

ENZO BIOCHEM INC
Form 10-K
October 09, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

(Mark one)

S ANNUAL REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended July 31, 2014

or

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

For the transition period from _____ to _____

Commission File Number 001-09974

ENZO BIOCHEM, INC.

(Exact name of registrant as specified in its charter)

New York	13-2866202
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

527 Madison Ave.	
New York, New York	10022
(Address of principal executive offices)	(Zip Code)

(212) 583-0100
(Registrant's telephone number, including area code)

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

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(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

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

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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 \$107,702,000 as of January 31, 2014.

The number of shares of the Company's common stock, \$.01 par value, outstanding at October 1, 2014 was 44,504,000.

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 16, 2015 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 focusing on harnessing biological processes to develop research tools, diagnostics and therapeutics and serving as a provider of esoteric and other state-of-the-art test services to the medical community. Since our founding in 1976, our strategy has been based on the development of enabling technologies based on molecular and cellular technologies in research, development, manufacture, licensing and marketing of innovative health care products, platforms and services. Our pioneering work in genomic analysis coupled with our extensive patent estate and enabling platforms have 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 149 key issued patents worldwide, and over 230 pending patent applications, along with extensive enabling technologies and platforms.

Operating Segments

We are comprised of three operating segments, of which the Therapeutics and Life Sciences segments have evolved out of our core competencies involving the use of nucleic acids as informational molecules and the use of compounds for immune modulation and augmented by the previous acquisitions of a number of related companies. Information concerning sales by geographic area and business segments for the years ended July 31, 2014, 2013 and 2012 is located in Note 15 in the Notes to Consolidated Financial Statements.

Below are brief descriptions of each of our operating segments:

Enzo Clinical Labs is a regional clinical reference 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 technological capabilities and the broader trends in predictive and personalized diagnostics. Enzo Clinical Labs offers an extensive menu of routine and esoteric clinical laboratory tests or procedures used in general patient care by physicians to establish or support a diagnosis, monitor treatment or medication, and search for an otherwise undiagnosed condition. We operate a full-service clinical laboratory in Farmingdale, New

York, a network of over 35 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, in-house logistics department, and information technology department.

Enzo Life Sciences manufactures, develops and markets products and tools to life sciences, drug development and clinical research customers world-wide and has amassed a large patent and technology portfolio. Enzo Life Sciences, Inc. is a recognized leader in labeling and detection technologies across research and diagnostic markets. Our strong portfolio of proteins, antibodies, peptides, small molecules, labeling probes, dyes and kits, many of which are proprietary, 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 40,000 products made by over 40 other original manufacturers. Our strategic focus is directed to innovative diagnostic platforms and high quality research reagents and kits in the primary key research areas of genomics, cellular analysis, small molecule chemistry, protein homeostasis epigenetics immunoassays and assay development.

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

Enzo Therapeutics is a biopharmaceutical venture that has developed multiple novel approaches in the areas of gastrointestinal, infectious, ophthalmic and metabolic diseases, many of which are derived from the pioneering work of Enzo Life Sciences. Enzo Therapeutics has focused its efforts on developing treatment regimens for diseases and conditions for which current treatment options are ineffective, costly, and/or cause unwanted side effects. This focus has generated a clinical and preclinical pipeline, as well as more than 95 patents and patent applications.

The Company's primary sources of revenue have historically been from the clinical laboratory services provided to the healthcare community and product revenues and royalty and licensing of Life Sciences' products utilized in life science research. The following table summarizes the sources of revenues for the fiscal years ended July 31, 2014, 2013 and 2012 (in thousands and percentages):

Fiscal year ended July 31,	2014		2013		2012	
Clinical laboratory services	\$58,689	61 %	\$55,889	59 %	\$59,403	58 %
Product revenues	32,850	34	32,526	35	37,722	37
Royalty and license fee income	4,408	5	5,292	6	5,958	5
Total	\$95,947	100%	\$93,707	100%	\$103,083	100%

Markets

Background

Deoxyribonucleic Acid ("DNA") is the source of biological information that governs the molecular mechanisms underlying life. This information is stored in the linear sequences of nucleotides that comprise DNA. The sequence of the human genome, comprising well over 30,000 genes, has been identified by genomic research in both the public and private sectors, including the Human Genome Project. The ongoing challenge of the scientific research community is to determine the function and relevance of each gene, as well as gene to gene and gene/environment interactions. In addition, scientists are looking in detail at the proteins that are expressed by genes, their control and regulation in the cellular environment. This information will facilitate the understanding of biological mechanisms and how variations and mutations in such mechanisms may result in disease, enabling more rapid and accurate detection of specific diseases and the development of new therapeutics to treat them.

Tools for biomedical and pharmaceutical research

There is a large, and growing global demand by biomedical and pharmaceutical researchers for research and diagnostic tools that both facilitate and accelerate the generation of biological information. This demand can be met by gene and protein target based diagnostics for which a variety of formats, or tools, have been developed that enable researchers to study biological pathways. These tools can identify mutations in gene sequences and variations in gene expression levels that can lead to disease, or they can quantify biomarkers that provide insight to disease and potential therapeutic solutions. These techniques use instruments including DNA sequencing and genotyping instruments, microarrays, fluorescent microscopes, high content screening systems, flow cytometers and plate readers. Common among these instruments is the need for reagents that allow the identification, quantification and characterization, and interactions of specific genes or nucleic acid sequences, proteins, cells and other cellular structures and organelles.

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

- long term commitment to research spending by academic, government and private organizations to determine the function and clinical relevance of the gene sequences and proteins that have been identified by genome research,
- development of commercial applications based on information derived from this research; and
- ongoing advancements in tools that accelerate these research and development activities.

Clinical diagnostics

The clinical diagnostics market has been reported by industry sources to be greater than \$23 billion annually domestically and over \$46 billion worldwide. It is comprised of a broad range of tests based on clinical chemistry, microbiology, immunoassays, genomics, proteomics, gene expression profiling blood banking, and cancer screening assays through histology as well as newer body fluid based approaches. Many of these tests employ traditional technologies, such as immunoassays and cell culture technologies, for the detection of diseases.

