivable credit risk exposure, with respect to these payers, is limited. While the Company also has receivables due from the Federal Medicare program, the Company does not believe that these receivables represent a credit risk since the Medicare program is funded by the federal government and payment is primarily dependent on our submitting the appropriate documentation.

Revenues, net of contractual adjustment, from direct billings under the Federal Medicare program during the years ended July 31, 2010, 2009 and 2008 were approximately 25%, 23% and 22%, respectively, of the clinical laboratory segment's total revenue. We estimate contractual adjustment based on significant assumptions and judgments, such as the interpretation of payer reimbursement policies which bears the risk of change. The estimation process is based on the experience of amounts approved as reimbursable and ultimately settled by payers, versus the corresponding gross amount billed to the respective payers. The contractual adjustment is an estimate that reduces gross revenue, based on gross billing rates, to amounts expected to be approved and reimbursed. Gross billings are based on a standard fee schedule we set for all third party payers, including Medicare, health maintenance organizations (HMOs) and managed care providers. We adjust the contractual adjustment estimate quarterly, based on our evaluation of current and historical settlement experience with payers, industry reimbursement trends, and other relevant factors. The other relevant factors that affect our contractual adjustment include the monthly and quarterly review of: 1) current gross billings and receivables and reimbursement by payer, 2) current changes in third party arrangements, 3) the growth of in-network provider arrangements and managed care plans specific to our Company. The clinical laboratory industry is characterized by a significant amount of uncollectible accounts receivable related to the inability to receive accurate and timely billing information in order to forward it on to the third party payers for reimbursement, and the inaccurate information received from the covered individual patients for unreimbursed unpaid amounts. Our provision for uncollectible accounts receivable is within historical expectations.

Other than the Medicare program, revenues from United Healthcare of New York, Inc. represented 25%, 25% and 26% of the Clinical Labs segment's net revenue for the fiscal year ended July 31, 2010, 2009 and 2008, 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 increases the collectability and 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 written off.

We incur significant additional costs as a result of our participation in Medicare, as billing and reimbursement for clinical laboratory testing is subject to considerable and complex federal and state regulations.



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These additional costs include those related to: (1) complexity added to our billing processes; (2) training and education of our employees and customers; (3) compliance and legal costs; and (4) costs related to, among other factors, medical necessity denials and advance beneficiary notices. The Centers for Medicare & Medicaid Services, or CMS (formerly the Health Care Financing Administration), establishes procedures and continuously evaluates and implements changes in the reimbursement process.

The permitted Medicare reimbursement rate for clinical laboratory services has been reduced by the Federal government in a number of instances over the past several years. 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. In 2010, approximately 25% of our Clinical Labs 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. 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 expanding our research product lines, given our increased manufacturing, distribution capability following the acquisitions of Axxora, Biomol International, and Assay Designs, as well as developing innovative new clinical diagnostic and therapeutic platforms. 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, 2010, 2009 and 2008, the Company incurred costs of approximately \$9,704,000, \$9,220,000 and \$8,637,000, respectively, for research and development activities.

### **Internal Research Programs**

Our professional staff of 82 scientists, including 76 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. We also have a number of external collaborations around the world to enhance our ongoing therapeutic development program.

### **Sales and Marketing**

Our sales and marketing strategy for Enzo Life Sciences is to sell our life science products through: (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), direct presence 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 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 adding clinical tests to our service menu to assist sales in new account penetration.

### **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.

### **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 2010 we owned or licensed over 70 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.

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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

#### 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.

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.





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There can be no assurance regarding the length of the clinical trial period, the number of patients that the FDA will require to be enrolled in the clinical trials in order to establish the safety, purity and potency of human gene medicine products, or that the clinical and other data generated will be acceptable to the FDA to support marketing approval.

After completion of clinical trials of a new product, FDA marketing approval must be obtained before the product can be sold in the United States. If the product is regulated as a new biologic, CBER requires the submission and approval of a Biologics License Application (BLA) before commercial marketing of the biologic product. If the product is classified as a new drug, we must file a New Drug Application ( NDA ) with CDER and receive approval before commercial marketing of the drug. The NDA or BLA must include results of product development, pre-clinical studies and clinical trials. The testing and approval processes require substantial time and effort and there can be no assurance that any approval will be granted on a timely basis, if at all. The median time to obtain new product approvals after submission to the FDA is approximately 12 months. If questions arise during the FDA review process, approval can take longer. Before completing its review, the FDA may seek guidance from an Advisory Panel of outside experts at a public or closed meeting. While the advice of these committees is not binding on the FDA, it is often followed. Notwithstanding the submission of relevant data, the FDA might ultimately decide that the NDA or BLA does not satisfy its regulatory criteria for approval and, thus, reject the application, refuse to approve it, or require additional clinical, preclinical or chemistry studies. Even after FDA regulatory approval or licensure, a marketed drug product is subject to continual review by the FDA.

In addition, if previously unknown problems are discovered or we fail to comply with the applicable regulatory requirements, we might be restricted from marketing a product, we might be required to withdraw the product from the market, and we might possibly become subject to seizures, injunctions, voluntary recalls, or civil, monetary or criminal sanctions. In addition, the FDA may condition marketing approval on the conduct of specific post-marketing studies to further evaluate safety and effectiveness.

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

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

### **Regulation of Diagnostics**

The diagnostic products that are developed by our collaborators, or by us, are likely to be regulated by the FDA as medical devices. Unless an exemption applies, medical devices must receive either 510(k) clearance or pre-market approval ( PMA ) from the FDA before marketing them in the United States. The FDA's 510(k) clearance process usually takes from four to 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.



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

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

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

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

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

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

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

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

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

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

## Clinical Laboratory Regulations

The clinical laboratory industry is subject to significant federal and state regulation, including inspections and audits by governmental agencies. Governmental authorities may impose fines or criminal penalties or take other actions to enforce laws and regulations, including revoking a clinical laboratory's federal certification to operate a clinical laboratory. 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 health care in January 2010, the Medicare Fee Schedule was reduced by 1.9% and future reductions are expected to continue (See Item 1A Risk Factors).



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

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

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

### **Anti Fraud and Abuse Laws**

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

Similarly, laboratories may not bill Medicare or Medicaid or any other party for services furnished pursuant to a prohibited referral. Violation of these provisions may result in disallowance of Medicare for the affected testing services, as well as the imposition of civil monetary penalties. New York State also has laws similar to the Federal Stark and Anti-Kickback laws.

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

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

The Company seeks to structure its arrangements with physicians and other customers to be in compliance with the Anti-Kickback, Stark and state laws, and to keep up-to-date on developments concerning their application by various means, including consultation with legal counsel. In addition, in order to address these various Federal and state laws, the Company has developed its own Corporate Compliance Program based upon the OIG model program. The Company's Program focuses on establishing clear standards, training and monitoring of the Company's billing and coding practices. Furthermore, as part of this Program, the Company's Corporate Compliance 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. All health care providers are able to use the electronic format to bill for their services and all health plans and providers are required to accept standard electronic claims, referrals, authorizations, and other transactions. The Company believes it is in compliance with these standards.

The privacy regulations, which have been in effect since 2003, created specific requirements for the use and disclosure of protected health information ( PHI ). We are required to maintain numerous policies and procedures in order to comply with these requirements. Furthermore, we need to continuously ensure that there 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, which were finalized in February 2003 and went into effect in April 2005, require us to ensure the confidentiality, integrity and availability of all electronic protected health information ( EPHI ) that we create, receive, maintain, or transmit. We have some flexibility to fashion our own security measures to accomplish these goals. 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.

## **Manufacturing and Research Facilities**

Our internal manufacturing, 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 for research and manufacturing with special handling capabilities and clean rooms suitable for our operations. In connection with the Axxora acquisition, the Life Sciences segment has added logistics operations in Lausen, Switzerland and in San Diego, California. In connection with the Biomol International acquisition, the Life Sciences segment added manufacturing and research operations in Plymouth Meeting, Pa. and a manufacturing and research facility in Exeter, United Kingdom. In connection with the Assay Designs acquisition, the Life Sciences segment added manufacturing and research operations in Ann Arbor, Michigan. 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, 2010, we employed 527 full-time and 62 part-time employees. Of the full-time employees, 178 were engaged in research, development, manufacturing, and marketing of research products, 6 in therapeutics research, 353 in performing testing, marketing and billing our clinical laboratories services and 52 in finance, legal, administrative and executive functions. Our scientific staff, including 76 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.

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](http://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 a net loss of \$22.2 million and \$23.6 million for the fiscal years ended July 31, 2010 and 2009, 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.

**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;

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.

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

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

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

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

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In the past four fiscal years we have made significant acquisitions in our Life Sciences segment. Our strategy envisions that a part 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 an aggressive marketing program designed to more directly service its end users, while simultaneously promoting numerous brands. We will continue to expand the reach of companies by our direct field sales force, the on-going enhancement of our interactive websites, continued attendance at top industry trade meetings, and publications 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) 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. 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.

As of July 31, 2010, goodwill and other intangible assets with indefinite lives represented approximately 29% 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 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 CPI market basket update beginning in 2011. In 2010, approximately 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. Furthermore, Medicare has mandated use of the Physicians Current Procedural Terminology, or CPT, for coding of laboratory services which has altered the way we bill these programs for some of our services, thereby reducing the reimbursement that we receive.

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

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

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

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

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

The HIPAA privacy and security regulations 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 2010. 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;
- 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.



