ENZO BIOCHEM INC
Form 10-K
October 13, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

(Mark one)

x ANNUAL REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended July 31, 2015

or

o TRANSITION REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission File Number 001-09974

ENZO BIOCHEM, INC.
(Exact name of registrant as specified in its charter)

New York	13-2866202
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
527 Madison Ave. New York, New York	10022
(Address of principal executive offices)	(Zip Code)

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

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

(Title of Each Class)	(Name of Each Exchange on Which Registered)
Common Stock, $.01 par value	The New York Stock Exchange

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

Yes o No x

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

Yes o No x

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 x No o

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

Yes x No o

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 x No o

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 o Accelerated filer x Non-accelerated filer o Smaller Reporting Company o

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

The aggregate market value of the registrant's voting stock held by non-affiliates of the registrant was approximately $133,362,557 as of January 31, 2015.

The number of shares of the Company's common stock, $.01 par value, outstanding at October 1, 2015 was 46,062,065.

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 21, 2016 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 biotechnology company focusing on delivering and applying advanced technology capabilities to produce affordable reliable products and services to allow our customers to meet their clinical needs. We develop, manufacture and sell our proprietary technology solutions and platforms to clinical laboratories, specialty clinics and researchers and physicians globally. Our pioneering work in genomic analysis coupled with our extensive patent estate and enabling platforms have positioned the Company to continue to play an important role in the rapidly growing molecular medicine marketplaces.

Enzo technology solutions and platforms and unique operational structure is designed to reduce overall healthcare costs to both government and private insurers. Our proprietary technology platforms reduces our customers’ need for multiple, specialized instruments, and offer a variety of throughput capabilities together with a demonstrated high level of accuracy and reproducibility. Our genetic test panels are focused on large and growing markets primarily in the areas of personalized medicine, women’s health, infectious diseases and genetic disorders.

For example, our AmpiProbe™ technology platform can lead to the development of an entire line of nucleic acid clinical products that can allow laboratories to offer a complete menu of services at a cost that allows them to enjoy an acceptable margin. Our technology solutions provide tools to physicians, clinicians and other health care providers to improve detection, treatment and monitoring of a broad spectrum of diseases and conditions. In addition, reduced patient to physician office visits translates into lower healthcare processing costs and greater patient services.

In the course of our research and development activities, we have built a substantial portfolio of intellectual property assets, comprising 245 issued patents worldwide, and over 170 pending patent applications, along with extensive enabling technologies and platforms.

Operating Segments

We are comprised of three interconnected operating segments which 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, 2015, 2014 and 2013 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 clinical reference laboratory providing a wide range of clinical services to a physicians, medical centers, other clinical labs and pharmaceutical companies. The Company believes having a College of American Pathologists ("CAP") certified medical laboratory located in New York provides us to the opportunity to more rapidly introduce cutting edge products and services to the clinical marketplace. Enzo Clinical Labs offers an extensive menu of molecular and other clinical laboratory tests or procedures used in patient care by physicians to establish or support a diagnosis, monitor treatment or medication, and search for an otherwise undiagnosed condition. Our laboratory is equipped with state of the art communication and connectivity solutions enabling the rapid transmission, analysis and interpretation of generated data. We operate a full service clinical laboratory in Farmingdale, New York, a network of over 30 patient service centers throughout New York and New Jersey, a free standing "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 clinical research, drug development and bioscience research customers worldwide. Underpinned by broad technological capabilities, Enzo Life Sciences has developed proprietary products used in the identification of genomic information by laboratories around the world. Information regarding our technologies can be found in the "Core Technologies" section. We are internationally recognized and acknowledged as a leader in the development, manufacturing validation and commercialization of numerous products serving not only the clinical research market but life sciences researchers in the fields of cellular analysis and drug discovery, among others. Our operations are supported by global operations allowing for the efficient marketing and delivery of our products around the world.

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 111 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, 2015, 2014 and 2013 (in thousands and percentages):

Fiscal year ended July 31,	**2015**		**2014**		**2013**	
Clinical laboratory services	$63,414	65 %	$58,689	61 %	$55,889	59 %
Product revenues	31,690	32	32,850	34	32,526	35
Royalty and license fee income	2,495	3	4,408	5	5,292	6
Total	$97,599	100%	$95,947	100%	$93,707	100%

Markets

Clinical diagnostics

The domestic clinical diagnostics market has been reported by industry sources to be greater than $23 billion annually 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 cell culture technologies.

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, gonorrhoea and chlamydia are difficult to culture.

Molecular-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 $7 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.

Diagnostic Products and Tools

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.

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 signalling pathway. One of the most notable cell signalling 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 develop, manufacture and sell high through-put, high value and affordable reliable molecular diagnostic products and services using our proprietary technologies to allow our customers to meet their clinical needs. Our proprietary technology platforms, if successful, will alter the existing business models and improve economics across the healthcare industry. Our strong intellectual property estate provides freedom to operate and compete in a rapidly growing molecular diagnostic healthcare marketplace.

We believe our expertise in developing and marketing proprietary technology platforms uniquely positions Enzo to provide products and services that will change the fundamental relationship between molecular diagnostic companies and clinical laboratories. Our technology platforms will provide economic and market optionality to use Enzo's products and services for margin improvement. As such, clinical laboratories will be able to compete and enter into markets that until now have been out of reach to do poor economics as a result of high costs of regents and equipment rental arrangements from molecular diagnostic companies coupled with lower reimbursement from governmental and commercial healthcare companies.

Our objective allows clinical laboratories to purchase low cost regents or kits to be run on open system platforms already in use in their labs, or use Enzo as a low cost reference laboratory. Enzo's integrated business model not only provides benefits to clinical laboratories but insurance providers will benefit from more clinical laboratories able to compete for testing services with national laboratories.

Increase investment in research and development & product development

We are increasing our research and development efforts to develop new leading edge solutions in the rapidly growing molecular diagnostic market place. Current technology platforms under development include:

- FlowScript® – enhanced flow cytometry for signal cell analysis
- Enhanced Immunohistochemistry – moving Pathology to the next generation
- Ampiprobe™ – low cost, real time DNA amplification and detection
- Enhanced Immunoassays – Pushing sensitivity to expand immunoassay applications

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

We believe our expertise in developing and securing approvals of novel platform technologies will enable us to shorten the development time and capture meaningful market share.

Continue to Commercialize New Platforms for Molecular Diagnostics via Multiple Channels

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 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.

We have already introduced the first product using our FlowScript™ platform technology for the identification of gene expression in clinical samples in detection of mRNA from Human papillomavirus (HPV) oncogenes, E6 and E7. Overexpression of these HPV oncogenes promotes the growth of malignant cells leading to the development of cervical cancer. The FlowScript™ technology platform is a proprietary, flow cytometry-based, molecular detection system for the multiplex analysis of cell function and identity, and was developed by cross-functional teams at Enzo. The HPV E6/E7 assay is the first product to utilize this novel platform. Analysis is performed on a small volume of a liquid cytology specimen and can thus be easily incorporated as a reflex test measure following abnormal Pap smear results. The assay, and the platform on which it is based, allows for the simultaneous analysis of several different genes expressed in every cell in a given sample. In this manner, it is possible to produce clinically relevant data at the single cell level. Unlike other assays that study mRNA expression, FlowScript™ assays are performed by a homogenous system that eliminates washing steps that can reduce fluctuation of results. Additionally, the assay's use of external control improves run-to-run consistency. As a result, both hands on time and the number of steps are reduced, allowing for improved economics. In data presented at a 2015 pathology conference in Italy, Enzo's assay was shown to produce reliable and consistent results near the limit of assay detection. Furthermore, Enzo anticipates applying this platform to a multiplicity of uses such as the study of other cancers, the evaluation of an individual immune state as well as products targeted to the drug development market, among others.