Immunoassays are based on the use of antibodies directed against a specific target, or antigen, to detect that antigen in a patient sample. Cell culturing techniques involve the growth, isolation and visual detection of the presence of a microorganism and often its susceptibility to FDA approved drugs.

There are several drawbacks to these more traditional technologies. Immunoassays do not allow for early detection of diseases because they require minimum levels of antigens to be produced by the microorganism in order to be identified. These levels vary by microorganism, and the delay involved could be several days or several months, as seen in HIV/AIDS. Cell cultures are slow, labor intensive and not amenable to all microorganisms. For example, gonorrhea and chlamydia are difficult to culture.

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

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

According to industry sources, the market for molecular diagnostic tools, assays and other products is currently more than \$6 billion per year, and is acknowledged as one of the fastest growing segments in the in-vitro diagnostic industry, growing at more than twice the rate of traditional diagnostics. Contributing to this growth is, among other factors:

- the increasing number of diagnostic tests being developed from discoveries in genome research;
- advances in formats and other technologies that automate and accelerate gene-based diagnostic testing;
- growing emphasis by the health care industry on early diagnosis and treatment of disease and;
- application of gene-based diagnostics as tools to match therapies to specific patient genetics commonly referred to as pharmacogenomics or companion diagnostics.

Therapeutics

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

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

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

Still other diseases result from either the expression of foreign genes, such as those residing in viruses and pathogenic organisms, or from the abnormal or unregulated expression of the body's own genes. In other cases, it is the failure to express, or over expression of, a gene that causes the disease. In addition, a number of diseases result from the body's failure to adequately regulate its immune system.

Advances in gene analysis have provided the information and tools necessary to develop drugs that interfere with the disease process at the genetic level. For a broad spectrum of diseases, this approach can be more precise and effective than interfering with downstream events such as protein synthesis or enzyme activation. Therapies targeting genetic processes are called gene medicines. There are two fundamental approaches to gene medicines, synthetic and genetic.

Synthetic gene medicine involves the administration of synthetic nucleic acid sequences called "oligos" that are designed to bind to, and thus deactivate, ribonucleic acid ("RNA") produced by a specific gene.

To date, this approach has demonstrated limited success. Since a single cell may contain thousands of strands of RNA, large amounts of oligos are necessary to shut down the production of unwanted proteins. Also, they are quickly metabolized or eliminated by the body. Consequently, large quantities of oligos must be delivered in multiple treatments, which can be both toxic to the body as well as costly.

Genetic medicine or gene therapy involves the insertion of a gene into a cell. The inserted gene biologically manufactures the therapeutic product within the cell on an ongoing basis. This gene may be introduced to bring about a beneficial effect or to disable a pathological mechanism within the cell. For example, the gene may be inserted to replace a missing or malfunctioning gene responsible for synthesizing an essential protein or the inserted gene may code for a molecule that would deactivate either an overactive gene or a gene producing an unwanted protein. As a permanent addition to the cellular DNA, the inserted gene produces RNA and/or proteins where needed.

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:

Using our core technology, Launch New Platform for Molecular Diagnostics

We have developed several enabling platform technologies that may have utility in the development of a new generation of molecular diagnostic products designed to meet the needs of the current clinical marketplace. Our lead platform is AmpiProbe which is a proprietary target amplification and detection technology that has been shown to require substantially less starting material than conventional methods such as polymerase chain reaction (PCR) based products. With AmpiProbe it may be possible to increase the number of analytes that can be assayed for from a single clinical specimen, which in turn may reduce the need for physicians to recall patients to obtain additional clinical material for testing. In addition by increasing the number of analytes tested in a single clinical preparation, AmpiProbe may be able to produce diagnostic tests at a significantly lower cost than conventional assays. Moreover, the need for less starting material may also lead to diagnostic tests with improved sensitivity, thus allowing detection of certain analytes present in minute quantities that are below the limit of detection of conventional assays

Maximize our resources by collaborating with others in research and commercialization activities

We enter into research collaborations with leading academic and other research centers to augment our core expertise on specific programs.

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

We have research and clinical collaborations with other institutions including Hadassah University Medical Center in Jerusalem, Israel relating to our immune regulation technology. Through collaborations such as these and other licensing agreements we continue to develop novel therapeutics for the stimulation and enhancement of bone formation and glucose control, among others. Such products, if any, emanating from this technology could provide potential therapy for bone disorders, including bone loss, bone fractures, periodontitis, diabetes and other indications. There can be no assurance that any of these collaborative projects will be successful.

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

Similarly, we may 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.

Exploit our marketing and distribution infrastructure

Enzo Life Sciences has developed its sales and marketing infrastructure to directly service its end users, while simultaneously positioning the Company for targeted product line expansion. Our global sales, marketing, manufacturing, product development and distribution infrastructure, have now been integrated and consolidated into a single global business. Enzo Life Sciences operates, under its own name, worldwide through wholly owned subsidiaries (in USA, Switzerland, Benelux, Germany, and the UK), a branch office in France and a network of third party distributors in most other significant markets worldwide. Our comprehensive product portfolio allows us to deliver integrated solutions to basic researchers, drug developers and clinical researchers around the globe. Our research allows us to provide solutions in all key research areas including: Genomics, Cell Biology Immunoassays and in a multitude of applied research markets including: Bioprocess, Personal Care, Cancer Research, and Neuroscience to name a few.

Expand our collaborations with major life sciences companies

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

The Company has a license agreement with QIAGEN Gaithersburg Inc. (“Qiagen”) that began in 2005, whereby the Company earns quarterly running royalties on the net sales of Qiagen products subject to the license until the expiration of the patent on April 24, 2018. In the license agreement, Qiagen was granted a world-wide, non-exclusive license to the Company U.S. Patent number 6,222,581, which is related to the use of a methodology called “hybrid-capture” in which certain nucleic acid probes are hybridized to target nucleic acids and then captured indirectly on a solid surface. The resulting nucleic acid hybrids are then detected by antibodies conjugated to signal-generating molecules which produce an amplified signal allowing for more sensitive detection of the resultant hybrids. This platform is one of the most desirable formats for the detection of nucleic acids in a reliable and economic manner, and has formed the basis for one of the most commonly ordered genomic-based assays. See Note 12 to the Notes to Consolidated Financial Statements.