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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

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Item 2. Properties

The following are the principal facilities of the Company:

<u>Location</u>	<u>Primary use</u>	<u>Segments</u>	<u>Leased/owned</u>	<u>Square footage</u>
Farmingdale, NY (Note 1)	Clinical laboratory and research	Clinical Labs, Therapeutics	Leased	43,000
Farmingdale, NY	Manufacturing, research, sales and administrative office	Life Sciences, Other	Owned	22,000
New York, NY (Note 2)	Corporate headquarters	Other	Leased	11,300
San Diego, CA (Note 3)	Sales, administration and distribution	Life Sciences	Leased	8,800
Lausen, Switzerland (Note 3)	Operational headquarters in Europe, including sales and distribution	Life Sciences	Leased	15,400
Plymouth Meeting, Pa (Note 4)	Sales, manufacturing, research, administration and distribution	Life Sciences	Leased	19,500
Exeter, United Kingdom (Note 4)	Sales, manufacturing, research, administration and distribution	Life Sciences	Leased	3,642
Ann Arbor, Michigan (Note 5)	Sales, manufacturing, research, administration 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 15 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, 2011, was extended through May 2020.

Note 3 The lease for this property was acquired in connection with the Axxora acquisition in May 2007.

Note 4 The leases for these properties were acquired in connection with the Biomol International acquisition in May 2008 and expire through 2017.

Note 5 - The lease for this property, which expires in 2013, was acquired in connection with the Assay Designs acquisition in March 2009.

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 ), Sigma Chemical Company, Inc., Molecular Probes, Inc. and Orchid Biosciences, Inc. The counts set forth in the suit are for breach of contract; patent infringement; unfair competition under state law; unfair competition under federal law; tortious interference with business relations; and fraud in the inducement of contract. The complaint alleges that these counts arise out of the defendants breach of distributorship agreements with the Company concerning labeled nucleotide products and technology, and the defendants infringement of patents covering the same. In April, 2003, the court directed that individual complaints be filed separately against each defendant. The defendants have answered the individual complaints and asserted a variety of affirmative defenses and counterclaims. Fact discovery is ongoing. The court issued a claim construction opinion on July 10, 2006. In January 2007, the remaining defendants moved for summary judgment. On March 13, 2009, the court denied defendants summary judgment motion and stayed the cases pending resolution of an appeal to the United States Court of Appeals for the Federal Circuit in Enzo s Connecticut litigation against Applera Corporation and Tropix, Inc. On March 26, 2010, the United States Court of Appeals for the Federal Circuit reversed the District of Connecticut s grant of summary judgment of invalidity as to various patents at issue in the Applera case, and remanded the Applera case for further proceedings consistent with the Federal Circuit s opinion. In light of the Federal Circuit s remand of the Applera case to the District of Connecticut and the impending trial, on May 27, 2010, the court maintained its stay of the cases until further notice. There can be no assurance that the Company will be successful with the remaining outstanding litigation. However, even if the Company is not successful, management does not believe that there will be a significant adverse monetary impact to the Company.

In October 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. In November 2003, Affymetrix, Inc. filed its own complaint against the Company and its subsidiary, Enzo Life Sciences, Inc., in the United States District Court for the Southern District of New York, seeking among other things, declaratory relief that Affymetrix, Inc., has not breached the parties agreement, that it has not infringed certain of Enzo s Patents, and that certain of Enzo s patents are invalid. The Affymetrix complaint also seeks damages for alleged breach of the parties agreement, unfair competition, and tortious interference, as well as certain injunction relief to prevent alleged unfair competition and tortious interference. The Company does not believe that the Affymetrix complaint has any merit and intends to defend vigorously. Affymetrix also moved to transfer venue of Enzo s action to the Southern District of New York, where other actions commenced by Enzo were pending as well as Affymetrix s subsequently filed action. On January 30, 2004, Affymetrix s motion to transfer was granted. Accordingly, the Enzo and Affymetrix actions are now both pending in the Southern District of New York. Initial pleadings have been completed and discovery has commenced. The Court issued a Markman (claim construction) opinion on July 10, 2006. In January 2007, Affymetrix moved for summary judgment. In March 2009, the court denied Affymetrix s motion and stayed the case pending resolution of an appeal in the United States Court of Appeals for the Federal Circuit in Enzo s Connecticut litigation against Applera Corporation and Tropix, Inc. On March 26, 2010, the United States Court of Appeals for the Federal Circuit reversed the District of Connecticut s grant of summary judgment of invalidity as to various patents at issue in the Applera case, and remanded the Applera case for further proceedings consistent with the Federal Circuit s opinion. In light of the Federal Circuit s remand of the Applera case to the District of Connecticut and the impending trial, on May 27, 2010, the court maintained its stay of the Affymetrix case until further notice.

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In June 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, among other things, alleged breach of contract and misappropriation of Enzo's assets. The complaint seeks declaratory judgment (i) of patent invalidity with respect to Enzo's 4,994,373 patent (the 373 patent), (ii) of no breach by Roche of its 1994 Distribution and Supply Agreement with Enzo (the 1994 Agreement), (iii) that non-payment by Roche to Enzo for certain sales of Roche products does not constitute a breach of the 1994 Agreement, and (iv) that Enzo's claims of ownership to proprietary inventions, technology and products developed by Roche are without basis. In addition, the suit claims tortious interference and unfair competition. The Company does not believe that the complaint has merit and intends to vigorously respond to such action with appropriate affirmative defenses and counterclaims. Enzo filed an Answer and Counterclaims on November 3, 2004 alleging multiple breaches of the 1994 Agreement and related infringement of Enzo's 373 patent. Discovery has commenced. The Court issued a Markman opinion on July 10, 2006. On January 3, 2007, Roche moved for summary judgment. In March 2009, the court denied Roche's motion and stayed the cases pending resolution of an appeal to the United States Court of Appeals for the Federal Circuit in Enzo's Connecticut litigation against Applera Corporation and Tropix, Inc. On March 26, 2010, the United States Court of Appeals for the Federal Circuit reversed the District of Connecticut's grant of summary judgment of invalidity as to various patents at issue in the Applera case, and remanded the Applera case for further proceedings consistent with the Federal Circuit's opinion. In light of the Federal Circuit's remand of the Applera case to the District of Connecticut and the impending trial, on May 27, 2010, the court maintained its stay of the Roche case until further notice.

On June 7, 2004, the Company and Enzo Life Sciences, Inc., filed suit in the United States District Court for the District of Connecticut against Applera Corporation and its wholly-owned subsidiary Tropix, Inc. The complaint alleges infringement of six patents (relating to DNA sequencing systems, labeled nucleotide products, and other technology). Yale University is the owner of four of the patents and the Company is the exclusive licensee. These four patents are commonly referred to as the Ward patents. Accordingly, Yale is also a plaintiff in the lawsuit. Yale and Enzo are aligned in protecting the validity and enforceability of the patents. Enzo Life Sciences is the owner of the remaining two patents. The complaint seeks permanent injunction and damages (including treble damages for willful infringement). Defendants answered the complaint on July 29, 2004. The answer pleads affirmative defenses of invalidity, estoppels and laches and asserts counterclaims of non-infringement and invalidity. A Markman hearing was held on May 25, 2006 and the district court issued a ruling on October 12, 2006. On August 17, 2007, the Company voluntarily dismissed the infringement claims for one of the patents in suit without prejudice. Defendants similarly dismissed their defenses and counterclaims as to that patent. On the same date, the Company conceded a judgment of non-infringement for another of the patents in suit based on the district court's claim construction, reserving the right to appeal their construction. The defendants filed motions for summary judgment for invalidity, laches and non-infringement of the Ward patents on March 5, 2007. The Company and other plaintiff filed a motion for summary judgment on infringement of the Ward patents on March 5, 2007. On September 6, 2007, the court granted defendants' motion for summary judgment of invalidity of three of the remaining Ward patents and entered judgment to that effect. The Company and other plaintiff filed a notice of appeal to the United States Court of Appeals for the Federal Circuit on September 7, 2007. On January 30, 2008, the Court of Appeals for the Federal Circuit granted the Company's alternative motion to dismiss its appeal and remand to the Connecticut Court for further proceedings incident to an entry of a final, appealable judgment. The Company requested the Connecticut Court to dispose of all outstanding issues (including the Company's claim under the fourth Ward patent and certain counterclaims of Applera's) and enter final judgment. The Connecticut Court granted this request. The Company subsequently filed an Appeal on April 7, 2009. On March 26, 2010, the Federal Circuit issued an order concluding that the claims of U.S. Patent Nos. 5,328,824 and 5,449,767 were not indefinite and that there were genuine issues of material fact as to anticipation. The Court reversed the district court's summary judgment of invalidity of those two patents and remanded the case back to the Connecticut Court. Applera and Tropix then filed a combined petition for panel rehearing and rehearing en banc. On May 26, 2010, the Federal Circuit issued an order denying both petitions. The Defendants then filed a motion to stay the case in Connecticut pending resolution of its impending petition for writ of certiorari to the U.S. Supreme Court. Judge Arterton has not yet ruled on the stay motion. Applera filed its petition for certiorari on September 23, 2010. If the petition is not granted, there can be no assurance that the Company will be successful in this litigation. Even if the Company is not successful, management does not believe that there will be a significant adverse monetary impact on the Company.

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In January 2006, the Company was named along with certain of its officers and directors among others, in several complaints titled Francis Scott Hunt, et al. v. Enzo Biochem Inc., et al., Index No. 06-CV-00170 (SAS) and Ken Roberts v. Enzo Biochem, Inc. et al., Index No. 06-CV-00213 (SAS), and Paul Lewicki v. Enzo Biochem Inc., et al., Index No. 06-CV-06347 (SAS) based only upon a claim for common law fraud. These three consolidated actions were all filed in the United States District Court for the Southern District of New York ( the Court ). The actions seek damages in excess of \$8 million and are all based on allegations of a fraudulent scheme to pump and dump Enzo securities as was initially set forth in a previous action (filed by the same attorney) which was dismissed by the Eastern District of Virginia and such dismissal was thereafter affirmed by the Fourth Circuit Court of Appeals and is now final since the U.S. Supreme Court denied a petition for certiorari. The Company and the other defendants likewise moved to dismiss all of the Complaints in these actions and that motion was granted by the Court. As a result, some of the Plaintiffs were no longer able to pursue their claims or choose not to pursue them further. Other Plaintiffs amended their Complaints and the Company and the other defendants moved once again to dismiss those Amended Complaints. The Court granted in part and denied in part those motions. The remaining Plaintiffs then conducted discovery, and following the completion of discovery, the Company and other defendants moved for summary judgment dismissal of the Amended Complaints. On June 5, 2009, the Court granted the defendants motion and dismissed all the Amended Complaints. The remaining Plaintiffs then filed a notice of appeal to the Second Circuit Court of Appeals. The appeal is still pending. The Company believes that the latest complaints in these actions have no merit and that the appeal also lacks merit. The Company will continue to defend these actions vigorously.