The FlowScript™ platform is used to help guide providers in assessing the risk of progression to cervical cancer and whether colposcopy or follow-up screening should be the preferred course of action. This assay demonstrates Enzo's commitment to utilize our proprietary technology and bring forward clinically relevant diagnostics that can inform patient and physician decision-making, with potential to reduce spending associated with advanced stage disease. Moreover, it is indicative of how well we are executing on our strategy of utilizing our integrated structure to produce products that are relevant to today's evolving healthcare marketplace.

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 a 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 such as clinical laboratories, researchers and pharmaceutical companies, 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 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 2015, we were issued 31 patents and expanded our patent estate in the area of nucleotides, amplification, labelling 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);
- labelling 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 AmpiProbe™ a broad technology base for the labelling, detection, amplification and formatting of nucleic acids for gene analysis which is supported by our significant proprietary position in these fields. This and other 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.

Flow Cytometry

We have developed and launched our first product using our proprietary FlowScript® platform using flow cytometry to analyse messenger RNA (mRNA) transcript expression in individual cells in a mixed cell population. By studying whether a gene or a set of genes is turned on or off, it is possible to obtain clinically relevant information at the single cell level. Our first product, the FlowScript® HPV E6/E7 Assay, examines the levels of E6/E& mRNA transcripts from multiple high risk types which account for over 95% of cervical cancers. We are planning to develop and introduce other products based on this platform technology in the future for applications such as immune-mediated disorders, metabolic disorders patient monitoring, and other cancers.

Non-radioactive labelling and detection

Traditionally, nucleic acid probes were labelled with radioactive isotopes. However, radioactively labelled 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 labelled 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 Signalling 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 signalling pathway thus producing a means to modify biologic activity in a number of physiological systems.

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

•generate biological, genetic, and structural information concerning LRP;

•determine the structure of LRP docking sites of its ligands;

•identify the functionally important residues via site-directed mutagenesis;

•build the fine structure map and employ it as the basis for virtual screening;

•show that compounds specifically bind to wild type LRP5, but not to mutated LRP5;

•generate a cell-based assay capable of identifying active compounds; and

•synthesize proprietary molecules that are active in animal models of disease.

Through this novel, proprietary, functional screening system, we have identified small molecules capable of reversing sclerostin-mediated inhibition of Wnt signalling. 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 signalling pathway. Therefore, this approach may be broadly applicable to the generation of therapeutic drug candidates for multiple indications.

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 signalling, 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.

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. 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 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, 2015, 2014 and 2013, respectively, approximately 65%, 61% and 59% of the Company's revenues were derived from the clinical laboratory. Revenues, net of contractual adjustment, from direct billings under the Federal Medicare program during the years ended July 31, 2015, 2014 and 2013 were approximately 19%, 22% and 22% respectively, of the clinical laboratory segment's total revenue. The contractual adjustment is an estimate that reduces gross revenue, based on gross billing rates, to amounts expected to be approved and reimbursed. 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. Other than the Medicare program, revenues from UnitedHealthcare and Oxford Health Plan represented approximately 28%, 25% and 22% of the Clinical Labs segment's net revenue for the fiscal year ended July 31, 2015, 2014 and 2013, respectively.

At July 31, 2015 and 2014, approximately 68% and 60% for each year of the Company's net accounts receivable was 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.

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.

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 add 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.

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 co-payments, which are subject to credit risk and patients' ability to pay. We must 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 decreased in calendar year 2013 by 2.95%, decreased in calendar year 2014 by 0.75% and was unchanged in calendar 2015. 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 2016 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 currently has no appointees and it is unclear whether when and if it will become operational.

Also, HIPAA requires certain health care providers such as Enzo Clinical Labs and its physicians, to use certain transaction and code set rules for specified electronic transactions, such as transactions involving claims submissions. Commencing July 1, 2012, CMS required that electronic claim submissions and related electronic transactions be conducted under a new HIPAA transaction standard called Version 5010. CMS has required this upgrade in connection with another new requirement applicable to the industry, the implementation of new diagnostic code sets to be used in claims submission. The new diagnostic code sets are called the ICD-10. They were originally to be implemented on October 1, 2013 (and CMS delayed the implementation date until October 1, 2014), but as part of the Protecting Access to Medicare Act of 2014, enacted on April 1, 2014, Congress prohibited the Secretary of Health and Human Services from implementing ICD-10 any earlier than October 1, 2015. CMS published a final rule on August 4, 2014 adopting the October 1, 2015 compliance date and requiring the use of ICD-9 code sets through September 30, 2015. It is possible that the transition to these new standards, particularly the transition to ICD-10, may result in a degree of disruption and confusion with physicians, thus potentially increasing accounts receivable at Enzo Clinical Lab due to delays in the timing of billing and payment of diagnostic tests performed.

Life Sciences

Enzo Life Sciences is a 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
Apotosis/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 labelling.

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 glycolsylation.

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

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 Cellestial® 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 our collaborator in Germany, 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. The study is designed as a randomized, double-masked, placebo-controlled proof-of-concept study with a long-term follow-up. Treatment has been concluded and no signs of safety issues were identified. Analysis of both immune system of the patient and clinical observation of the patient beyond the limited trial duration are being conducted and analysed, within subgroups of the patient population. This analysis is independent and beyond the trial endpoints which presented drug/placebo equivalents. This data will be important guidance in future uveitis and macular degeneration trials by immune modulation.

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.

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 and 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, 2015, 2014 and 2013, the Company incurred costs of approximately $3.4 million, $3.1 million and, $3.9 million, respectively, for research and development activities. During fiscal 2015, 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 47 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. 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 2015 we owned or licensed 245 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 tests 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 2015 reimbursement rates have remained constant with 2014 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 (and in certain instances Medicaid) 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, which contain similar prohibitions and penalties and apply regardless of payor.

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 Department of Health and Human Services, Office of the Inspector General (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”) 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 ("EPHI") that we create, receive, maintain, or transmit. We have some flexibility to fashion our own security measures to accomplish these goals. The security regulations strongly emphasize that we must periodically conduct an accurate and thorough assessment of the potential risks and vulnerabilities of the confidentiality, integrity and availability of our EPHI and then document our response to the various security regulations on the basis of that assessment.

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 Diagnostic Products

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 tests 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. The draft guidance was released in late September 2014, and a 120 – day public comment period ended February 2015.

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, 2015, we employed 443 full-time and 40 part-time employees. Of the full-time employees, 109 were engaged in research, development, manufacturing, and marketing of research products, 1 in therapeutics research, 284 in performing testing, marketing and billing our clinical laboratories services and 49 in finance, legal, administrative and executive functions. Our scientific staff, including 47 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," "conti 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

Financial Risks

We have experienced significant losses in our previous 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 $2.3 million, $10.0 million, and $18.2 million for the fiscal years ended July 31, 2015, 2014 and 2013, 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 favourable 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.