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

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

We continue to test technologies we believe can serve as enabling platforms for developing medicines that genetically target and inhibit viral functions, as well as medicines that regulate the immune response. In addition to such therapeutic products, we continue to capitalize on our nucleic acid labeling, target and signal amplification, and detection technologies and intellectual property to develop diagnostic and monitoring tests for various diseases.

Expand and protect our intellectual property estate

Since our inception, we have followed a strategy of creating a broad encompassing patent position in the life sciences and therapeutics areas. We have made obtaining patent protection a central strategic policy, both with respect to our proprietary platform technologies and products, as well as broadly in the areas of our research activities. During Fiscal 2014, we were issued 34 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.

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. These proprietary technologies become the building blocks of our Molecular Diagnostic platforms.

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

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

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

Therapeutic Platform Development Cell Signaling Pathway

One area of Enzo's therapeutic platform development is related to the development of pharmaceutical agents that affect protein-protein interactions. Over the past several years, our scientists and collaborators have unlocked the secrets of a major cell signaling pathway thus producing a means to modify biologic activity in a number of physiological systems.

Further investigation into the design and control of this system has allowed our scientists and their collaborators to determine the structure of key regulatory proteins and to identify active sites that can then become targets for Enzo's proprietary technology generating system. Our technology is capable of generating active compounds that range from orally delivered small molecules to peptides, oligonucleotides or antibodies. We have performed pioneering work on the structure and function of LRP and its ligands, developed a screening technology to identify active compounds, and have synthesized proprietary molecules capable of producing biological effects in cell-based systems and animal models of disease. Specifically, this system allows the Company to successfully:

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

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

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

The anabolic induction of new bone formation and prevention of bone loss by our small molecule compounds may promise new paths for the treatment of osteoporosis. In addition, our proprietary technology has enabled the generation of novel chemical entities that have significant glucose lowering activity. These effects are separate from its effects on bone metabolism indicating a specificity of action conferred by the interaction of a particular compound with the cell signaling pathway. Therefore, this approach may be broadly applicable to the generation of therapeutic drug candidates for multiple indications.

Immune Regulation

Oral Immune Regulation. We continue to explore a novel therapeutic approach based on immune regulation. Our immune regulation technology seeks to control an individual's immune response to a specific antigen in the body. An antigen is a substance that the body perceives as foreign and, consequently, against which the body mounts an immune response. This platform technology is being developed as a means to manage immune-mediated diseases, such as autoimmune uveitis and Crohn's disease.

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

Gene Regulation

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

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

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

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

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

Products and Services

We are applying our core technologies to develop novel therapeutics as well as research tools for the life sciences and clinical diagnostics markets. In addition, we provide clinical laboratory services to physicians and other health care providers in the New York, New Jersey and Eastern Pennsylvania medical communities.

Research Products

We are organized to lead in the development, production, marketing and sales of innovative life science research reagents worldwide based on over 30 years of experience in building strong international market recognition, implementing outstanding operational capabilities, through two main channels to market:

Enzo Life Sciences - “Scientists enabling Scientists”

Enzo Life Sciences is positioned as a leading manufacturer and supplier of high quality reagents, kits and products supplied to customers in Life Sciences Research, Clinical Research and Drug Development. With direct sales operations in US, Switzerland, Germany, UK, France and Benelux, Enzo Life Sciences also supports its over 9,000 products through a global network of dedicated distributors.

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

The products supplied by Enzo Life Sciences include small molecules, proteins, antibodies, peptides, probes, assay kits and custom services. Our comprehensive portfolio of high quality reagents and kits in key research areas are sold to scientific experts in the following fields:

Adipokines	Interferons
Antibiotics	In Vitro Toxicology
Apoptosis/Cell Death	Kinases/Inhibitors
Biologically Active Peptides	Leukotrienes/Prostaglandins/Thromboxanes
Bone Metabolism	Microarray Labeling
Cancer Research	Multidrug Resistance
Cell Death	Natural Products/Antibiotics
Cell Cycle	Neuroscience
Chemokines/Cytokines	Nitric Oxide Pathway
Cytoskeletal Research	Nuclear Receptors
Dependence Receptors	Oxidative Stress
DNA Fragmentation/Damage/Repair	Protein Aggregation
DNA Regulation	Proteosome/Ubiquitin
Epigenetics	Receptors
FISH	Signal Transduction
Growth Factors/Cytokines	Stem Cell/Cell Differentiation

Hypoxia	Stress Proteins/Heat Shock Proteins
Immunology	Toxicology
Viral Signaling	TNF/TNF Receptor Superfamily
Inflammation/Innate Immunity	Transcription Factors

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

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

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

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

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

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

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

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

Therapeutic Development Program

Autoimmune Uveitis

Autoimmune uveitis, which results from inflammation of a part of the eye known as the uvea, is believed to result from an immune reaction to antigens in the eye, specifically the S-antigen and the interphotoreceptor retinoid-binding protein (IRBP).

There is no known cure for uveitis, which in the United States, according to the American Uveitis Society, is newly diagnosed in approximately 38,000 people every year.

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

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

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

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, diagnosis, evaluation, monitoring and treatment of diseases and other medical conditions. Clinical laboratory testing is generally categorized as clinical testing or 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. Many clinical laboratory tests are considered routine and can be performed by most commercial clinical laboratories. Tests that are not routine and that require more sophisticated equipment and highly skilled personnel are considered esoteric tests and may be performed less frequently than routine tests.