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 ). Pursuant to the Agreement, the Company acquired the assets of Mayflower, and agreed, among other things, to make certain contingent earn-out payments to Mayflower, accounted for as additional purchase price consideration, if certain performance thresholds were met for each of the two annual periods following the closing. Mayflower alleges that Enzo breached the Agreement by allegedly failing to operate the acquired business in good faith during the second earn-out period and engaging in conduct the primary purpose of which was to avoid making a second earn-out period payment under the Agreement. In addition, Mayflower claims that Enzo breached the Agreement by allegedly failing to provide the documentation appropriate to support the calculation of defined financial criteria for the second earn-out period as required under the Agreement. Enzo denies that it is in breach of the Agreement and will vigorously defend the suit.

As part of the litigation, Mayflower moved by Order to Show cause to enjoin the accounting procedure specified under the Agreement. Mayflower s motion was heard by a District Court Judge on September 27, 2010, who directed that the parties first go forward with the accounting as provided under the Agreement before moving further with the litigation. As provided under the Agreement, Mayflower s maximum recovery in the event that it is successful on either the accounting or in litigation is settlement of the \$2.5 million contingent earn-out in either Enzo common stock or cash, as set forth in the Agreement, plus attorney s fees.

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

Item 4. (Removed and Reserved)

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

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

2010 Fiscal Year (August 1, 2009 to July 31, 2010):

	<u>High</u>	<u>Low</u>
1st Quarter	\$ 7.66	\$ 4.51
2nd Quarter	\$ 6.24	\$ 4.52
3rd Quarter	\$ 6.67	\$ 4.66
4th Quarter	\$ 6.18	\$ 3.90

2009 Fiscal Year (August 1, 2008 to July 31, 2009):

	<u>High</u>	<u>Low</u>
1st Quarter	\$ 14.90	\$ 4.44
2nd Quarter	\$ 6.97	\$ 4.23
3rd Quarter	\$ 5.58	\$ 2.86
4th Quarter	\$ 5.64	\$ 3.75

As of September 30, 2010, the Company had approximately 1,009 stockholders of record of its common stock.

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

**Securities Authorized for Issuance Under Equity Compensation Plans**

The following table sets forth information regarding our existing equity compensation plans as of July 31, 2010.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuances under equity compensation plans (excluding securities reflected in column (a) (c)
Equity compensation plans approved by security holders	1,132,450	\$ 14.30	169,000
Equity compensation plans not approved by security holders			
<b>Total</b>	<b>1,132,450</b>	<b>\$ 14.30</b>	<b>169,000</b>



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Item 6. Selected Financial Data

The following table, which is derived from the audited consolidated financial statements of the Company for the fiscal years 2006 through 2010 should be read together with the discussion in Management's Discussion and Analysis of Financial Condition and Results of Operations and the Company's consolidated financial statements and notes to those statements included elsewhere in this Annual Report on Form 10-K.

Operating Results (1)	For the fiscal year ended July 31, (In thousands, except per share amounts)				
	2010	2009	2008	2007	2006
Operating revenues	\$ 97,082	\$ 89,572	\$ 77,795	\$ 52,908	\$ 39,826
Other income	44	74	171	2,699	
Interest income	19	581	3,696	5,092	3,144
Loss before income taxes	(22,261)	(23,477)	(10,892)	(13,175)	(17,009)
Benefit (provision) for income taxes	28	(87)	239	(85)	1,342
Net loss	\$ (22,233)	\$ (23,564)	\$ (10,653)	\$ (13,260)	\$ (15,667)
Basic net loss per common share:	\$ (0.59)	\$ (0.63)	\$ (0.29)	\$ (0.38)	\$ (0.49)
Diluted net loss per common share:	\$ (0.59)	\$ (0.63)	\$ (0.29)	\$ (0.38)	\$ (0.49)
Weighted average common shares					
Basic	38,001	37,511	36,883	35,017	32,215
Diluted	38,001	37,511	36,883	35,017	32,215

Financial Position:	July 31, (in thousands)				
	2010	2009	2008	2007	2006
Working capital	\$ 42,181	\$ 60,518	\$ 92,392	\$ 113,850	\$ 80,161
Total assets	115,245	133,128	154,522	159,002	101,524
Long term obligations					
Stockholders' equity	97,016	116,781	138,289	141,894	95,587

(1) See Note 2 in the Notes to Consolidated Financial Statements regarding the acquisitions and cash paid for acquisitions in Fiscal 2009, 2008 and 2007.

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

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

The Company is a life sciences and biotechnology company focused on harnessing biological processes to develop research tools, diagnostics and therapeutics and on serving as a provider of diagnostic services to the medical community. Since our founding in 1976, our strategic focus has been on the development of enabling technologies in 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.

We are comprised of three operating companies that have evolved out of our core competence: the use of nucleic acids as informational molecules and the use of compounds for immune modulation. These wholly owned operating companies conduct their operations through three reportable segments. Below are brief descriptions of each of the three operating segments (see Note 17 in the Notes to Consolidated Financial Statements):

**Enzo Life Sciences** is a company that manufactures, develops and markets functional biology and cellular biochemistry products and tools to research and pharmaceutical 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 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 9,000 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 protein homeostasis, epigenetics, live cell analysis, molecular biology and immunoassays. The segment is an established source for a comprehensive panel of products to scientific experts in the fields of Natural Products/Antibiotics, Autophagy, Cancer, Cell Cycle, Cell Death, Cell Signaling, Cellular Analysis, Endocrinology/Hormones, DNA regulation, Compound Screening, Genomics/Molecular Biology, GPCRs, Immunology, Inflammation, Metabolism, Neuroscience, Nitric Oxide pathway, Obesity/Adipokines, Oxidative Stress, Proteases and Proteosomes, Protein Expression and modification, Signal Transduction, Stress/Heat Shock proteins and Ubiquitin/Ubl signaling.

**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 30 patient service centers throughout greater New York, New Jersey and Eastern Pennsylvania, a stand alone stat or rapid response laboratory in New York City, and a full-service phlebotomy and logistics department. Payments for clinical laboratory testing services are made by the Medicare program, healthcare insurers and patients.

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

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The following table summarizes the sources of revenues for the fiscal years ended July 31, 2010, 2009 and 2008, (in \$000 s and percentages):

Fiscal year ended July 31,	2010		2009		2008	
Product revenues	\$ 43,111	44%	\$ 40,592	45%	\$ 28,087	36%
Royalty and license fee income	9,793	10	9,376	11	7,630	10
Clinical laboratory services	44,178	46	39,604	44	42,078	54
Total	\$ 97,082	100%	\$ 89,572	100%	\$ 77,795	100%

### Recent Events

In September 2010, the Company announced that it had streamlined its operations, which is expected to result in a reduction in annualized operating expenses beginning in the fiscal 2011 first quarter. These initiatives are also expected to result in increased gross margins. The operating cost reductions affect all of its operating businesses as well as corporate overhead. The overall improvements are primarily a result of streamlining operations at Enzo Life Sciences, where the Company completed a series of acquisitions over the past three years, and Enzo Clinical Labs, where Enzo has invested significantly over the past year in technology and process improvements.

At Enzo Clinical Labs, the Company expects gross margin improvements and expense reductions, primarily through selective work force rationalization and process improvements, including customer service and billing designed to reduce processing and collection costs of receivables, improved laboratory service operations and lower reagent costs. At Enzo Life Sciences, as a result of the acquisitions that the Company has completed, certain operations have become redundant, which provided opportunities to reduce costs through realignment or centralization of R&D, customer service and manufacturing activities. Enzo Life Sciences has also undertaken a repositioning of its product offerings, refocusing its marketing efforts on higher-margin, higher volume products. As a result, the Company recorded a charge in the fiscal 2010 fourth quarter of \$1.3 million as certain low-volume products were rationalized. Enzo expects the benefits of the operational improvements to occur commencing with the Company's fiscal 2011 first quarter ending October 31, 2010. In connection with the streamlining, the Company also recorded a one-time charge of approximately \$500,000 in its fiscal 2010 fourth quarter to reflect severance payments to terminated employees.

### Assay Designs, Inc.

On March 12, 2009, Enzo Life Sciences, Inc. and Enzo Life Sciences Acquisition, Inc., a newly formed wholly owned subsidiary of Enzo Life Sciences, Inc. ( Acquisition Sub ), entered into an asset purchase agreement ( Purchase Agreement ) dated as of March 12, 2009 with Assay Designs, Inc. ( Assay Designs ). Assay Designs, a privately owned company with annual sales of approximately \$11 million, was engaged in researching, developing, manufacturing, distributing, marketing and selling specialty immunological and biochemical protein detection kits, assays, reagents, antibodies, recombinant proteins and related products and providing related services for use in the biotechnology, pharmaceutical and life sciences research industries ( Business ). Under the terms of the Purchase Agreement, Acquisition Sub purchased from Assay Designs substantially all of its assets, including trade accounts receivable, inventory, fixed assets, and intellectual property, used in or related to the Business and assumed certain of Assay Designs' liabilities, including trade accounts payable, capital lease obligations and certain other current liabilities.