Business Risks

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, develop and introduce new products and realize commercial acceptance of those products, in a rapidly changing technological environment.

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, develop and introduce new products, and realize commercial acceptance of those 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.

During the fiscal years 2007 through 2009 we 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. Failure to implement successfully our 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 significant competition, which could cause us to decrease the prices for our products or services or render our products uneconomical or obsolete, any of which could reduce our revenues and limit our growth.

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

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

These competitive conditions could, among other things:

•Require us to reduce our prices to retain market share;

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

•Increase our cost of labor to attract qualified personnel;

•Render our biotechnology products uneconomical or obsolete or;

•Reduce our revenue.

Ethical, legal and social concerns surrounding the use of genetic information could reduce demand for our products.

Genetic testing has raised ethical issues regarding privacy and the appropriate uses of the resulting information. For these reasons, governmental authorities may call for limits on or regulation of the use of genetic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Similarly, such concerns may lead individuals to refuse to use genetics tests even if permissible. Any of these scenarios could reduce the potential markets for our molecular diagnostic products, which could have a material adverse effect on our business, financial condition and results of operations.

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

Our Life Sciences segment manufactures and distributes our own brand products and the products of third party manufacturers and suppliers. Distributors also sell our branded products. To the extent we are unable to maintain or replace a distributor in a reasonable time period, or on commercially reasonable terms, if at all, our operations could be disrupted.

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

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

Our manufacturing, clinical laboratory and research and development processes involve the storage, use and disposal of hazardous substances, including hazardous chemicals, biological hazardous materials and radioactive compounds. We are subject to governmental regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. Although we believe that our safety and environmental management practices and procedures for handling and disposing of these hazardous materials are in accordance with good industry practice and comply with applicable laws, permits, licenses and regulations, the risk of accidental environmental or human contamination or injury from the release or exposure of hazardous materials cannot be completely

eliminated. In the event of an accident, we could be held liable for any damages that result, including environmental clean-up or decontamination costs, and any such liability could exceed the limits of, or fall outside the coverage of, our insurance.

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

We are required to expend significant resources for research and development for our products in development and these products may not be developed successfully. Failure to successfully develop these products may prevent us from earning a return on our research and development expenditures.

The products we are developing are at various stages of development and clinical evaluations and may require further technical development and investment to determine whether commercial application is practicable. There can be no assurance that our efforts will result in products with valuable commercial applications. Our cash requirements may vary materially from current estimates because of results of our research and development programs, competitive and technological advances and other factors. In any event, we will require substantial funds to conduct development activities and pre-clinical and clinical trials, apply for regulatory approvals and commercialize products, if any, that are developed.

We do not have any commitments or arrangements to obtain any additional financing and there is no assurance that required financing will be available to us on acceptable terms, if at all. Even if we spend substantial amounts on research and development, our potential products may not be developed successfully.

If our product candidates on which we have expended significant amounts for research and development are not commercialized, we will not earn a return on our research and development expenditures, which may harm our business.

Risks relating to our Intellectual Property and Regulatory Approval

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

Our potential revenue and success depends in large part on our ability to obtain, maintain and enforce our patents. Our ability to commercialize any product successfully will largely depend on our ability to obtain and maintain patents of sufficient scope to prevent third parties from developing similar or competitive products. In the absence of patent

protection, competitors may impact our business by developing and marketing substantially equivalent products and technology.

Patent disputes are frequent and can preclude the commercialization of products. We have in the past been, are currently, and may in the future be, involved in material patent litigation, such as the matters discussed under “Part I - Item 3. Legal Proceedings” in this report. Patent protection litigation is time-consuming and we have incurred and anticipate continuing to incur significant legal costs. In addition, an adverse decision could force us to either obtain third-party licenses at a material cost or cease using the technology or product in dispute.

We have filed applications for United States and foreign patents covering certain aspects of our technology, but there is no assurance that pending patents will issue or as to the degree of protection which any issued patent might afford.

Lawsuits, including patent infringements, in the biotechnology industry are not uncommon. If we become involved in any significant litigation, we would suffer as a result of the diversion of our management’s attention, the expense of litigation and any judgments against us.

In addition to intellectual property litigation for infringement, other substantial, complex or extended litigation could result in large expenditures by us and distraction of our management. Patent litigation is time-consuming and costly in its own right and could subject us to significant liabilities to third parties. In addition, an adverse decision could force us to either obtain third-party licenses at a material cost or cease using the technology or product in dispute. In addition, lawsuits by employees, stockholders, collaborators or distributors could be very costly and substantially disrupt our business. Disputes from time to time with companies or individuals are not uncommon in the biotechnology industry, and we cannot assure you that we will always be able to resolve them out of court.

We also utilize certain unpatented proprietary technology and no assurance can be given that others will not independently develop substantially equivalent proprietary technology, that such proprietary technology will not be disclosed or that we can meaningfully protect our rights to such proprietary technology.

We may incur impairment charges on our goodwill and intangibles which would reduce our earnings.

We are subject to Statement of Financial Accounting Standards ASC 350, “Intangibles - Goodwill and Other (“ASC 350”) which requires that goodwill and other intangible assets that have an indefinite life be tested at least annually for impairment. Goodwill and other intangible assets with indefinite lives must also be tested for impairment between the annual tests if a triggering event occurs that would likely reduce the fair value of the asset below its carrying amount.

As of July 31, 2015 and 2014, goodwill and intangible assets represented approximately 20% and 24%, respectively, of our total assets. If we determine that there has been impairment, our financial results for the relevant period would be reduced by the amount of the impairment, net of tax effects, if any. The Company has no intangible assets with indefinite lives.

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

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

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

In November 2013 the FDA issued a Guidance document entitled “Distribution of *In Vitro* Diagnostic Products Labeled for Research Use Only or Investigational Use Only,” or the RUO Guidance, which highlights the FDA’s interpretation that distribution of RUO products with any labeling, advertising or promotion that suggests that clinical laboratories can validate the test through their own procedures and subsequently offer it for clinical diagnostic use as an LDT is in conflict with RUO status. The RUO Guidance further articulates the FDA’s position that any assistance offered in performing clinical validation or verification, or similar specialized technical support, to clinical laboratories, is in conflict with RUO status. More recently, on October 3, 2014, the FDA announced the availability of

a draft guidance entitled “Framework for Regulatory Oversight of Laboratory-Developed Tests,” a risk-based oversight framework for LDTs. If the draft guidance is finalized as presently written, such oversight framework includes a premarket review for higher-risk LDTs, such as those that have the same intended use as an FDA-approved or cleared companion diagnostic currently on the market, as well as other high risk and moderate risk LDTs over time. As a result of the draft guidance, we may be required to seek clearance or approval to offer our tests for clinical use earlier than we otherwise might have done. If we engage in any activities that are in conflict with the RUO status held by some of the tests that we sell or intend to sell, we may be subject to immediate, severe and broad FDA enforcement action that would adversely affect our ability to continue operations. Accordingly, if the FDA finds that we are distributing our RUO products in a manner that is inconsistent with its guidance, we may be forced to stop distribution of our RUO tests until we are in compliance, which, would reduce our revenue, increase our costs and adversely affect our business, prospects, results of operations and financial condition.