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

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

Patient specimens are delivered to our laboratory facilities primarily by our logistics department accompanied by a test requisition form. These forms, which are completed by the ordering physician, indicate the tests to be performed and demographic patient information and in most instances are transmitted to us via EnzoDirect, our proprietary computer-based ordering and results delivery system. Once the information is entered into the laboratory computer system the tests are performed on the corresponding laboratory testing instrumentation and the results are uploaded primarily through an interface from the laboratory testing instrumentation or in some instances, manually entered into the laboratory computer system. Most routine testing is completed by early the next morning, and test results are reported to the ordering physician.

These test results are either reported electronically via our EnzoDirect system or delivered by our logistics department directly to the ordering physicians’ offices. Physicians who request that they be called with a particular result are so notified by our customer service personnel.

For fiscal years ended July 31, 2014, 2013 and 2012, respectively, approximately 61%, 59% and 58% of the Company’s revenues were derived from the clinical laboratory. At July 31, 2014 and 2013, approximately 60% for each year of the Company’s net accounts receivable were derived from its clinical laboratory business. The Company believes that the concentration of credit risk with respect to the Clinical Labs accounts receivable is mitigated by the diversity of its third party payers that insure individuals.

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, 2014, 2013 and 2012 were approximately 22%, 22% and 21% respectively, of the clinical laboratory segment’s total revenue. We estimate contractual adjustment based on significant assumptions and judgments, such as the interpretation of payer reimbursement policies which bears the risk of change. The estimation process is based on the experience of amounts approved as reimbursable and ultimately settled by payers, versus the corresponding gross amount billed to the respective payers. The contractual adjustment is an estimate that reduces gross revenue, based on gross billing rates, to amounts expected to be approved and reimbursed.

Gross billings are based on a standard fee schedule we set for self-payers, all third party payers, including Medicare, health maintenance organizations (“HMO’s) and managed care providers. We adjust the contractual adjustment estimate quarterly, based on our evaluation of current and historical settlement experience with payers, industry reimbursement trends, and other relevant factors. The other relevant factors that affect our contractual adjustment include the monthly and quarterly review of: 1) current gross billings and receivables and reimbursement by payer, 2) current changes in third party arrangements, and 3) the growth of in-network provider arrangements and managed care plans specific to our Company. The clinical laboratory industry is characterized by a significant amount of uncollectible accounts receivable related to the inability to receive accurate and timely billing information in order to forward it on to the third party payers for reimbursement, and the inaccurate information received from the covered individual patients for unreimbursed unpaid amounts. Our provision for uncollectible accounts receivable is within historical expectations.

Other than the Medicare program, revenues from United Healthcare and Oxford Health Plan represented approximately 25%, 22% and 21% of the Clinical Labs segment’s net revenue for the fiscal year ended July 31, 2014, 2013 and 2012, respectively. Billing for laboratory services is complicated. Depending on the billing arrangement and applicable law, we must bill various payers, such as patients, insurance companies and the Federal Medicare Program, all of which have different requirements. In both New York and New Jersey, the law prohibits the Company from billing the ordering physician. Compliance with applicable laws and regulations as well as, internal compliance policies and procedures adds further complexity to the billing process. We depend on the ordering physician to provide timely, accurate billing demographic and diagnostic coding information to us. Additional factors complicating the billing process include:

- pricing differences between our standard gross fee schedules and the reimbursement rates of the payers;
- disputes with payers as to which party is responsible for payment; and
- disparity in coverage and information requirements among various payers.

We believe that most of our bad debt expense is primarily the result of inaccurate billing information on requisitions received from the ordering physician. In addition, the bad debts includes the balances, after receipt of the approved settlements from third party payers for the insufficient diagnosis information received from the ordering physician, which result in denials of payment and the uncollectible portion of receivables from self payers, including deductibles and copayments, which are subject to credit risk and patients' ability to pay. We perform the requested tests and report test results regardless of whether the billing or diagnostic coding information is inaccurate or missing. We subsequently attempt to contact the ordering physician to obtain and rectify incorrect billing information.

Missing or inaccurate information on the requisitions adds complexity to and may slow the billing process, creates backlogs of unbilled requisitions, and generally decreases the collectability and increases the aging of accounts receivable. When all issues relating to the missing or inaccurate information are not resolved in a timely manner, the related receivables are fully reserved to the allowance for doubtful accounts or allowances for contractual adjustments or written off.

We incur significant additional costs as a result of our participation in Medicare, as billing and reimbursement for clinical laboratory testing is subject to considerable and complex and stringent federal and state regulations including those relating to coverage, billing and reimbursements. Future changes in regulations could further complicate our billing and increase our billing expenses.

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

The established Medicare reimbursement rate for clinical laboratory services has been reduced by the Federal government in a number of instances over the past several years. In March 2010, U.S. federal legislation was enacted to reform healthcare. The legislation provides for reductions in the Medicare clinical laboratory fee schedule of 1.9% for five years beginning in 2010 and also includes a productivity adjustment which reduces the Consumer Price Index ("CPI") market basket update beginning in 2011. Based on these calculations, the Medicare Fee Schedule was increased in calendar year 2012 by 0.65%, decreased in calendar year 2013 by 2.95%, and decreased in calendar year 2014 by 0.75%. Future reductions/increases may occur depending on percentage changes in the CPI-U. In connection with recent government sequestration Medicare reimbursement rate were further reduced by 2% in April 2013. Under the Patient Protection and Affordable Care Act, expansion in the pool of covered lives may expand the market for clinical diagnostic testing while at the same time various policies aimed at reducing cost or bundling care may reduce the rates paid for such services the net impact of these factors on the market for our tests is not clear. In April 2014, Congress passed the Protecting Access to Medicare Act of 2014, which included substantial changes to the way in which clinical laboratory services will be paid under Medicare. Beginning in 2017, Medicare payments for clinical laboratory services will be paid based upon private payer rates as reported by clinical laboratories across the US replacing the current system which is based upon fee schedules derived from historical charges for tests from approximately 30 years ago. The impact of the new payment system on rates for tests we perform or our customers' tests that may use our products is not clear at this time.