The execution of the Purchase Agreement and the closing of the transaction occurred simultaneously on March 12, 2009. The purchase price consisted of \$12,228,000 in cash, exclusive of acquisition costs of approximately \$540,000, and was subject to an upward or downward post-closing purchase price adjustment based on Assay Designs' working capital as of the closing date and \$328,000 representing estimated costs to consolidate an acquired facility and involuntary termination of certain employees. At the closing, \$100,000 was held in escrow to secure the payment of any downward post-closing purchase price adjustment and \$750,000 was held in escrow for 12 months to secure the payment of any indemnification obligations of Assay Designs under the Purchase Agreement. The acquisition was funded with the Company's cash. Effective March 12, 2009, Assay Designs became a wholly-owned subsidiary of Enzo Life Sciences. The Assay Design acquisition strengthens the Company's position as a global provider of life sciences reagents by broadening our product offerings and manufacturing capabilities. The consolidated financial statements include the results of operations for Assay Designs from the date of acquisition.

Subsequent to the acquisition date, the Company paid \$270,000 in additional purchase price in connection with the working capital adjustment and released the \$100,000 and \$750,000 escrow amounts.



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

	<u>2010</u>	<u>2009</u>	<u>Increase (Decrease)</u>	<u>% Change</u>
<b>Revenues:</b>				
Product revenues	\$ 43,111	\$ 40,592	\$ 2,519	6
Royalty and license fee income	9,793	9,376	417	4
Clinical laboratory services	44,178	39,604	4,574	12
<b>Total revenues</b>	<b>97,082</b>	<b>89,572</b>	<b>7,510</b>	<b>8</b>
<b>Operating expenses:</b>				
Cost of product revenues	22,547	26,766	(4,219)	(16)
Cost of clinical laboratory services	29,570	26,295	3,275	12
Research and development	9,704	9,220	484	5
Selling, general, and administrative	48,395	41,314	7,081	17
Provision for uncollectible accounts receivable	3,480	5,189	(1,709)	(33)
Legal	1,746	4,195	(2,449)	(58)
Litigation settlement and related legal costs	3,698		3,698	
<b>Total operating expenses</b>	<b>119,140</b>	<b>112,979</b>	<b>6,161</b>	<b>5.5</b>
<b>Operating loss</b>	<b>(22,058)</b>	<b>(23,407)</b>	<b>1,349</b>	<b>(6)</b>
<b>Other income (expense):</b>				
Interest	19	581	(562)	(97)
Other	44	74	(30)	(41)
Foreign currency	(266)	(725)	459	(63)
<b>Loss before income taxes</b>	<b>\$ (22,261)</b>	<b>\$ (23,477)</b>	<b>\$ 1,216</b>	<b>(5)</b>

**Fiscal 2010 compared to Fiscal 2009****Consolidated Results:**

The 2010 period and the 2009 period refer to the fiscal years ended July 31, 2010 and 2009, respectively. The 2010 period includes the twelve months results of ADI which was acquired on March 12, 2009. The 2009 period includes the results of ADI from March 12, 2009 to July 31, 2009.

Product revenues increased overall by \$2.5 million in the 2010 period to \$43.1 million as compared to the 2009 period. Acquisition growth from the acquired ADI business was \$6.5 million or 16% which was partially offset by a net organic decline of \$4.4 million or 11% due to a \$5.2 million decline in low margin, third-party distribution business. Our core product revenues demonstrated organic growth of \$0.8 million or 2%. Foreign currency fluctuation positively affected revenues by \$0.4 million or 1%.

Royalty and license fee income during the 2010 period was \$9.8 million compared to \$9.4 million in the 2009 period, an increase of \$0.4 million or 4%. Royalties are primarily earned from the reported net sales of Qiagen products subject to a license agreement and from a license agreement with Abbott. During the 2010 and 2009 periods, the Company recognized royalties of approximately \$6.8 million and \$6.7 million, respectively from Qiagen and royalties and license fees under the Abbott License Agreement of approximately \$3.0 million and \$2.7 million respectively, an increase of \$0.3 million in the 2010 period. There are no direct expenses relating to royalty and license fee income.

Clinical laboratory revenues during the 2010 period were \$44.2 million compared to \$39.6 million in the 2009 period. The 2010 period's increase over the 2009 period was \$4.6 million or 12%. During the 2010 period, revenue increased due to organic

growth of 5.4% after giving consideration to the 2009 period contractual adjustment of \$2.3 million.

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The 2010 increase resulted from increased service volume, including higher priced testing volume, despite a noted general slowdown in physician office visits due to the slowed economy and a 1.9% decrease in Medicare reimbursement rates effective January 1, 2010. During the 2009 period, revenues were negatively affected by contractual adjustments of \$2.3 million. These immaterial contractual adjustments in 2009 related to computational errors that affected the calculated expected reimbursement rate in fiscal 2008, and for periods prior to August 1, 2008 for the majority of payers, and credits issued which were not accrued for timely.

The cost of product revenues during the 2010 period was \$22.5 million compared to \$26.7 million in the 2009 period, a decrease of \$4.2 million or 16%. The decrease is primarily due to the impact of \$4.7 million in lower costs from low margin third-party distribution business, reduced fair value accounting adjustments of \$1.8 million in accordance with purchase accounting rules and reclassification of \$1.6 million in costs relating to the realignment of manufacturing facilities and personnel. Such decreases in 2010 were partially offset by product cost relating to ADI of \$2.8 million, by the cost of sales from organic growth, and \$1.0 million of higher inventory reserves for excess and obsolete inventory due primarily to a strategic realignment of marketing efforts for core products. We believe that cost of product revenues for future periods will be affected by, among other things, competitive conditions and foreign currency rates.

The cost of clinical laboratory services during the 2010 period was \$29.6 million as compared to \$26.3 million in the 2009 period, an increase of \$3.3 million or 12%. The Company incurred increased costs due to increased reagent costs and supplies of \$1.3 million, laboratory personnel and related costs of \$1.6 million and outside reference lab costs of \$0.4 million, partially due to increased service volumes. Laboratory personnel and related costs increased primarily due to additional headcounts in phlebotomists to expand patient collection sites and other personnel to manage expanded operations.

Research and development expenses were approximately \$9.7 million during the 2010 period, compared to \$9.2 million in the 2009 period, an increase of \$0.5 million or 5%. The increase was principally attributed to higher costs of \$1.4 million at Enzo Life Sciences primarily related to Assay Designs offset by \$0.9 million in lower clinical trial and related activities and payroll costs at the Therapeutics segment.

Selling, general and administrative expenses were approximately \$48.4 million during the 2010 period as compared to \$41.3 million in the 2009 period, an increase of \$7.1 million or 17%. The increase was primarily due to the net increase at the Enzo Life Sciences segment of \$5.4 million in the 2010 period which included approximately \$2.3 million of selling, general and administrative expenses related to Assay Designs operations, the impact of realigning manufacturing facilities and certain personnel of \$1.6 million, \$1.1 million in payroll and benefit costs, and increased depreciation and amortization of \$0.7 million, which were offset by a decrease in marketing costs of \$0.3 million. The Clinical Lab segment's selling general and administrative increased \$3.1 million primarily due to increased payroll and related benefits of \$2.2 million attributed to increases in headcounts in our sales force and management personnel partially related to increased service volume and the marketing and development of esoteric and gene based testing capabilities, information technology costs of \$0.2 million, and other overhead expenses of \$0.7 million. These increases were offset by a decrease in the Other segment's selling general and administrative of approximately \$1.4 million, primarily due to decreases in professional fees of \$0.3 million, outside consulting costs of \$0.7 million, payroll and payroll related costs of \$0.2 million, and other operating cost of \$0.2 million.

The provision for uncollectible accounts receivable, primarily relating to the Clinical Labs segment was \$3.5 million for the 2010 period as compared to \$5.2 million in the 2009 period, a decrease of \$1.7 million or 33%. The decrease is attributed to a charge in 2009 attributed to increased provisions for the Clinical Labs legacy billing system, which was replaced in August 2008, due to reduced collection efforts relating to the legacy billing system, the correction of an immaterial error relating to fiscal 2008, and increased provisions required based on changes in payer mix, offset by a reduced requirement under the new billing system.

Legal expense was \$1.7 million during the 2010 period compared to \$4.2 million in the 2009 period, a decrease of \$2.5 million, due to overall reduction in legal services provided relating to certain patent litigation matters and general matters of \$2.1 million, the reimbursement of \$0.5 million in legal costs under our insurance policy, reductions in fees due to negotiated fee settlements and other adjustments of \$0.5 million offset by approximately \$0.6 million in incremental legal costs incurred for proxy related costs for the January 2010 annual meeting.

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 paid a lump sum payment of \$2.7 million. The Company recorded a settlement expense of approximately \$3.7 million in the fiscal quarter ending January 31, 2010, consisting of the lump sum payment of \$2.7 million and approximately \$1.0 million of legal expenses incurred in connection with the claims (See Note 16 in Notes to Consolidated Financial Statements).

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Interest income was \$19,000 during the 2010 period as compared to \$0.6 million during the 2009 period. The interest income decrease during the 2010 period is attributed to the decline in interest rates. Furthermore, the Company had higher average invested balances during the 2009 period. The Company earns interest by investing in short term U.S. Treasury bills and money market accounts.

The loss on foreign currency was \$0.3 million during the 2010 period, due to a \$0.1 million non-cash loss on an intercompany term loan denominated in British pounds sterling and the fluctuations of other foreign currencies relative to the US dollar during the period and the impact that had on settled transactions during the period. During the 2009 period, the loss on foreign currency transactions was \$0.7 million primarily due to a non-cash loss on the intercompany term loan denominated in British pounds sterling. The British currency depreciated more significantly against the US dollar during the 2009 period than in the 2010 period.