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

- significant delays in obtaining or failing to obtain required approvals;
- loss of, or changes to, previously obtained approvals;
- failure to comply with existing or future regulatory requirements and;
- changes to manufacturing processes, manufacturing process standards or Good Manufacturing Practices following approval or changing interpretations of these factors.

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

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

Risks relating to our Clinical Labs segment

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

The clinical laboratory industry is subject to significant governmental regulation at the Federal, state and local levels. Under the Clinical Laboratory Improvement Act of 1967 and the Clinical Laboratory Improvement Amendments of 1988 (collectively, as amended, "CLIA") virtually all clinical laboratories, including ours, must be certified by the Federal government. Many clinical laboratories also must meet other governmental standards, undergo proficiency testing and are subject to inspection. Certifications or licenses are also required by various state and local laws. The failure of our clinical laboratory to obtain or maintain such certifications or licenses under these laws could interrupt our ability to operate our clinical laboratory business and injure our reputation. The Protecting Access to Medicare Act ("PAMA") of 2014 is impacting the clinical laboratory testing industry. Key parts of this legislation include provisions that provide for the establishment of an advisory panel and a market-based process to rebase the clinical laboratory fee schedule, developing a new fee schedule and limiting reductions in that fee schedule. If this process does not recognize the value that clinical laboratory testing brings to the healthcare system, our business can be materially adversely impacted.

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

Our clinical laboratory business is primarily dependent upon reimbursement from third-party payers, such as Medicaid, Medicare (which principally serves patients 65 and older) and commercial insurers. We are subject to variances in reimbursement rates among different third-party payers, as well as constant renegotiation of those reimbursement rates. Government and non-government payers have in the past sought, and continue to seek, to reduce and limit utilization and reimbursement of healthcare services, including in the area of genetic testing. We also are

subject to audit by Medicare and the commercial insurers, which can result in the return of payments made to us under these programs. These variances in reimbursement rates and audit results could reduce our margins and thus our earnings.

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

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

Government oversight of and attention to the healthcare industry in the United States is significant and increasing. Under the Patient Protections 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 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 include 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 reported by clinical laboratories across the US replacing the current system, which is based upon fee schedules derived from historical charges for test 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. The legislation also establishes the Independent

Payment Advisory Board, which will be responsible, beginning in 2014, annually to submit proposals aimed at reducing Medicare cost growth while preserving quality. 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.

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

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

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

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

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

Intense competition in the clinical laboratory business, increasing administrative burdens upon the reimbursement process, reduced patient traffic, and reduced coverage and payments by insurers make it necessary for us to increase our volume of laboratory services. To do so, we must obtain new customers while retaining existing customers.

Our failure to attract new customers or the loss of existing customers or a reduction in business from those customers could significantly reduce our revenues and impede our ability to grow.

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

Containment of health care costs, including reimbursement for clinical laboratory services, has been a focus of ongoing governmental activity. Clinical laboratories must bill Medicare directly for the services provided to Medicare beneficiaries and may only collect the amounts permitted under this fee schedule. Reimbursement to clinical laboratories under the Medicare Fee Schedule has been steadily declining since its inception. Because a significant portion of our costs is fixed, these Medicare reimbursement reductions and changes have a direct adverse effect on our net earnings and cash flows.

The development of new, more cost-effective tests that can be performed by our customers or by patients, and the continued internalization of testing by hospitals or physicians, could negatively impact our testing volume and revenues.

The diagnostic industry is faced with changing technology and new product introductions, including technology that enables more convenient or cost-effective testing. Some of our competitors also may offer testing to be performed outside of a commercial clinical laboratory, such as point-of-care testing that can be performed by physicians in their offices; complex testing that can be performed by hospitals in their own laboratories; and home testing that can be carried out without requiring the services of outside providers.

Advances in technology also may lead to the need for less frequent testing. Further, diagnostic tests approved or cleared by the FDA for home use are automatically deemed to be "waived" tests under CLIA and may be performed by patients in their homes; test kit manufacturers could seek to increase sales to patients of such test kits. Development of such technology and its use by our customers would reduce the demand for our laboratory-based testing services and negatively impact our revenues.

Our business could be harmed from the loss or suspension of a license or imposition of a fine or penalties under, or future changes in, or changing interpretations of, CLIA or state laboratory licensing laws to which we are subject.

The clinical laboratory testing industry is subject to extensive federal and state regulation, and many of these statutes and regulations have not been interpreted by the courts. The Clinical Laboratory Improvement Amendments of 1988, or CLIA, are federal regulatory standards that apply to virtually all clinical laboratories (regardless of the location, size or type of laboratory), including those operated by physicians in their offices, by requiring that they be certified by the federal government or by a federally approved accreditation agency. CLIA does not pre-empt state law, which in some cases may be more stringent than federal law and require additional personnel qualifications, quality control, record maintenance and proficiency testing. The sanction for failure to comply with CLIA and state requirements may be suspension, revocation or limitation of a laboratory's CLIA certificate, which is necessary to conduct business, as well as significant fines and/or criminal penalties. Several states have similar laws and we may be subject to similar penalties.

We cannot assure that applicable statutes and regulations will not be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that would adversely affect our business. Potential sanctions for violation of these statutes and regulations include significant fines and the suspension or loss of various licenses, certificates and authorizations, which could have a material adverse effect on our business. In addition, compliance with future legislation could impose additional requirements on us, which may be costly.

Regulations requiring the use of "standard transactions" for healthcare services may negatively impact our profitability and cash flows.

The administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, or HIPAA, were designed to improve the efficiency and effectiveness of the healthcare system by facilitating the electronic exchange of information in certain financial and administrative transactions while protecting the privacy and security of the information exchanged. The administrative simplification provisions address standards for electronic transactions, security regulations and privacy regulations.

The HIPAA transaction standards are complex, and subject to differences in interpretation by payers. For instance, some payers may interpret the standards to require us to provide certain types of information, including demographic information not usually provided to us by physicians. While most of our transactions are submitted and/or received in

ANSI standard format, inconsistent application of transaction standards by some remaining payers or our inability to obtain certain billing information not usually provided to us by physicians could increase our costs and the complexity of billing. In addition, new requirements for additional standard transactions, such as claims attachments, could prove technically difficult, time-consuming or expensive to implement. We are working closely with our payers to establish acceptable protocols for claims submissions and with our industry trade association and an industry coalition to present issues and problems as they arise to the appropriate regulators and standards setting organizations.

Our business could be adversely impacted by CMS' adoption of the new coding set for diagnoses.

CMS has adopted a new coding set for diagnosis, commonly known as ICD-10, which significantly expands the coding set for diagnoses. The new coding set was required to be implemented by October 1, 2015. We must adequately implement the new coding set. In addition, physicians may fail to provide appropriate codes for desired tests; historically, delays in billing have resulted in increased costs and decreased collection of payment.

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

The HIPAA privacy and security and breach notification regulations establish comprehensive federal standards with respect to the uses and disclosures PHI by Covered Entities. These regulations were recently amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, or HITECH, to, among other things directly apply to business associates (i.e., individuals or entities who create, receive, maintain or transmit PHI on behalf of a Covered Entity in performing functions or activities regulated by HIPAA or who perform certain services, other than treatment, on behalf of Covered Entities and receive PHI in order to perform such services) with regard to certain requirements. The regulations also specify that business associates include subcontractors that create, receive, maintain or transmit PHI on behalf of a business associate. The regulations establish a complex regulatory framework on a variety of subjects, including:

- the circumstances under which uses and disclosures of PHI are permitted or required without a specific authorization by the patient, including but not limited to treatment purposes, activities to obtain payments for our services, and our healthcare operations activities;
- a patient's rights to access, amend and receive an accounting of certain disclosures of PHI;
- requirements to notify individuals if there is a breach of their PHI;
- the requirements for business associates and the terms of business associate agreements;
- the content of notices of privacy practices for protected health information and;
- administrative, technical and physical safeguards required of entities that use or receive PHI.