The Patient Protection and Affordable Care Act also 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 and establishes the Independent Payment Advisory Board (“IPAB”). If the projected growth in per capita Medicare costs exceeds a specified target level, the IPAB must submit proposals to reduce or eliminate the difference. For calendar years 2015 through 2019, the target growth rate is the projected average of the increases in the Consumer Price Index and the medical care expenditure category of the Consumer Price Index; for 2020 and thereafter, the target growth rate is the rate of increase in gross domestic product per capita plus one percentage point. If it is necessary for the IPAB to submit proposals, they will automatically be implemented unless Congress enacts alternative proposals that achieve the same savings targets. We could experience a significant decrease in revenue from Medicare as a result of these pieces of legislation, which could have a material adverse effect on us. The IPAB current has no appointees and it is unclear whether when and if it will become operational.

Research and Development

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

In the fiscal years ended July 31, 2014, 2013 and 2012, the Company incurred costs of approximately \$3.1 million, \$3.9 million and, \$6.3 million, respectively, for research and development activities. During fiscal 2014, the Company’s research and development program was refocused to areas that had greater opportunity to maximize revenues.

Internal Research Programs

Our professional staff, including 56 with post graduate degrees, performs our internal research and development activities. Our product development programs incorporate various scientific areas of expertise, including recombinant DNA, monoclonal antibody development, enzymology, microbiology, biochemistry, molecular biology, organic chemistry, and fermentation. In addition, we continuously review in-licensing opportunities in connection with new technology.

External Research Collaborations

We have and continue to explore collaborative relationships with prominent companies and leading-edge research institutions in order to maximize the application of our technology in areas where we believe such relationship will benefit the development of our technology.

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) distributors in major geographic markets. We operate with an understanding of local markets and a well-functioning distribution network system across the globe. Scientists around the world who recognize the brands (Alexis, Assay Designs, Biomol, Enzo and Stressgen) now receive products directly from Enzo Life Sciences where we are recognized for innovative high quality products, supported directly by our qualified technical staff. We sell the same products through our Axxora electronic market place which is also the source for life science research reagents from over 40 original manufacturers. Our direct marketing and sales network includes fully-owned subsidiaries (USA, Switzerland, Germany, Benelux, and UK), a branch office in France and a network of third party distributors in most other significant markets worldwide.

For Enzo Clinical Labs, we focus our sales efforts on obtaining and retaining profitable accounts. We market the clinical laboratory services to a broad range of ordering physicians in the metro New York, New Jersey and Eastern Pennsylvania region through our direct sales force who are supported by customer service and patient service representatives. We monitor and where appropriate, change the service levels and terminate ordering physician accounts that are not profitable. We are focusing our efforts to attract and retain clients who participate with the providers with whom we have regional contracts and are consistently looking to add higher value molecular and esoteric testing, both internally developed and with partners, to our menu to assist sales in new account penetration as well as to improve our level of service to existing clients.

Distribution Arrangements

We also distribute our life science products internationally through a network of distributors. Through these arrangements, we are able to leverage the established marketing and distribution infrastructure of these companies in certain market places.

Competition

We compete with other life science and biotechnology companies, as well as pharmaceutical, chemical and other companies. Competition in our industry is intense. Many of these companies are performing research targeting the same technology, applications and markets. Many 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 2014 we owned or licensed over 145 patents relating to products, methods and procedures resulting from our internal or sponsored research projects. There can be no assurance that patents will be issued on pending applications or that any issued patents will not be challenged (see Item 3, Legal Proceedings), or that they will have commercial benefit. We do not intend to rely on patent protection as the sole basis for protecting our proprietary technology. We also rely on our trade secrets and continuing technological innovation. We require each of our employees to sign a confidentiality agreement that prohibits the employee from disclosing any confidential information about us, including our technology or trade secrets.

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

Nucleic Acid Chemistry

We currently have broad patent coverage in the area of nucleic acid chemistry. We have done extensive work on the labeling of nucleic acids for the purpose of generating a signal that dates back over twenty years. Enzo has multiple issued patents covering the modification of nucleic acids at their sugar and phosphate sites. The claims contained in these patents cover products that incorporate a signaling moiety into a nucleic acid attached to a sugar or phosphate for the purpose of nucleic acid detection or quantification, including sequencing and real time nucleic acid amplification. Enzo also has patents directed to proprietary dyes that may be used to label the sugar, base or phosphate positions of nucleic acids.

Signal Delivery

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

Nucleic Acid Analysis Format

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

In some instances, we may enter into royalty agreements with collaborating research parties in consideration for the commercial use by us of the developments of their joint research. In other instances the collaborating party might obtain a patent, but we receive the license to use the patented subject matter.

In such cases, we will seek to secure exclusive licenses. In other instances, we might have an obligation to pay royalties to, or reach a royalty arrangement with, a third party in consideration of our use of developments of such third party.

REGULATION AFFECTING OUR BUSINESSES

Clinical Laboratory

The clinical laboratory industry is subject to significant federal and state regulation, including inspections and audits by governmental agencies. Governmental authorities may impose fines, criminal penalties or take other actions to enforce laws and regulations, including, but not limited to, revocation of a clinical laboratory's certificate and/or license to operate a clinical laboratory. Changes in regulation may also increase the cost of performing clinical laboratory tests, increase administrative requirements, or decrease the amount of reimbursement. Our clinical laboratory and (where applicable) patient service centers are licensed and accredited as required by law.

CLIA (The Clinical Laboratory Improvement Act of 1967, and the Clinical Laboratory Improvement Amendments of 1988) regulates virtually all clinical laboratories in the United States. Among other things, CLIA requires laboratories to earn certification from 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. As such, certain clinical laboratories must meet state specific standards and undergo proficiency testing and inspections. Clinical laboratory certificates or licenses are also required by various state and local laws.

CLIA assigns test into one of three categories on the basis 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 that if granted, would exempt the laboratory from most CLIA requirements. Our facility is certified to perform high complexity tests. In general, regulations promulgated by the United States Department of Health and Human Services (“HHS”) 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 that personnel meet specified standards, conduct proficiency testing by approved agencies, and undergo biennial inspections, among other requirements.