The Company's effective income tax rate benefit (provision) for the 2010 period was 0.1% compared to (0.4%) during the 2009 period. The tax benefit (provision) for the 2010 and 2009 periods were based on state and local taxes, domestic and foreign tax for tax deductible goodwill and indefinite lived intangibles, and book to tax differences for acquired inventory and differed from the expected net operating loss carry forward benefit at the U.S. federal statutory rate of 34% primarily due to the inability to recognize such benefit. The carry forward benefit cannot be recognized because of uncertainties relating to future taxable income, in terms of both its timing and its sufficiency. In the 2010 period, the Company recognized a benefit of \$0.1 million primarily as a result of the expiration of the statute of limitations for an uncertain tax position.

### Segment Results

The Life Sciences segment's income before taxes was \$2.9 million for the 2010 period as compared to \$1.7 million for the 2009 period. Product revenues increased by \$2.5 million in the 2010 period primarily due to the contribution of product revenues from the March 2009 acquisition of Assay Designs and organic growth from our core products which replaced low margin, high volume distribution product revenues principally to one customer. Royalty and license fee income increased \$0.4 million from the Qiagen agreement and the Abbott license agreement. The segment's gross margin of \$30.4 million increased by \$7.2 million in 2010. Gross profit margins increased to 57% from 47% due to favorable impact from ADI's higher margin, which replaced lower margin revenue in 2009, lower inventory fair value adjustments and realignment of personnel from manufacturing to trading activity. The segment's other operating expenses, including selling, general and administrative, legal and research and development, increased by approximately \$6.4 million during the 2010 period primarily due to the inclusion of Assay Designs expenses of \$3.3 million, the impact of the aforementioned realignment of personnel of payroll and related costs of \$1.6 million, increased payroll and other costs of \$1.2 million, and depreciation and amortization of \$0.7 million, offset by lower legal costs of \$0.3 million and lower marketing costs of \$0.3 million. The segment experienced a foreign currency loss of \$0.3 million during the 2010 period resulting from the impact that fluctuations in foreign currencies had on settled transactions and on an intercompany loan denominated in pounds sterling. In aggregate, the inventory fair value adjustment and amortization of intangibles negatively impacted the segment operating results in the 2010 period by \$1.9 million.

The Clinical Laboratory segment's loss before taxes was \$7.5 million for the 2010 period as compared to a loss of \$7.3 million in the 2009 period. The revenue from laboratory services increased in the 2010 period by \$4.6 million due to increased service volume, despite a general slowdown in physician office visits since the fiscal third quarter, a decrease in Medicare reimbursement rates effective January 1, 2010 and during the 2009 period revenues were negatively impacted by contractual adjustments of \$2.3 million. The 2010 period gross profit of \$14.6 million increased \$1.3 million over the 2009 period due to service volume increases, offset by increased headcount and other costs to perform increased testing, and the impact the aforementioned \$2.3 million contractual adjustment had on the 2009 period gross profit. In the 2010 period, the selling, general and administrative and legal costs increased by approximately \$3.2 million primarily due to increases in payroll and payroll related costs of \$2.2 million attributed to increases in headcount in our sales force and management personnel partially related to increased service volume and the marketing and development of esoteric and gene-based testing capabilities, information technology costs of \$0.2 million, and other operating costs of \$0.7 million. The provision for uncollectible accounts receivables decreased by \$1.8 million as compared to the 2009 period. During the 2009 period, the Company recorded a charge attributed to increased provisions for the Clinical Labs legacy billing system, which was replaced in August 2008, due to reduced collection efforts relating to the legacy billing system and the correction of an immaterial error relating to fiscal 2008.

The Therapeutics segment's loss before income taxes was approximately \$2.5 million for the 2010 period as compared to a loss of \$3.4 million for the 2009 period. The decrease in the segment loss of \$0.9 million was primarily due to decreases in clinical trial activities of \$0.6 million and decreases in salaries and related costs of \$0.3 million.



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The Other segment's loss before taxes for the 2010 period was approximately \$15.1 million as compared to \$14.5 million in the 2009 period, an increase of \$0.6 million. The Other segment's 2010 period loss reflects the litigation settlement of \$3.7 million, offset by a decrease in professional fees, consulting costs and public relations expenses of \$1.0 million, payroll and payroll related costs of \$0.2 million, and \$0.3 million in other costs. Legal expenses decreased \$2.1 million due to the reimbursement of \$0.5 million in legal fees; reduced services provided relating to certain patent litigation activity and general matters of \$1.7 million and reductions in fees recorded due to negotiated fee settlements and other adjustments of \$0.5 million offset by \$0.6 million incremental legal costs incurred for proxy related matters in 2010. Interest income declined \$0.5 million due to the decline in interest rates. The Company earns interest by investing in short term U.S. Treasury bills and money market accounts.

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

	<u>2009</u>	<u>2008</u>	<u>Increase (Decrease)</u>	<u>% Change</u>
<b>Revenues:</b>				
Product revenues	\$ 40,592	\$ 28,087	\$ 12,505	45
Royalty and license fee income	9,376	7,630	1,746	23
Clinical laboratory services	39,604	42,078	(2,474)	(6)
<b>Total revenues</b>	<b>89,572</b>	<b>77,795</b>	<b>11,777</b>	<b>15</b>
<b>Operating expenses:</b>				
Cost of product revenues	26,766	19,159	7,607	40
Cost of clinical laboratory services	26,295	22,209	4,086	18
Research and development	9,220	8,637	583	7
Selling, general, and administrative	41,314	33,272	8,042	24
Provision for uncollectible accounts receivable	5,189	3,716	1,473	40
Legal	4,195	5,588	(1,393)	(25)
<b>Total operating expenses</b>	<b>112,979</b>	<b>92,581</b>	<b>20,398</b>	<b>22</b>
<b>Operating loss</b>	<b>(23,407)</b>	<b>(14,786)</b>	<b>(8,621)</b>	<b>58</b>
<b>Other income (expense):</b>				
Interest	581	3,696	(3,115)	(84)
Other	74	171	(97)	(57)
Foreign currency	(725)	27	(752)	
<b>Loss before income taxes</b>	<b>\$ (23,477)</b>	<b>\$ (10,892)</b>	<b>\$ (12,585)</b>	<b>116</b>

***Fiscal 2009 compared to Fiscal 2008*****Consolidated Results:**

The 2009 period and the 2008 period refer to the fiscal years ended July 31, 2009 and 2008, respectively. The 2009 period includes the full year results of Biomol which was acquired on May 8, 2008 and the results of Assay Designs from March 12, 2009, the date of acquisition, to July 31, 2009.

Product revenues during the 2009 period were \$40.6 million compared to \$28.1 million in the 2008 period, an increase of \$12.5 million or 45%. Acquisition growth represented \$12.1 million or a 43% increase over product revenues in the 2008 period, primarily from Biomol and Assay Designs, \$1.4 million or 5% was from organic growth, offset by \$1.0 million or 4% negative effect from foreign currency.

Royalty and license fee income during the 2009 period was \$9.4 million compared to \$7.6 million in the 2008 period, an increase of \$1.7 million or 23%. Royalties are primarily earned from net sales of Qiagen products subject to a license and from a License Agreement with Abbott. During the 2009 period, the Company recognized royalties of approximately \$6.7 million from Qiagen, an increase of approximately \$1.2 million over the 2008 period, and royalties and license fees under the Abbott License Agreement of approximately \$2.7 million, an increase of \$0.5 million over the 2008 period. There are no direct expenses relating to royalty and license fee income.

Clinical laboratory revenues during the 2009 period were \$39.6 million compared to \$42.1 million in the 2008 period, a decrease of \$2.5 million or 6%. Revenues were adversely affected by contractual adjustments of \$2.3 million. These immaterial adjustments related to computational errors that affected the calculated expected reimbursement rate in fiscal 2008, 2007 and 2006

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and for periods prior to August 1, 2005 for the majority of payers and credits issued which were not accrued for timely. The reduced service volume was partially impacted by reduced billings on our legacy billing system in fiscal 2009, including the investigation of and rebilling of denials during the period, as a result of the realignment of certain billing personnel to implement our new comprehensive billing and accounts receivable system.

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This new system was effective for all laboratory services performed after August 1, 2008. We believe that the new billing and accounts receivable system enhances our billing and collection process.

The cost of product revenues during the 2009 period was \$26.8 million compared to \$19.2 million in the 2008 period, an increase of \$7.6 million or 40%. The increase is principally due to the inclusion of Biomol and Assay Designs cost of product revenues of approximately \$7.4 million in the 2009 period, which includes the impact of an inventory fair value adjustment of \$2.2 million related to sales of inventory acquired from Biomol and Assay Designs.

The cost of clinical laboratory services during the 2009 period was \$26.3 million as compared to \$22.2 million in the prior period, an increase of \$4.1 million or 18%. The Company incurred increased costs primarily relating to reagent and supplies costs of \$1.1 million, laboratory personnel costs of \$1.8 million, and outside testing labs of \$0.7 million, and other related lab costs of \$0.5 million. Laboratory personnel costs increases resulted from additional headcounts in phlebotomists to expand patient collection sites and other personnel to manage expanded internal operations.

Research and development expenses were approximately \$9.2 million during the 2009 period compared to \$8.6 million in the 2008 period an increase of \$0.6 million or 7%. Research and development costs increased \$2.4 million at the Life Sciences segment, principally related to the inclusion of Biomol and Assay Designs, offset by a decrease at the Therapeutic segment of \$1.8 million due to a decrease in clinical trial activities.

Selling, general and administrative expenses were approximately \$41.3 million during the 2009 period as compared to \$33.3 million in the 2008 period, an increase of \$8.0 million or 24%. Life Sciences selling, general and administrative costs increased by \$5.2 million over the 2008 period, which principally related to the inclusion of Biomol and Assays Designs. The increase in the Company's other segments' selling, general and administrative expenses of approximately \$2.9 million was primarily due to payroll and related personnel costs approximating \$0.5 million, consulting and professional fees of \$1.2 million, other overhead costs of \$1.0 million and information technology costs of \$0.3 million.