We have implemented practices to meet the requirements of the HIPAA privacy, security and breach notification regulations, and updated these practices to comply with HITECH. HIPAA establishes a "floor" and does not supersede state laws that are more stringent. Therefore, we are required to comply with federal privacy security and breach notification regulations and varying state privacy, security and breach notification laws and regulations. In addition, for healthcare data transfers from other countries relating to citizens of those countries, we must comply with the laws of those other countries. The federal privacy regulations restrict our ability to use or disclose patient-identifiable laboratory data, without patient authorization, for purposes other than payment, treatment, healthcare operations and certain other specified disclosures such as public health and governmental oversight of the health care industry. The privacy, security and breach notification regulations provide for significant fines and other penalties for wrongful use or disclosure of PHI, including potential civil and criminal fines and penalties. Although the HIPAA statute and regulations do not expressly provide for a private right of damages, we also could incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information.

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

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

The FDA has regulatory responsibility over instruments, test kits, reagents and other devices used to perform diagnostic testing by clinical laboratories. In the past, the FDA has claimed regulatory authority over laboratory-developed tests, but has exercised enforcement discretion in not regulating tests performed by high complexity CLIA-certified laboratories. 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 tests. In the notice, FDA indicates that it intends to end its policy of general enforcement discretion towards laboratory-developed tests, and proposes the implementation of a risk-based regulatory framework. Under the proposed framework many laboratory-developed tests would be subject to FDA's regulations for medical devices, including registrations 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. On September 30, 2014, the FDA issued draft guidelines and announced a 120 day public comment period on its proposal.

In December 2000, the HHS Secretary's Advisory Committee on Genetic Testing recommended that the FDA be the lead federal agency to regulate genetic testing. In late 2002, a new HHS Secretary's Advisory Committee on Genetics, Health and Society, or SACGHS, was appointed to replace the prior Advisory Committee. Ultimately, SACGHS decided that it would continue to monitor the progress of the federal agencies in the oversight of genetic technologies, but it did not believe that further action was warranted. In the meantime, the FDA is considering revising its regulations on analyte specific reagents, which are used in laboratory-developed tests, including laboratory-developed genetic testing. We cannot predict whether FDA regulation – including premarket review requirements – will apply to the laboratory-developed tests that we perform or the tests in which our customers may use our products. FDA interest in or actual regulation of laboratory-developed tests or increased regulation of the various medical devices used in laboratory-developed testing could lead to increased regulatory burdens and increased costs and delays in introducing new tests, including genetic tests and decreased demand for our products.

In the past, the clinical laboratory industry has received negative publicity. This publicity has led to increased legislation, regulation, and review of industry practices. These factors may adversely affect our ability to market our services, require us to change our

services and increase the regulatory burdens under which we operate, further increasing the costs of doing business and adversely affecting our operating results. If we experience a significant disruption in our information technology systems, including our website, or if we fail to implement new systems and software successfully, our business could be adversely affected.

We are subject to federal and state healthcare fraud and abuse and other laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.

As a provider of clinical laboratory testing services, we are subject to extensive and frequently changing federal, state and local laws and regulations governing various aspects of our business. For example, we are subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business. These healthcare laws and regulations include, for example:

- the federal Anti-Kickback Law, which constrains our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, including third-party laboratories, by prohibiting, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, in return for or to induce either the referral of an individual for, or the purchase, lease order or recommendation of, any good, facility, item or services for which payment may be made, in whole or in part, under a federal healthcare program such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payers that are false or fraudulent, and which may apply to entities like us to the extent that our interactions with customers may affect their billing or coding practices;

- the federal Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information, and also established federal crimes for knowingly and willfully executing a scheme to defraud any healthcare benefit program or making false statements in connection with the delivery of or payment for healthcare benefits, items or services, and which imposed certain requirements relating to privacy, security, and transmission of individually identifiable health information;

- the federal physician self-referral law, commonly known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services reimbursed by Medicare or Medicaid if the physician (or a member of the physician's family) has a financial relationship with the entity, and which also prohibits the submission of any claims for reimbursement for designated health services furnished pursuant to a prohibited referral;

- the federal Physician Payment Sunshine Act, and its implementing regulations, which requires manufacturers of certain drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payer, including commercial insurers and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, with differing effects.

We are unable to predict what additional federal or state legislation or regulatory initiatives may be enacted in the future regarding our business or the healthcare industry in general, or what effect such legislation or regulations may have on us. Federal or state governments may impose additional restrictions or adopt interpretations of existing laws that could have an adverse effect on us.

We incur significant costs in complying with these laws and regulations. Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations, or our sales techniques or product placement strategies, are found to be in violation of, or to encourage or assist the violation by third parties of, any of the laws described above or any other governmental regulations that apply to us, or if we fail to maintain, renew or obtain necessary permits, licenses and approvals related to our in-house laboratory, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, suspension or revocation of

certifications or licenses that are required to operate our business, injunctions and other associated remedies, the curtailment or restructuring of our operations, denial or withdrawal of product clearances, or private "qui tam" actions brought by individual whistleblowers in the name of the government, any of which could have an adverse effect on our business. If we or others determine that any of our existing customer relationships do not comply with applicable laws and regulations, either due to changes in such laws and regulations or evolving interpretations of such laws and regulations, we may be required to renegotiate or terminate such relationships. Any penalties, damages, fines, exclusions, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of these laws are broad and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Other risks relating to our business

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

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

Cyber security risks and the failure to maintain the confidentiality, integrity, and availability of our computer hardware, software, and Internet applications and related tools and functions could result in damage to the Company's reputation and/or subject the Company to costs, fines, or lawsuits.

The integrity and protection of our own data, and that of its customers and employees, is critical to the Company's business. The regulatory environment governing information, security and privacy laws is increasingly demanding and continues to evolve. Maintaining compliance with applicable security and privacy regulations may increase the Company's operating costs and/or adversely impact the Company's ability to market its products and services to customers. Although the Company's computer and communications hardware is protected through physical and software safeguards, it is still vulnerable to fire, storm, flood, power loss, earthquakes, telecommunications failures, physical or software break-ins, software viruses, and similar events. These events could lead to the unauthorized access, disclosure and use of non-public information. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. As a result, the Company may not be able to address these techniques proactively or implement adequate preventative measures. If the Company's computer systems are compromised, it could be subject to fines, damages, litigation, and enforcement actions, customers could curtail or cease using its applications, and the Company could lose trade secrets, the occurrence of which could harm its business.

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

Most of our products and services are highly technical in nature. In general, only highly qualified and trained scientists and technician personnel have the necessary skills to develop proprietary technological products and market our products, support our research and development programs and provide our Clinical Lab services.

In addition, some of our manufacturing, quality control, safety and compliance, information technology and e-commerce related positions are highly technical as well. Further, our sales personnel highly trained and are important to retaining and growing our businesses. Our success depends in large part upon our ability to identify, hire, retain and motivate highly skilled professionals.