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 a licensure program that is CLIA-exempt, 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 are in compliance with all applicable regulatory requirements.

Sanctions for non-compliance with applicable regulations may include, but are not limited to, suspension, revocation, or limitation of a laboratory’s CLIA certificate or state license, as well as fines and criminal penalties. The loss of, or adverse action against, a certificate or license, the imposition of fines, penalties or other sanctions, or future changes in Federal, state or 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 complex federal and state laws, rules and regulations, the violation of which may include, but is not necessarily limited to: (1) exclusion from participation in federal health care programs (including Medicare and Medicaid); (2) asset forfeitures; (3) civil monetary penalties; (4) criminal fines and penalties; and (5) the loss of licenses, certificates and/or authorizations necessary to operate some or all of a clinical laboratory’s business.

The health care industry has been undergoing significant change because third-party payers, such as Medicare, Medicaid, 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 current and future health care reform measures, 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 Clinical Laboratory Fee Schedule. Under the Patient Protection and Affordable Act, expansion in the pool of covered lives may expand the market for clinical diagnosis testing while at the same time, various policies aimed at reducing costs or bundling care may reduce the rates paid for such services; the net impact of these factors on the market for our tests is not clear. In April 2014, Congress passed the Protecting Access to Medicare Act of 2014, which included substantial changes to the way in which clinical laboratory services will be paid under Medicare. Beginning in 2017, Medicare payments for clinical laboratory services will be paid based upon private payer rates as reported by clinical laboratories across the US replacing the current system, which is based upon fee schedules derived from historical charges for tests from approximately 30 years ago. The impact of the new payment system on rates for test perform or our customers' tests that may use our products is not clear at this time.

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, 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. During calendar year 2013 the Medicare reimbursement rates were reduced by an additional 2% in connection with the government's sequestration cuts. During fiscal 2014 reimbursement rates have remained constant with 2013 levels.

Anti Fraud and Abuse Laws

Existing Federal and state laws also regulate certain aspects of the relationship among healthcare providers, including clinical laboratories, and their referral sources (i.e., physicians, hospitals, other laboratories, etc.). One of these laws, known as the “Anti-Kickback Statute,” contains extremely broad prohibitions against giving, accepting, soliciting (i.e., asking for) or arranging for remuneration in any form (i.e., cash, gifts, certain discounts, cross-referrals between parties, etc.), either directly or indirectly, for the purpose of inducing or rewarding another party for referrals of items or services paid for by a federal government health care program. The Anti-Kickback statute is very broad and includes the purchasing, ordering, leasing or arranging for, or recommending the purchase, leasing or ordering of, services paid for by a federal health care program in exchange for remuneration (i.e., anything of value).

Violation of the Anti-Kickback Statute may result in, among other things, a criminal conviction, significant monetary penalties and exclusion from federal health care programs (including Medicare and Medicaid). Any person or entity involved in a prohibited transaction is potentially subject to criminal and civil penalties. A laboratory that claims payment for business generated by the Anti-Kickback Statute may also be subject to prosecution for violating a separate civil statute, the federal False Claims Act.

The False Claims Act is also a broad statute that the government often utilizes to combat fraud and abuse in the health care environment. Among other things, the statute is violated by any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; conspires to commit the above (or other specified) violations; or knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government. The False Claims Act also provides that private parties may bring an action on behalf of (and in the name of) the United States to prosecute a False Claims Act violation. These private parties (known as “qui tam relators”) may share in a percentage of the proceeds that result from a False Claims Act action or settlement. A person or entity found to have violated the False Claims Act may be held liable for a per claim civil penalty of not less than \$5,500 and not more than \$11,000, plus three times the amount of damages sustained by the government. A person violating the False Claims Act is also liable for the costs of the civil action brought to recover any such penalty or damages. Other consequences may also result from a violation of the False Claims Act. New York has also adopted its own False Claims Act statute, which closely mirrors its federal counterpart.

Another Federal law, commonly known as the “Stark” law, prohibits physicians who have a financial relationship with an entity that furnishes “designated health services,” which includes clinical laboratory services (including anatomic pathology and clinical chemistry services), from referring Medicare beneficiaries to that entity for laboratory tests unless a specific exception applies.

In addition, laboratories may not bill federal health care programs, or any other payor, for services furnished pursuant to a prohibited referral. Violation of the Stark law may result not only in denial of payment for the underlying testing services, but also the imposition of civil monetary penalties and, potentially, False Claims Act liability. New York

State has adopted laws that are similar to the Federal Stark law and Anti-Kickback Statute, which contain similar prohibitions and penalties.

The Stark law and New York State regulations have also placed restrictions on the supplies and other items that laboratories may provide to their clients. These laws specify that laboratories may only provide clients with items or devices that are used solely to collect, transport or store specimens for the laboratory or to communicate results or tests. Items such as biopsy needles, snares and reusable needles are specifically prohibited from being supplied by laboratories to their clients. The Company has implemented procedures to ensure compliance with these laws and restrictions.

In February 1997, the OIG released model voluntary compliance program guidance for laboratories. One key aspect of the model compliance guidance was an emphasis on the responsibility of laboratories to notify physicians that Medicare covers only medically necessary services. This requirement, and the likely effect on physician test ordering habits, focuses 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, it could potentially affect physicians' test ordering habits more broadly. The Company is unable to predict whether, or to what extent, these developments have impacted, or may impact, utilization of the Company's services.

The federal health care reform legislation adopted in March, 2010, known as the Patient Protection and Affordable Care Act, contains provisions requiring providers to establish compliance programs as a condition of enrollment in Medicare, Medicaid and the State Children's Health Insurance Program. Implementing regulations and guidance for clinical laboratories has not yet been issued yet by the Centers for Medicare and Medicaid Services. In addition, New York State has adopted mandatory compliance program requirements for certain specified providers, including those who directly or indirectly bill or collect more than \$500,000 annually in Medicaid payments, and entities licensed under certain articles of the Public Health Law and Mental Hygiene Law, respectively. The Company has adopted its own Corporate Compliance Program based upon the OIG model program guidance and in accordance with New York State's requirements.