The provision for uncollectible accounts receivable, primarily relating to the Clinical Labs segment, was \$5.2 million for the 2009 period as compared to \$3.7 million in the 2008 period. The increase in the 2009 period of \$1.5 million or 40% was attributed to 1) increased provisions for the Clinical Labs legacy billing system, which was replaced in August 2008, due to reduced collection efforts relating to the legacy billing system, 2) the correction of the immaterial \$0.6 million error in the allowance for doubtful accounts determined relating to 2008, and 3) increased provisions required based on changes in payer mix. Outstanding receivables, which are fully reserved, will remain on the legacy system until the earlier of: all invoices are collected, all collection efforts are exhausted, or all invoices are written off in accordance with our critical accounting policy.

Legal expense was \$4.2 million during the 2009 period compared to \$5.6 million in the 2008 period, a decrease of \$1.4 million or 25%, primarily due to a decrease in patent litigation activity in the current period of \$2.6 million offset by increases in the Life Science segment of \$0.2 million for realignment of existing and establishment of new global operating units and increases in other legal costs of \$1.0 million.

Interest income decreased by \$3.1 million or 84% to \$0.6 million during the 2009 period compared to \$3.7 million during the 2008 period. Interest income decreased during the 2009 period due to the decline in interest rates in response to monetary policy actions taken by the U.S. Federal Reserve and lower invested balances. The Company earns interest by investing primarily in short term and liquid U.S. government instruments and money market accounts.

Other income was \$0.1 million during the 2009 period versus \$0.2 million in the year ago period.

The loss on foreign currency was \$0.7 million during the 2009 period. During the 2009 period, the Company's Life Sciences segment incurred a non-cash foreign currency loss of approximately \$0.7 million on an intercompany term loan denominated in pounds sterling due to the strengthening of the US dollar as at July 31, 2009 versus July 31, 2008.

The Company's effective income tax rate (provision) benefit for the 2009 period was (0.4%), compared to 2.2% during the 2008 period. The tax provision for both periods was based on state and local taxes and book to tax differences for inventory acquired from Biomol and differed from the expected net operating loss carry forward benefit at the U.S. federal statutory rate of 34% primarily due to the inability to recognize such benefit. The carry forward benefit cannot be recognized because of uncertainties relating to future taxable income, in terms of both its timing and its sufficiency.

### Segment Results

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The Life Sciences segment's income before taxes was approximately \$1.7 million for the 2009 period and \$3.4 million for the 2008 period. Revenues from product shipments increased by \$12.5 million primarily due to the inclusion of products sales of \$12.1 million from Biomol and Assay Designs in the 2009 period. Royalty and license fee income increased \$1.7 million primarily from the existing Qiagen and Abbott licensing and royalty agreements.

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The segment's gross margin of \$23.2 million increased \$6.6 over the prior year period, after being negatively impacted by a \$2.2 million fair value adjustment attributed to the sale of inventory acquired from Biomol and Assay Designs. Segment operating expenses, including selling, general and administrative and legal of \$14.9 million and research and development of \$5.9 million, increased by approximately \$7.5 million during the 2009 period primarily due to the inclusion of Biomol and Assay Designs expenses of \$7.5 million. The 2009 expenses include amortization of intangibles of \$1.2 million, \$0.4 million in legal costs to establish new and realign existing global entities, and marketing costs of \$0.2 million relating to the integration of our brands. The segment experienced a non-cash foreign currency loss of \$0.7 million resulting from an intercompany loan denominated in pounds sterling. In aggregate, the inventory fair value adjustment, amortization of intangibles, the one-time legal and marketing costs and the non-cash foreign currency loss, negatively impacted the segment operating results by \$4.7 million.

The Clinical Labs segment's loss before taxes was \$7.3 million for the 2009 period as compared to income before taxes of \$2.0 million in the 2008 period. The 2009 results were negatively impacted by lower service volume of \$2.5 million partially due to a charge of \$2.3 million relating to contractual adjustments discussed above. The decrease in the 2009 period's gross margin of \$6.6 million was due to the decreased service revenues, change in fiscal 2009 payer mix and increased cost of laboratory services. Selling, general and administrative increased approximately \$1.1 million primarily due to increases in office support salaries and operational costs to maintain the facility. The provision for uncollectible accounts increased by \$1.5 million primarily due to an increased provision related to the legacy billing system and the correction of the previously noted immaterial error \$0.6 million in the allowance for doubtful accounts related to fiscal 2008. The segment earned interest in the 2009 period of \$0.1 million and \$0.2 million in the 2008 period.

The Therapeutics segment's loss before income taxes was approximately \$3.4 million for the 2009 period as compared to a loss of \$5.1 million for the 2008 period. The decrease in the loss of \$1.7 million was primarily due to a decrease in clinical trial activities of \$1.8 million offset by a non-recurring government grant of \$0.1 million which was recognized in the 2008 period.

The Other segment's loss before taxes for the 2009 period was approximately \$14.6 million compared to \$11.3 million in the 2008 period, an increase of \$3.3 million. Selling, general, and administrative and legal increased by \$0.3 million as the result of a \$1.6 million decrease in legal expenses due to decreased patent litigation activity, partially offset by increases in professional and consulting fees of \$1.2 million, and payroll and related costs of \$0.7 million. The decrease in interest income of \$2.9 million due to the decline in interest rates and lower levels of cash available for investment.

### Liquidity and Capital Resources

At July 31, 2010, the Company had cash and cash equivalents of \$8.8 million and short-term investments of \$24.8 million, or \$33.6 million in aggregate as compared to \$50.2 million at July 31, 2009. Short term investments are in US Treasury bills. The Company had working capital of \$42.2 million at July 31, 2010 compared to \$60.5 million at July 31, 2009. The decrease in working capital of \$18.3 million was primarily the result of the 2010 period net loss, which included the litigation settlement to a former officer and related legal costs of \$3.7 million, and funding for capital expenditures of \$3.3 million.

Net cash used in operating activities for the year ended July 31, 2010 was approximately \$13.5 million as compared to \$11.5 million for the year ended July 31, 2009. The increase in net cash used in operating activities in the 2010 period over the 2009 period of approximately \$2.0 million was primarily due to a decrease in changes in operating assets and liabilities of \$3.0 million, relating primarily to increases in accounts receivable and inventory, offset by an increase in accounts payable trade, and the effect of lower non-cash adjustments in the 2010 period over the 2009 period of \$0.3 million, partially offset by the decrease in the period net loss of \$1.3 million.

Net cash provided by investing activities was approximately \$15.3 million as compared to a use of cash of \$60.2 million in the year ago period. The change from 2009 to 2010 of \$75.5 million is primarily due to the net increase in short term investments in US Treasury bills of \$43.3 million in 2009 as compared to a decrease due to net maturities of short-term investments of \$18.5 million in 2010 and cash used in acquisitions of \$14.5 million in the 2009 period. In the 2010 and the 2009 periods cash used for capital expenditures was \$3.3 million and \$2.7 million, respectively.

There were no financing activities in 2010. Net cash provided by financing activities was approximately \$0.3 million in the 2009 period, attributed primarily to stock option exercise proceeds. There were no stock option exercises in the 2010 period.

We believe that our current cash and cash equivalents are sufficient for our foreseeable liquidity and capital resource needs, including any requirement to satisfy the earnout relating to the Biomol International acquisition which is currently in dispute (See Notes 2 and 16 to the Consolidated Financial Statements) over the next twelve months, although there can be no assurance that future events will not alter such view.



**Effect of New Accounting Pronouncements**

In October 2009, the FASB issued a Consensus of the FASB Emerging Issues Task Force relating to Multiple Deliverable Revenue Arrangements. This standard provides application guidance on whether multiple deliverables exist, how the deliverables should be separated and how the consideration should be allocated to one or more units of accounting. This update establishes a selling price hierarchy for determining the selling price of a deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific or third-party evidence is available. This guidance is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted. The Company will adopt this guidance effective August 1, 2010. The Company has assessed the impact of adoption and it is not expected to have a material effect on our consolidated results of operations and financial condition.

In August 2009, the Company adopted the provisions of the accounting standard on fair value measurements that apply to nonfinancial assets and liabilities that are recognized or disclosed at fair value on a non-recurring basis. The adoption of these provisions did not have an impact on the consolidated financial statements or disclosures.

In June 2009, the FASB issued authoritative guidance to establish the FASB Accounting Standards Codification as the source of authoritative accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the United States. This guidance only impacted references for accounting guidance.

On August 1, 2009, the Company adopted the revised authoritative guidance on business combinations which changed existing practice, in part, as follows: (1) contingent consideration arrangements are now fair valued at the acquisition date and included on that basis in the purchase price consideration; (2) transaction costs are now expensed as incurred, rather than capitalized as part of the purchase price; (3) reversal of valuation allowances created in purchase accounting are now recorded through the income tax provision; and (4) in order to accrue for a restructuring plan in purchase accounting, all authoritative guidance would have to be met at the acquisition date. While the adoption of this standard did not have a material impact on the Company's financial statements, it could materially change the accounting for business combinations consummated in the future and for tax matters relating to prior acquisitions settled subsequent to July 31, 2009.

**Contractual Obligations**

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

The following is a summary of future payments under the Company's contractual obligations as of July 31, 2010:

Payments Due by Period

<u>In 000 s</u>	<u>Total</u>	<u>Less than 1 year</u>	<u>1-3 years</u>	<u>4-5 years</u>	<u>Over 5 years</u>
Real estate and equipment leases	\$ 23,838	\$ 4,718	\$ 7,107	\$ 5,373	\$ 6,640
Employment agreements	2,741	1,530	1,211		
<b>Total contractual cash obligations</b>	<b>\$ 26,579</b>	<b>\$ 6,248</b>	<b>\$ 8,318</b>	<b>\$ 5,373</b>	<b>\$ 6,640</b>

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

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



**Critical Accounting Policies**General

The Company's discussion and analysis of its financial condition and results of operations are based upon Enzo Biochem, Inc. consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses; these estimates and judgments also affect related disclosure of contingent assets and liabilities.