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

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

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

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

Risks relating to our international operations

Foreign currency exchange rate fluctuations may adversely affect our business.

Since we operate as a multinational corporation that sells and sources products in many different countries, changes in exchange rates could in the future, adversely affect our cash flows and results of operations.

Furthermore, reported sales and purchases made in non-U.S. currencies by our international businesses, when translated into U.S. dollars for financial reporting purposes, fluctuate due to exchange rate movement. Due to the number of currencies involved, the variability of currency exposures and the potential volatility of currency exchange rates, we cannot predict the effect of exchange rate fluctuations on future sales and operating results.

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

We operate internationally primarily through wholly-owned subsidiaries located in North America and Europe. Revenues outside the United States were approximately 10% of total revenues in fiscal 2015. Our sales and earnings could be adversely affected by a variety of factors resulting from our international operations, including

•future fluctuations in exchange rates;

•complex regulatory requirements and changes in those requirements;

•trade protection measures and import or export licensing requirements;

•multiple jurisdictions and differing tax laws, as well as changes in those laws;

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

- changes in the political or economic conditions in a country or region, particularly in developing or emerging markets;

- changes in shipping costs; and

- difficulties in collecting on accounts receivable.

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

As we expand our commercialization activities outside of the United States, we will be subject to an increased risk of inadvertently conducting activities in a manner that violates the U.S. Foreign Corrupt Practices Act and similar laws. If that occurs, we may be subject to civil or criminal penalties which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We are subject to the U.S. Foreign Corrupt Practices Act ("FCPA"), which prohibits corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. We are also subject to the UK Anti-Bribery Act, which prohibits both domestic and international bribery, as well as bribery across both public and private sectors.

In the course of establishing and expanding our commercial operations and seeking regulatory approvals outside of the United States, we will need to establish and expand business relationships with various third parties and we will interact more frequently with foreign officials, including regulatory authorities. Expanded programs to maintain compliance with such laws will be costly and may not be effective. Any interactions with any such parties or individuals where compensation is provided that are found to be in violation of such laws could result in substantial fines and penalties and could materially harm our business. Furthermore, any finding of a

violation under one country's laws may increase the likelihood that we will be prosecuted and be found to have violated another country's laws. If our business practices outside the United States are found to be in violation of the FCPA, UK Anti-Bribery Act or other similar law, we may be subject to significant civil and criminal penalties which could have a material adverse effect on our financial condition and results of operations.

Risks Relating to our Common Stock

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

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

•fluctuations in our quarterly operating and earnings per share results;

•the gain or loss of significant contracts;

•the carrying value of our goodwill and intangible assets;

•loss of key personnel;

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

•delays in the development and introduction of new products;

•legislative or regulatory changes;

•general trends in the industries we operate;

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

•biological or medical discoveries;

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

•public concern as to the safety of new technologies;

•sales of common stock of existing holders;

•securities class action or other litigation;

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

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

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

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

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

We currently intend to retain our retained earnings and future earnings, if any, to finance the expansion of our business and do not expect to pay any cash dividends on our common stock in the foreseeable future. As a result, the success of an investment in our

common stock will depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which investors purchased their shares.

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

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

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

- a staggered board of directors, so that it would take three successive annual meetings to replace all directors; and
- advance notice requirements for the submission by stockholders of nominations for election to the board of directors and for proposing matters that can be acted upon by stockholders at a meeting.

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

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

Risk relating to our debt

Our use of leverage may expose us to substantial risks, including interest rate risk.

As of July 31, 2015 and 2014, we had $3.0 million in borrowings under our Revolving Loan and Security Agreement (“credit agreement”). In addition, we may incur additional indebtedness in the future. Accordingly, we are exposed to the typical risks associated with the use of leverage. Increased leverage makes it more difficult for us to withstand adverse economic conditions or business plan variances, to take advantage of new business opportunities, or to make necessary capital expenditures. The existing credit agreement contains restrictive covenant restrictions that limit our ability to conduct our business, including restrictions on our ability to incur additional indebtedness. Our ability to maintain our compliance with these covenants is dependent on our financial performance, which is influenced by a number of factors. Violation of any of these covenants would result in an event of default under the credit agreement. Upon the occurrence of an event of default that is not cured or waived, the lender would have the ability to accelerate the repayment of all amounts then outstanding under the credit agreement. In the event of a default, and during the continuance of an event of default under the credit agreement, we would no longer have the right to borrow additional funds under the credit agreement. Under these circumstances, we may not be able to pay our debt or borrow sufficient funds to refinance it on terms that are acceptable to us or at all.

Our credit agreement requires the payment of interest based on 3 month LIBOR plus a fixed rate. Fluctuations in this variable interest rate could negatively impact our financial results.

Item 1B. Unresolved Staff Comments

None

Item 2. Properties

The following are the principal facilities of the Company:

Location	Primary use	Segments	Leased / owned	Square footage
Farmingdale, NY (Note1)	Clinical laboratory and research	Clinical Labs	Leased	43,000
Farmingdale, NY	Manufacturing, research, sales and administrative office	Life Sciences, Therapeutics	Owned	22,000
New York, NY (Note 2)	Corporate headquarters	Other	Leased	11,300
Lausen, Switzerland (Note 3)	Operational headquarters in Europe, including sales and distribution	Life Sciences	Leased	9,626
Ann Arbor, Michigan (Note 4)	Manufacturing, research, and distribution	Life Sciences	Leased	26,820

Note 1 - In March 2005, the Company amended and extended the lease for its Farmingdale laboratory for a period of 12 years. On October 9, 2015, this lease was amended and extended through March 31, 2027.

Note 2 - In February 2010, the lease, which includes 4,100 square feet under a sublease rental agreement through December 31, 2015, was extended through May 2020.

Note 3 - The lease for this property was acquired in connection with the Axxora acquisition in May 2007. In July 2014, the Company amended and extended the lease through December 2016.

Note 4 - The lease for this property was acquired in connection with the Assay Designs acquisition in March 2009 and was amended and extended through May 2021.

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

Item 3. Legal Proceedings

On June 7, 2004, the Company and Enzo Life Sciences, Inc., filed suit in the United States District Court for the District of Connecticut against Applera Corporation and its wholly-owned subsidiary Tropix, Inc., which became Life Technologies, Inc. (NASDAQ:LIFE) and was acquired by Thermo Fisher Scientific, Inc. (NYSE:TMO) on February 3, 2014. The complaint alleged infringement of six patents relating to DNA sequencing systems, labeled nucleotide products, and other technology. Yale University is the owner of four of the patents and the Company is the exclusive licensee. These four patents are commonly referred to as the "Ward" patents. On November 12, 2012, a jury in New Haven found that one of these patents (United States Patent No. 5,449,667) was infringed and not proven invalid. The jury awarded $48.5 million for this infringement. On January 6, 2014, the judge awarded prejudgment interest of approximately $12.5 million and additional post-interest on the full amount will also be awarded starting November 7, 2012 until the total award is satisfied. The final award to Enzo could be reduced or be subject to possible claims from third parties. On March 16, 2015, the Court of Appeals for the Federal Circuit vacated that judgment in a decision remanding the matter to the district court for further proceedings. Enzo has moved for reconsideration of that decision by the panel and for en banc rehearing by the full Court. There can be no assurance that the Company will be successful in this litigation. Even if the Company is not successful, management does not believe that there will be a significant adverse monetary impact on the Company.