The Company's compliance program focuses on, among other things, establishing clear compliance standards; auditing and monitoring of the Company's billing and coding practices; training personnel on compliance standards, policies and procedures; preventing and detecting fraud, waste and abuse, enforcing a policy of non-retaliation and non-intimidation for good faith participation in the compliance program; and establishing good faith reporting of actual or suspected compliance violations.

The Company seeks to structure its arrangements with physicians and other customers in compliance with federal and state Anti-Kickback laws, Stark laws, False Claims Acts, and other applicable laws, rules and regulations, and to keep current on developments concerning their application to the Company, including consultation with legal counsel. However, the Company is unable to predict how such laws and regulations will be interpreted and applied in the future, and thus no assurances can be given that its arrangements or processes will not become subject to scrutiny by a governmental agency.

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 security and breach notification standards and include the requirement to use a National Provider Identifier in electronic health care transactions. The National Provider Identifier is an identifier that replaced all other identifiers that are currently used or healthcare transactions (e.g., UPIN, Medicaid provider numbers, identifiers assigned by commercial insurers). The regulations promulgated under HIPAA have very broad applicability, including by specifically applying to health care providers, which include physicians and clinical laboratories that conduct an electronic transaction for which HIPAA has articulated standards. Together, health plans, health care clearinghouses and health care providers that conduct standard transactions subject to HIPAA are referred to as "Covered Entities".

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 health care provider, health care clearinghouse or health plan, we must comply with the standards set forth in the regulations. The regulations established standard data content and format for submitting electronic claims and other administrative health transactions. Health care providers and health plans are required to use standard formats when transmitting claims, referrals, authorizations, and certain other transactions electronically. The Company believes it is in compliance with these standards.

Privacy, security and breach notification requirements regarding protected health information ("PHI").

We are required to maintain numerous policies and procedures in order to comply with the HIPAA privacy security and breach notification requirements. Furthermore, we need to continuously ensure that there are mechanisms in place to safeguard the privacy of PHI that is transmitted or maintained in any format (e.g. oral, written, or electronic). Failure to comply with these requirements can result in criminal and civil penalties.

To comply with the HIPAA security regulations in particular, we must ensure the confidentiality, integrity and availability of all electronic PHI (“E PHI”) 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 periodically conduct an accurate and thorough assessment of the potential risks and vulnerabilities of the confidentiality, integrity and availability of our E PHI and then document our response to the various security regulations on the basis of that assessment.

The privacy, security and breach notification regulations were last modified in 2013 as a result of final regulations published pursuant to the Health Information Technology Act (“HITECH”). HITECH requires, among other things, that providers, such as laboratories, notify patients of breaches of unsecured PHI, enter into new business associate agreements with existing business associates and revise many of their existing privacy policies. In addition, HITECH makes business associates directly liable to the Federal government for compliance with certain aspects of the privacy, security and breach notification regulations. As implemented in regulations, a downstream subcontractor of a business associate that creates, receives, maintains, or transmits PHI on behalf of the business associate is also itself considered a business associate. Under the regulations issued in 2013, health care providers, such as laboratories, that are subject to HIPAA as a Covered Entity are vicariously liable for violations of HIPAA based on acts or omissions of their agents, including business associates, when the agent is acting within the scope of the agency.

Complying with the electronic transaction, privacy, security and breach notification rules requires significant effort and expense for virtually all entities that conduct health care transactions electronically and handle PHI.

Medical Regulated Waste

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

Occupational Safety

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

Other Regulation

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

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

at a remote location could result in material liability.

Regulation of Diagnostics

The diagnostic products that are developed by our collaborators, or by us, are likely to be regulated by the FDA as medical devices. Unless an exemption applies, medical devices must receive either “510(k) clearance” or pre-market approval (“PMA”) from the FDA before marketing them in the United States. Both the 510(k) clearance and PMA processes may be costly and time consuming, but the process of obtaining PMA approval is much more costly, lengthy and uncertain. 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. In a pre-market notification, the applicant must demonstrate that the proposed device is “substantially equivalent” in intended use and in safety and effectiveness to a legally marketed “predicate device” that is either in class I, class II, or is a “pre-amendment” class III device (i.e., one that was in commercial distribution before May 28, 1976) for which the FDA has not yet called for submission of a PMA application.

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

Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or deemed not substantially equivalent to a legally marketed class I or class II predicate device, or to a preamendment class III device, for which PMAs have not been called, are placed in class III. Such devices are required to undergo the PMA approval process in which the manufacturer must provide sufficient valid scientific evidence of the safety and effectiveness of the device. A PMA application typically requires the collection of 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 certain in vitro diagnostic (“IVDs”) tests are exempt from the IDE requirement 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 for use in the laboratory research phase of development and not represented as an effective IVD (i.e. labeled for Research Use Only (RUO)) or for use in product testing prior to full commercial marketing (i.e. for Investigational Use Only (IUO)). Because RUO and IUO-labeled products are exempt from most regulatory requirements it is important that they are not distributed for clinical diagnostics use. Mere placement of an RUO or IUO label on an IVD product does not render the device exempt from otherwise applicable regulatory requirements; indeed, FDA may determine that the device is intended for use in clinical diagnosis on the basis of other evidence, including how the device is marketed. FDA recommends that manufacturers assess the totality of the circumstances surrounding the distribution of their RUO and IUO labeled products to ensure that they are not engaging in practices that conflict with their labeling. 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 sale and distribution of RUO devices could result in enforcement action by the FDA, including the imposition of restrictions on our distribution of these products.