On an on-going basis, we evaluate our estimates, including those related to contractual expense, allowance for uncollectible accounts, inventory, intangible assets and income taxes. The Company bases its estimates on experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Product revenues

Revenues from product sales are recognized when the products are shipped and title transfers, the sales price is fixed or determinable and collectibility is reasonably assured.

Royalties

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

License fees and multiple element arrangements

When evaluating multiple element arrangements, the Company considers whether the components of the arrangement represent separate units of accounting. The evaluation requires subjective determinations and requires management to make judgments about the fair value of the individual elements and whether such elements are separable from the other aspects of the contractual relationship. License fees 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 2010		Year ended July 31 2009		Year ended July 31 2008	
	(In 000 s)	(in %)	(In 000 s)	(in %)	(In 000 s)	(in %)
Medicare	\$ 11,158	25	\$ 9,138	23	\$ 9,078	22
Third-party payers	19,534	44	20,073	51	24,768	59
Patient self-pay	8,758	20	6,056	15	3,582	8
HMO's	4,728	11	4,337	11	4,650	11
Total	\$ 44,178	100%	\$ 39,604	100%	\$ 42,078	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

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and regulations and is not aware of any pending or threatened investigations involving allegations of potential wrongdoing.

Other than the Medicare program, one provider whose programs are included in the Third-party payer and Health Maintenance Organizations ( HMO s ) categories represented 25%, 25%, and 26% of the Clinical Labs segment s services net revenues for the fiscal years ended July 31, 2010, 2009 and 2008 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 (HMOs) and managed care. The Company adjusts the contractual adjustment estimate quarterly, based on its evaluation of current and historical settlement experience with payers, industry reimbursement trends, and other relevant factors.

The other relevant factors that affect our contractual adjustment include the monthly and quarterly review of: 1) current gross billings and receivables and reimbursement by payer, 2) current changes in third party arrangements. 3) the growth of in-network provider arrangements and managed care plans specific to our Company.

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

During the years ended July 31, 2010, 2009 and 2008, the contractual adjustment percentages, determined using current and historical reimbursement statistics, were 83.0%, 80.8% and 81.8%, 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 \$2,589,000 and \$2,040,000, for the years ended July 31, 2010 and 2009, respectively, and a change in the net accounts receivable of approximately \$339,000 and \$287,000 as of July 31, 2010 and 2009, 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, 2010 and 2009, approximately 45% and 40%, 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 \$1.9 million or 27% and \$2.1 million or 28% represents foreign receivables as of July 31, 2010 and 2009 respectively, includes royalty receivables of \$2.5 million, as of July 31, 2010 and 2009, of which approximately \$1.8 million and \$1.9 million, respectively is from Qiagen Corporation.



Net accounts receivable

Billing category	As of July 31, 2010		As of July 31, 2009	
	(In 000 s)	(in %)	(In 000 s)	(in %)
Clinical Labs				
Medicare	\$ 849	14	\$ 1,113	22
Third party payers	2,664	46	2,003	40
Patient self-pay	2,024	35	1,635	32
HMO s	296	5	303	6
Total Clinical Labs	5,833	100%	5,054	100%
Total Life Sciences	7,173		7,426	
Total accounts receivable	\$ 13,006		\$ 12,480	

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

In 000 s	July 31, 2010	July 31, 2009
Beginning balance	\$ 4,786	\$ 886
Provision for doubtful accounts	3,480	5,189
Write-offs, net	(5,427)	(1,289)
Ending balance	\$ 2,839	\$ 4,786

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, 2010 and 2009, the Company determined an allowance for doubtful accounts less than 210 days and wrote off 100% of accounts receivable over 210 days, as it assumed those accounts are uncollectible, except for certain fully reserved balances, principally related to Medicare. These accounts have not been written off because the payer's filing date deadline has not occurred or the collection process has not been exhausted. The Company's collection experience on Medicare receivables beyond 210 days has been insignificant. The Company adjusts the historical collection analysis for recoveries, if any, on an ongoing basis.

The Company's ability to collect outstanding receivables from third party payers is critical to its operating performance and cash flows. The primary collection risk lies with uninsured patients or patients for whom primary insurance has paid but a patient portion remains outstanding. The Company also assesses the current state of its billing functions in order to identify any known collection or reimbursement issues in order to assess the impact, if any, on the allowance estimates, which involves judgment. The Company believes that the collectibility of its receivables is directly linked to the quality of its billing processes, most notably, those related to obtaining the 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.

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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.

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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.

<b>As of July 31, 2010</b>	<b>Total Amount</b>	<b>%</b>	<b>Medicare Amount</b>	<b>%</b>	<b>Third Party Payers Amount</b>	<b>%</b>	<b>Self-pay Amount</b>	<b>%</b>	<b>HMO s Amount</b>	<b>%</b>
1-30 days	\$ 21,678	66%	\$ 2,886	57%	\$ 10,846	64%	\$ 4,242	59%	\$ 3,704	99%
31-60 days	4,256	13%	439	9%	2,458	15%	1,344	18%	15	1%
61-90 days	2,565	8%	281	6%	1,337	8%	935	13%	12	%
91-120 days	1,771	5%	248	5%	850	5%	671	9%	2	%
121-150 days	936	3%	236	4%	696	4%	2	%	2	%
Greater than 150 days*	1,733	5%	967	19%	711	4%	52	1%	3	%
<b>Totals</b>	<b>\$ 32,939</b>	<b>100%</b>	<b>\$ 5,057</b>	<b>100%</b>	<b>\$ 16,898</b>	<b>100%</b>	<b>\$ 7,246</b>	<b>100%</b>	<b>\$ 3,738</b>	<b>100%</b>

<b>As of July 31, 2009</b>	<b>Total Amount</b>	<b>%</b>	<b>Medicare Amount</b>	<b>%</b>	<b>Third Party Payers Amount</b>	<b>%</b>	<b>Self-pay Amount</b>	<b>%</b>	<b>HMO s Amount</b>	<b>%</b>
1-30 days	\$ 19,251	70%	\$ 3,193	61%	\$ 9,695	73%	\$ 2,882	51%	\$ 3,481	99%
31-60 days	4,508	17%	894	16%	1,957	15%	1,635	29%	22	1%
61-90 days	1,783	6%	256	5%	680	5%	836	15%	11	%
91-120 days	1,019	4%	249	5%	483	4%	280	5%	7	%
121-150 days	340	1%	134	3%	202	2%		%	4	%
Greater than 150 days**	636	2%	536	10%	100	1%		%		%
<b>Totals</b>	<b>\$ 27,537</b>	<b>100%</b>	<b>\$ 5,262</b>	<b>100%</b>	<b>\$ 13,117</b>	<b>100%</b>	<b>\$ 5,633</b>	<b>100%</b>	<b>\$ 3,525</b>	<b>100%</b>

\* Total includes \$805 fully reserved over 210 days as of July 31, 2010.

\*\* Total includes \$340 fully reserved over 210 days as of July 31, 2009.

At July 31, 2009 the Company fully reserved and excluded from the above table all receivables on its legacy billing system which was replaced in August 2008. During fiscal 2010 all such reserved balances were written off.

*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. The Company adopted the accounting standard related to unrecognized tax benefits on August 1, 2007. The cumulative effect of adopting the standard did not have a material impact on the Company's financial position or results of operations.

### *Inventory*

The Company values inventory at the lower of cost (first-in, first-out) or market. Work-in-process and finished goods inventories consist of material, labor, and manufacturing overhead. On a quarterly basis, we review inventory quantities on hand and analyze the provision for excess and obsolete inventory based on our estimate of sales forecasts based on sales history and anticipated future demand. Our estimate of future product demand may not be accurate and we may understate or overstate the provision for excess and obsolete inventory. Accordingly, unanticipated changes in demand could have a significant impact on the value of our inventory and results of operations. At July 31, 2010 and 2009, our reserve for excess and obsolete inventory was \$3,821,000 and \$2,477,000 respectively.

### *Goodwill and Indefinite-Lived Intangibles*

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

### *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.

### *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. As of July 31, 2010, the Company has established a reserve of \$0.6 million, which is included in accrued liabilities, for claims that have been reported but not paid and incurred but not reported.



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) and, to a much lesser extent, interest rates on investments in short-term instruments, that could impact our results of operations and financial position. We do not currently engage in any hedging or market risk management tools.

*Foreign Currency Exchange Rate Risk*

The financial reporting of our non-U.S. subsidiaries is denominated in currencies other than the U.S. dollar. Since the functional currency of our non-U.S. subsidiaries is the local currency, foreign currency translation adjustments are accumulated as a component of accumulated other comprehensive income in stockholders' equity. Assuming a hypothetical aggregate change of 10% in the exchange rates of foreign currencies against the U.S. dollar at July 31, 2010, our assets and liabilities would increase or decrease by \$1.8 million and \$0.9 million, respectively, and our net sales and net earnings (loss) would increase or decrease by \$1.4 million and \$0.2 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 aggregate change of 10% in the exchange rates of foreign currencies against the U.S. dollar at July 31, 2010, our pre-tax earnings (loss) would be favorably or unfavorably impacted by approximately \$0.3 million on an annual basis.