As of August 1, 2014 the Company was engaged in litigation in the United States District Court for the Southern District of New York against Roche Diagnostic GmbH and its related company Roche Molecular Systems, Inc. ("Roche"), as declaratory judgment defendant. This case was commenced in May 2004. Roche seeks a declaratory judgment of non-breach of contract and patent invalidity against the Company. Roche has also asserted tort claims against the Company. The Company has asserted breach of contract and patent infringement causes of action against Roche. There has been extensive discovery in the case. In 2011, Roche moved for summary judgment of non-infringement regarding the Company's patent claims. In 2012, the motion was granted in part and denied in part. In December 2012, Roche moved for summary judgment on the Company's non-patent claims. Additional discovery was taken and the Company responded to the motions in May 2013. On December 6, 2013, the Court granted in part and denied in part Roche's summary judgment motion. On October 22, 2014, the Court ordered that damages discovery concerning the Company's remaining contract and patent claims and Roche's claims should be completed by January 30, 2015, and expert discovery should be completed following the Court's not-yet-issued claim construction ruling concerning the Company's patent infringement claim against Roche. Roche dropped its tort claims during damages discovery, which is now closed. On April 28, 2015, the Court heard oral argument on claim construction issues. The litigation in the United States District Court for the Southern District of New York between the Company and Molecular Probes, Inc. terminated on May 11, 2015, with a settlement in favor of the Company in the amount of $170,000. The Company's former counsel, Greenberg Traurig LLP, is also engaged in litigation against the Company in the United States District Court for the Southern District of New York concerning Greenberg Traurig's request for a charging lien relating to its representation of the Company in the Roche and other cases.

On April 22, 2014, the Company as plaintiff finalized and executed a settlement agreement with Affymetrix, Inc. to settle a patent litigation lawsuit (the "Agreement") in the amount of $5.1 million. Under terms of the Agreement, Affymetrix paid to the Company $4.3 million and paid to the Company's attorneys $0.8 million, which is included in legal fees in the statements of operations for the year ended July 31, 2014. The amount of the settlement is included in the statement of operations under Legal settlements, net within the Life Science segment.

On June 20, 2014, the Company, as plaintiff finalized and executed a settlement agreement with PerkinElmer, Inc., and PerkinElmer Health Sciences, Inc. (formerly known as PerkinElmer Life Sciences, Inc.) (together, "PerkinElmer"), with respect to an action between the Company and PerkinElmer before the U.S. District Court, Southern District of New York, Case No 03-CV-3817. PerkinElmer paid $7.0 million in escrow pursuant to the agreement because of a former counsel's motion requesting a charging lien for fees allegedly owed for past services rendered to the Company. Because the settlement proceeds are held in escrow, and the amount the Company will ultimately receive is indeterminable, it did not include the settlement or any additional amounts which may be payable to the attorney in the financial statements as of and for the fiscal years ended July 31, 2015 and 2014.

As previously disclosed, in 2012, the Company received a Subpoena Duces Tecum (the "Subpoena") from the Department of Health and Human Services, Office of Inspector General ("OIG"). The Subpoena was issued as part of an investigation being conducted by the US Attorney's Office for the Eastern District of New York in conjunction with the OIG. While a number of potential issues were raised initially by the government, the investigation came to focus primarily on an alleged failure to collect diagnosis codes from physicians who ordered tests through Enzo Clinical Labs. The time period initially covered by the investigation was from 2004 through 2011. In response to the Subpoena, the Company cooperated with the government. On September 22, 2014, the Company and the U.S. Department of Justice reached a settlement agreement to resolve this matter, in substantive form as disclosed in the Company's fiscal quarter ended April 30, 2014. During the quarter ended April, 30, 2014, the Company recorded a charge of $2.0 million in the statement of operations under legal settlements, net within the Clinical Labs segment. The settlement amount will be paid with interest over a five-year period. As of July 31, 2015, the Company carried a balance of $0.4 million as other current

liabilities and $1.2 million as a non-current liability. Under certain circumstances, the Company may be required to accelerate payments and/or pay up to an additional $1.5 million based upon (i) a favorable recovery and collection related to the judgment in the Life Technologies matter discussed above, (ii) receipt of additional capital greater than $10.0 million in a fiscal year (in that case, the Company is required to pay 20% of any amount over $10.0 million plus interest, or (iii) sale of the Company. The final settlement covers the time period 2004-2014.

As a result of the settlements with Affymetrix and the US Department of Justice, noted above, the Company recorded $3.1 million as legal settlements, net during the fiscal year ended July 31, 2014.

On July 2, 2015, the Company as Plaintiff executed a settlement agreement with Luminex Corporation with respect to an action between the Company and Abbott Laboratories and Abbott Molecular, Inc (Defendants) and Luminex Corporation (Intervening Defendant) before the U.S. District Court for the District of Delaware for alleged patent infringement. Luminex paid the Company a total of $7.1 million as consideration for this agreement and the dismissal of the litigation against Luminex. The amount of the settlement, net of attorney’s fees is included in the statement of operations under Legal settlements, net within the Life Science segment.

On July 20, 2015, the Company as Plaintiff finalized and executed a settlement agreement with Siemens Healthcare Diagnostics Inc. (“Siemens”) to settle a patent litigation lawsuit before the U.S. District Court for the District of Delaware in the amount of $9.5 million. Under terms of the agreement, Siemens will also pay the Company additional royalties of $1.0 million per annum on sales of its molecular products manufactured and/or sold in the United States during the its fiscal years 2015 through 2019 if sales of such products exceed a contractual amount. The amount of the settlement, net of attorney’s fees is included in the statement of operations under Legal settlements, net within the Life Sciences segment. The net settlement amount is included in Other receivables in the consolidated balance sheet as of July 31, 2015 and was received in August 2015.

As a result of the settlements during fiscal 2015 noted above, the Company recorded $11.5 million as legal settlements, net during the fiscal year ended July 31, 2015.

On October 9, 2015, the Company reached and finalized a settlement with Affymetrix, Inc. in the amount of $10 million in an infringement action brought by the Company regarding its US Patent no. 7,064,197. The case was originally brought by the Company in the United States District Court for the District of Delaware. This settlement will be recorded in the first quarter of fiscal year 2016.

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

Item 4. Mine Safety Disclosures

Not Applicable

Part II

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

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

2015 Fiscal Year (August 1, 2014 to July 31, 2015):

	High	Low
1st Quarter	$6.08	$4.55
2nd Quarter	$5.27	$3.13
3rd Quarter	$3.43	$2.57
4th Quarter	$3.25	$2.43

2014 Fiscal Year (August 1, 2013 to July 31, 2014):

	High	Low
1st Quarter	$2.62	$2.21
2nd Quarter	$2.92	$2.34
3rd Quarter	$4.55	$2.75
4th Quarter	$5.41	$3.44

As of September 30, 2015, the Company had approximately 755 stockholders of record of its common stock.