Although FDA has long asserted it has jurisdiction over laboratory-developed tests, the agency has historically exercised discretion enforcement with respect to most such test and not required laboratories that furnish these tests to comply with FDA’s regulatory requirements for medical devices. However, on July 31, 2014, the FDA issued a 60-day notice to Congress indicating that the FDA intends to issue Draft Guidance on the regulation of laboratory-developed test. In the notice, FDA indicates that it intends to end its policy of general enforcement discretion towards laboratory-developed test, and proposes the implementation of a risk-based regulatory framework. Under the proposed framework, many laboratory-developed tests would be subject to FDA’s requirements for medical devices, including registration and listing premarket review, medical device reports and quality systems regulations. The implementation of this framework would not begin until after a Final Guidance is issued and would occur over a nine year period with those tests that FDA considers to be highest risk falling under FDA’s review requirements first. It is unclear at this time

whether the Draft Guidance will be released officially in late September 2014, and if it is released officially at that time, it is unclear whether or if such Guidance will be finalized.

In so far as the devices that we manufacture or distribute are subject to the premarket notification or premarket approval requirements a host of additional regulatory requirements may apply, including registration and listing 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 may also be subject to 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 with applicable requirements, 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, operating restrictions, partial suspension or total shutdown of production, refusal of our requests for 510(k) clearance or PMA approval of new products, withdrawal of 510(k) clearance or PMA approvals already granted, and criminal prosecution.

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

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

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

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

Regulation of Pharmaceutical Products

New drugs and biological drug products are subject to regulation under the Federal Food, Drug and Cosmetic Act, and biological products are also regulated under the Public Health Service Act. We believe that certain 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 approval 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 review and approve 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 our pharmaceutical products, we (as the sponsor) file an Investigational New Drug (“IND”) application with FDA 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 also reviewed approved and overseen by an Institutional Review Board (IRB). In considering an application to perform a clinical trial, IRB will consider, among other things, ethical factors and the safety of human subjects participating in the trial. 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 may take several years to complete, but the period may vary.

Certain regulations promulgated by the FDA may shorten the time periods and reduce the number of patients required to be tested in the case of certain life-threatening diseases, which lack available alternative treatments. The FDA receives reports on the progress of each phase of clinical testing, and it may require the modification, suspension or termination of clinical trials if an unwarranted risk is presented to patients. Human gene medicine products are a new category of therapeutics.

There can be no assurance regarding the length of the clinical trial period, the number of patients that the FDA will require to be enrolled in the clinical trials in order to establish the efficacy, safety, purity and/or 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.

Manufacturing and Research Facilities

Our internal integrated laboratory and scientific efforts for our three segments take place primarily at our two adjacent facilities in Farmingdale, New York. A major part of one facility is utilized by Life Science as its global headquarters, and also for research and manufacturing with special handling capabilities and clean rooms suitable for our operations. The Life Sciences segment has centered its US logistics, reagent and kit manufacturing at its facility in Ann Arbor, Michigan, and has European logistics operations in Lausen, Switzerland. We also contract with qualified third-party contractors to manufacture our products in cases where we deem it appropriate, for example, when it is not cost-effective to produce a product ourselves or where we seek to leverage the expertise of another manufacturer in a certain area.

Employees

As of July 31, 2014, we employed 433 full-time and 42 part-time employees. Of the full-time employees, 101 were engaged in research, development, manufacturing, and marketing of research products, 3 in therapeutics research, 294 in performing testing, marketing and billing our clinical laboratories services and 35 in finance, legal, administrative and executive functions. Our scientific staff, including 56 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,” “contemplates,” or other similar expressions. These statements are based on the Company’s current expectations of future events and are subject to a number of risks and uncertainties that may cause the Company’s actual results to differ materially from those described in the forward-looking statements. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, estimated or projected. The Company assumes no obligation to revise or update any forward-looking statements for any reason, except as required by law.

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

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

Enzo Biochem, Inc.

527 Madison Ave.

New York, New York 10022

Tel: (212) 583-0100

Attn: Investor Relations

Item 1A. Risk Factors

Risks relating to our Company and our industries

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

We incurred net losses of \$10.0 million, \$18.2 million, and \$39.3 million, inclusive of a non-cash impairment charge of \$22.4 million net of tax of \$2.1 million (See Note 2, to the Consolidated Financial Statements) for the fiscal years ended July 31, 2014, 2013 and 2012, respectively. If our revenues do not increase, or if our operating expenses exceed expectations or cannot be reduced, we will continue to suffer substantial losses and use cash in operations which could have an adverse effect on our business and adversely affect your investment in our Company.

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

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

Our operating results may vary from period to period.

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

- competitive conditions, including changes in third-party reimbursements;

- health care reform regulations affecting providers and plan sponsors;
- changes in reimbursement policies from third party payers;
- exchange rate fluctuations;
- changes in tax laws, the results of tax audits or the measurement of tax uncertainties;
- the timing of our research and development, sales and marketing expenses;
- the introduction of new products by us or our competitors;
- the success of identifying, acquiring and integrating businesses that complement our product offerings, add new technology or add presence in a market;
- expenses associated with defending our intellectual property portfolio;
- customer demand for our products due to changes in purchasing requirements and research needs;
- general worldwide economic conditions affecting funding of research and
- seasonal fluctuations affected by weather and holiday periods.

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

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

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

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

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

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

The market for our products is characterized by rapidly changing technology, evolving industry standards and new product introductions, which may make our existing products obsolete.

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

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

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

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

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

The Life Sciences segment continues a marketing program designed to more directly service its end users, while simultaneously promoting the Enzo Life Science brand, with reference to our acquired brands. We will continue to reach out to our customers using our direct field sales force, in house business team, the on-going enhancement of our interactive websites, continued attendance at top industry trade meetings, and publications to customers and in leading scientific journals. In addition to our direct sales, we operate worldwide through wholly-owned subsidiaries (in USA, Switzerland, Belgium, Germany, and the UK), a branch office in France and a network of third-party distributors in most other significant markets. If we are unable to successfully continue these programs, we may be unable to grow and our business could suffer.

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

Our competitors in the biotechnology industry in the United States and abroad are numerous and include major pharmaceutical, energy, food and chemical companies, as well as specialized genetic engineering firms. Many of our large competitors have substantially greater resources than us and have the capability of developing products which compete directly with our products. Many of these companies are performing research in the same areas as we are. The markets for our products are also subject to competitive risks because markets are highly price competitive. Our competitors have competed in the past by lowering prices on certain products.

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