*Interest Rate Risk*

Our excess cash is invested in highly liquid short term U.S. Treasury Bills and money market funds with high credit ratings. Changes in interest rates may affect the investment income we earn on cash and cash equivalents and therefore affect our cash flows and results of operations. As of July 31, 2010, we were exposed to interest rate change market risk with respect to our short-term investments in US Government instruments of \$24.8 million. The short-term investments bear interest rates ranging from 0% to 0.5%. Each 100 basis point (or 1%) fluctuation in interest rates will increase or decrease interest income on the short-term investments by approximately \$0.2 million on an annual basis.

As of July 31, 2010, we did not maintain any fixed or variable interest rate financing.

Item 8. Financial Statements and Supplementary Data

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

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

Not applicable.

Item 9A. Controls and Procedures

**Evaluation of Disclosure Controls and Procedures**

As required by Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act), we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of July 31, 2010. 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, 2010, 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, 2010 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, 2010. Ernst & Young LLP, our independent registered public accounting firm, has issued an attestation report on our internal control over financial reporting as of July 31, 2010. This report, in which Ernst & Young LLP has expressed an unqualified opinion, appears in this Item 9A.

**Report of Independent Registered Public Accounting Firm**

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

We have audited Enzo Biochem, Inc.'s internal control over financial reporting as of July 31, 2010, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Enzo Biochem, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, Enzo Biochem, Inc. maintained, in all material respects, effective internal control over financial reporting as of July 31, 2010 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, 2010 and 2009 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, 2010 of Enzo Biochem, Inc. and our report dated October 14, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Jericho, New York  
October 14, 2010

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 30, 2010 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 30, 2010 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 30, 2010 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 30, 2010 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 30, 2010 and is incorporated herein by reference.

**PART IV**

Item 15. Exhibits, Financial Statement Schedules

- (a) (1) Consolidated Financial Statements
  - Consolidated Balance Sheets - July 31, 2010 and 2009
  - Consolidated Statements of Operations- Years ended July 31, 2010, 2009 and 2008
  - Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss) - Years ended July 31, 2010, 2009 and 2008
  - Consolidated Statements of Cash Flows - Years ended July 31, 2010, 2009 and 2008
  - 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.

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### (3) Exhibits

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

<b>Exhibit No.</b>	<b>Description</b>
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)	Lease agreement with Pari Management (8)
10 (e)	Settlement and Release Agreement between the Company and Sigma Aldrich (9)
10 (f)	Stock Purchase Agreement By and Among Enzo Life Sciences, Inc., Axxora Life Sciences Inc., and the Stock holders, Option holders and Warrant holders (10)
10 (g)	Stock Asset Purchase Agreement By and Among Buyer Parties and Seller Parties with respect to the Biomol International and affiliate acquisition (11)
10 (h)	Asset Purchase Agreement By and Among Enzo Life Sciences, Acquisition, Inc. and Assay Designs, Inc.(12)
10 (i)*	Amended and Restated Employment Agreement with Elazar Rabbani
10(j)*	Amended and Restated Employment Agreement with Barry Weiner
14 (a)	Code of Ethics (10)
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

**Notes to  
exhibits**

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- \* Filed herewith
- (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, 2005 and is incorporated herein by reference.
  - (8) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 2006 and is incorporated herein by reference.
  - (9) This exhibit was filed with the Company's Current Report on Form 8-K on September 21, 2006 and is incorporated herein by reference.
  - (10) This exhibit was filed with the Company's Current Report on Form 8-K May 30, 2007 and is incorporated herein by reference.
  - (11) This exhibit was filed with the Company's Current Report on Form 8-K May 8, 2008 and is incorporated herein by reference.
  - (12) This exhibit was filed with the Company's Current Report on Form 8-K March 13, 2009 and is incorporated herein by reference.

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SIGNATURES

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

ENZO BIOCHEM, INC.

Date: October 14, 2010

By: /s/ Elazar Rabbani Ph.D.

\_\_\_\_\_  
Chairman of the Board

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

By: /s/ Elazar Rabbani Ph.D. October 14, 2010

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

By: /s/ Barry W. Weiner October 14, 2010

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

By: /s/ Irwin Gerson October 14, 2010

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Irwin Gerson, Director

By: /s/ Stephen B. H. Kent Ph.D. October 14, 2010

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Stephen B. H. Kent, Director

By: /s/ Bernard L. Kasten MD October 14, 2010

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Bernard Kasten, Director

By: /s/ Melvin F. Lazar October 14, 2010

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Melvin F. Lazar, Director

By: /s/ Gregory M. Bortz October 14, 2010

\_\_\_\_\_  
Gregory M. Bortz, 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, 2010 and 2009</u>	F-3
<u>Consolidated Statements of Operations Years ended July 31, 2010, 2009 and 2008</u>	F-4
<u>Consolidated Statements of Stockholders Equity and Comprehensive Income (Loss) Years ended July 31, 2010, 2009 and 2008</u>	F-5
<u>Consolidated Statements of Cash Flows Years ended July 31, 2010, 2009 and 2008</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7
<u>Schedule II - Valuation and Qualifying Accounts Years ended July 31, 2010, 2009 and 2008</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. as of July 31, 2010 and 2009, 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, 2010. 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, 2010 and 2009, and the consolidated results of their operations and their cash flows for each of the three years in the period ended July 31, 2010, 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.

As discussed in Note 1 to the consolidated financial statements, effective August 1, 2009, the Company adopted revised authoritative guidance related to accounting for business combinations.

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, 2010, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated October 14, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Jericho, New York  
October 14, 2010

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

	<u>July 31, 2010</u>	<u>July 31, 2009</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 8,759	\$ 6,929
Short term investments	24,807	43,306
Accounts receivable, net of allowance for doubtful accounts of \$2,839 in 2010 and \$4,786 in 2009	13,006	12,480
Inventories	8,882	9,264
Prepaid expenses	2,284	2,482
	<u>57,738</u>	<u>74,461</u>
Total current assets	57,738	74,461
Property, plant, and equipment, net	11,858	11,323
Goodwill	24,943	24,896
Intangible assets, net	20,368	22,009
Other	338	439
	<u>115,245</u>	<u>133,128</u>
Total assets	\$ 115,245	\$ 133,128
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable trade	\$ 6,455	\$ 4,242
Accrued liabilities	8,509	8,426
Other current liabilities	572	1,062
Deferred taxes	21	213
	<u>15,557</u>	<u>13,943</u>
Total current liabilities	15,557	13,943
Deferred taxes	2,582	2,366
Other	90	38
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, \$.01 par value; authorized 25,000,000 shares; no shares issued or outstanding		
Common Stock, \$.01 par value; authorized 75,000,000 shares; shares issued: 38,782,725 at July 31, 2010 and 38,589,880 at July 31, 2009	388	386
Additional paid-in capital	306,561	306,280
Less treasury stock at cost: 623,848 shares at July 31, 2010 and 735,554 shares at July 31, 2009	(8,854)	(10,440)
Accumulated deficit	(201,954)	(179,721)
Accumulated other comprehensive income	875	276
	<u>97,016</u>	<u>116,781</u>
Total stockholders' equity	97,016	116,781
Total liabilities and stockholders' equity	\$ 115,245	\$ 133,128

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

	Years ended July 31,		
	2010	2009	2008
<b>Revenues:</b>			
Product revenues	\$ 43,111	\$ 40,592	\$ 28,087
Royalty and license fee income	9,793	9,376	7,630
Clinical laboratory services	44,178	39,604	42,078
	<u>97,082</u>	<u>89,572</u>	<u>77,795</u>
<b>Operating expenses:</b>			
Cost of product revenues	22,547	26,766	19,159
Cost of clinical laboratory services	29,570	26,295	22,209
Research and development	9,704	9,220	8,637
Selling, general, and administrative	48,395	41,314	33,272
Provision for uncollectible accounts receivable	3,480	5,189	3,716
Legal	1,746	4,195	5,588
Litigation settlement and related costs	3,698		
	<u>119,140</u>	<u>112,979</u>	<u>92,581</u>
Total operating expenses			
	119,140	112,979	92,581
Operating loss	(22,058)	(23,407)	(14,786)
<b>Other income (expense):</b>			
Interest	19	581	3,696
Other	44	74	171
Foreign exchange (loss) gain	(266)	(725)	27
	<u>(22,261)</u>	<u>(23,477)</u>	<u>(10,892)</u>
Loss before income taxes	(22,261)	(23,477)	(10,892)
Benefit (provision) for income taxes	28	(87)	239
	<u>(22,233)</u>	<u>(23,564)</u>	<u>(10,653)</u>
Net loss	(\$ 22,233)	(\$ 23,564)	(\$ 10,653)
<b>Net loss per common share:</b>			
Basic	(\$ 0.59)	(\$ 0.63)	(\$ 0.29)
Diluted	(\$ 0.59)	(\$ 0.63)	(\$ 0.29)
<b>Weighted average common shares outstanding:</b>			
Basic	38,001	37,511	36,883
Diluted	38,001	37,511	36,883

**ENZO BIOCHEM, INC.**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**  
**AND COMPREHENSIVE INCOME (LOSS)**  
**Years ended July 31, 2010, 2009, and 2008**  
(In thousands, except share data)

	<i>Common Stock Shares</i>	<i>Treasury Stock Shares</i>	<i>Common Stock Amount</i>	<i>Additional Paid-in Capital</i>	<i>Treasury Stock Amount</i>	<i>Accumulated Comprehensive Deficit</i>	<i>Accumulated Other (Loss) Income</i>	<i>Total Stockholders Equity</i>	<i>Comprehensive income (loss)</i>
Balance at July 31, 2007	37,280,723	596,456	\$ 372	\$ 295,899	\$ (8,915)	\$ (145,504)	\$ 42	\$ 141,894	
Net (loss) for the year ended July 31, 2008						(10,653)		(10,653)	\$ (10,653)
Purchase of treasury stock		181,263			(2,416)			(2,416)	
Exercise of stock options	267,345		3	2,881				2,884	
Vesting of restricted stock	70,963		1					1	
Stock based compensation charges				1,566					