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

Performance Graph

The graph below compares the five-year cumulative shareholder total return based upon an initial $100 investment (assuming the reinvestment of dividends) for Enzo Biochem, Inc. shares of Common Stock with the comparable return for the New York Stock Exchange Market Value Index and two peer issuer indices selected on an industry basis. The two peer group indices include: (i) 147 biotechnology companies engaged in the research and development

of diagnostics substances and (ii) 18 companies engaged in the medical laboratories business. All of the indices include only companies whose common stock has been registered under Section 12 of the Security Exchange Act of 1934 for at least the time frame set forth in the graph.

The total shareholder returns depicted in the graph are not necessarily indicative of future performance. The Performance Graph and related disclosure shall not be incorporated by reference in any filing by the Company under the Securities Act of 1933 of the Securities Act of 1934, except to the extent that the Company specifically incorporates the graph and such disclosure by reference.

COMAPRISON OF 5-YEAR CUMULATIVE TOTAL RETURN AMONG ENZO BIOCHEM, INC., NYSE MARKET INDEX, MORNINGSTAR DIAGNOSTIC AND RESEARCH INDEX AND MEDICAL LABORATORIES INDEX

ASSUMES $100 INVESTED ON AUGUST 1, 2010

ASSUMES DIVIDEND REINVESTED

COMPARISON OF CUMULATIVE TOTAL RETURN OF ONE OR MORE

COMPANIES, PEER GROUPS, INDUSTRY INDEXES AND/OR BROAD MARKETS

	7/31/2010	7/31/2011	7/31/2012	7/31/2013	7/31/2014	7/31/2015
Company/Market/Peer Group						
Enzo Biochem, Inc.	100.00	83.48	32.61	47.39	104.35	65.22
NYSE Composite Index	100.00	118.40	118.60	148.22	170.59	177.37
Morningstar Diagnostic & Research	100.00	128.61	123.41	165.38	199.01	237.80
SIC 8071 - Medical Laboratories	100.00	121.09	121.33	132.04	140.60	162.01
Medical Laboratories + Enzo Biochem Inc.	100.00	120.71	120.37	131.13	140.28	160.95

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Item 6. Selected Financial Data

The following table, which is derived from the audited consolidated financial statements of the Company for the fiscal years 2011 through 2015 should be read together with the discussion in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the Company's consolidated financial statements and notes to those statements included elsewhere in this Annual Report on Form 10-K.

	For the fiscal year ended July 31, (In thousands, except per share amounts)				
Operating Results	2015	2014	2013	2012	2011
Revenues	$97,599	$95,947	$93,707	$103,083	$102,029
Impairment charges (1)	$—	—	—	(24,540)	—
Operating loss	$(1,206)	$(10,180)	$(18,890)	$(40,479)	$(12,928)
Net loss	$(2,285)	$(9,977)	$(18,237)	$(39,269)	$(12,960)
Basic and diluted net loss per common share:	$(0.05)	$(0.23)	$(0.46)	$(1.01)	$(0.34)

Financial Position (in thousands)	July 31, 2015	2014	2013	2012	2011
Working capital	$22,528	$15,771	$8,704	$21,412	$33,670
Total assets (1)	$68,394	$64,411	$58,958	$69,123	$109,474
Stockholders' equity (1)	$42,606	$36,950	$34,132	$49,101	$88,715

Notes to Selected Financial Data:

(1) In the fourth quarter of fiscal 2012, the Company recorded an impairment charge on goodwill and indefinite lived intangible assets.

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

See in this Form 10-K for the fiscal year ended July 31, 2015 Part 1. Item 1. *Business*, for Forward Looking Cautionary Statements.

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

We are comprised of three operating companies that have evolved out of our core competence: the use of nucleic acids as informational molecules and the use of compounds for immune modulation. These wholly-owned operating companies and the foreign subsidiaries of Enzo Life Sciences conduct their operations through three reportable segments. Below are brief descriptions of each of the three operating segments (see Note 15 in the Notes to Consolidated Financial Statements):

Enzo Clinical Labs is a regional clinical laboratory serving the greater New York, New Jersey and Eastern Pennsylvania medical communities. The Company believes having clinical diagnostic services allows us to capitalize first hand on our extensive advanced molecular and cytogenetic capabilities and the broader trends in predictive and personalized diagnostics. We offer a menu of routine and esoteric clinical laboratory tests or procedures used in general patient care by physicians to establish or support a diagnosis, monitor treatment or medication, or search for an otherwise undiagnosed condition. We operate a full-service clinical laboratory in Farmingdale, New York, a network of over 30 patient service centers throughout greater New York, New Jersey and Eastern Pennsylvania, a free-standing "STAT" or rapid response laboratory in New York City, and a full-service phlebotomy and an in-house logistics department. Payments for clinical laboratory testing services are made by the Medicare program, healthcare insurers and patients.

The Clinical Lab reporting unit is impacted by various risk factors, including among others, reduced reimbursements from third party payers for testing performed and from recent health care legislation. Despite the growth we have experienced, there can be no assurance future growth can be achieved. The introduction of new molecular and esoteric tests is expected to increase our revenue per test and could offset impacts from the above factors. The Company anticipates improved profitability with increased service volume. Clinical Labs experienced year over year growth in fiscal 2015 and 2014 of 8% and 5% respectively.

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 labelling and detection technologies across research and diagnostic markets. Our strong portfolio of proteins, antibodies, peptides, small molecules, labelling probes, dyes and kits provides life science researchers tools for target identification/validation, high content analysis, gene expression analysis, nucleic acid detection, protein biochemistry and detection, and cellular analysis. We are internationally recognized and acknowledged as a leader in manufacturing, in-licensing, and commercialization of over 9,000 of our own products

and in addition distribute over 40,000 products made by over 40 other original manufacturers. Our strategic focus is directed to innovative high quality research reagents and kits in the primary key research areas of genomics, cellular analysis, small molecule chemistry, protein homeostasis and epigenetics and immunoassays and assay development. The segment is an established source for a comprehensive panel of products to scientific experts in the fields of cancer, cardiovascular disease, neurological disorders, diabetes and obesity, endocrine disorders, infectious and autoimmune disease, hepatotoxicity and renal injury.

Enzo Therapeutics is a biopharmaceutical 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. The Company has focused its efforts on developing treatment regimens for diseases and conditions in which current treatment options are ineffective, costly, and/or cause unwanted side effects. This focus has generated a clinical and preclinical pipeline, as well as more than 111 patents and patent applications.

The following table summarizes the sources of revenues for the fiscal years ended July 31, 2015, 2014 and 2013 (in $000's and percentages):

	2015		2014		2013	
Clinical laboratory services	$63,414	65 %	$58,689	61 %	$55,889	59 %
Product revenues	31,690	32	32,850	34	32,526	35
Royalty and license fee Income	2,495	3	4,408	5	5,292	6
Total	$97,599	100%	$95,947	100%	$93,707	100%

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Results of Operations

Fiscal year ended July 31, 2015 compared to July 31, 2014
(in 000s)

Comparative Financial Data for the Fiscal Years Ended July 31,

	2015	2014	Increase (Decrease)	% Change
Revenues:				
Clinical laboratory services	$63,414	$58,689	$ 4,725	8
Product revenues	31,690	32,850	(1,160)	(4)
Royalty and license fee income	2,495	4,408	(1,913)	(43)
Total revenues	97,599	95,947	1,652	2
Operating expenses:				
Cost of clinical laboratory services	39,589	38,948	641	2
Cost of product revenues	15,183	15,320	(137)	(1)
Research and development	3,350	3,141	209	7
Selling, general, and administrative	41,069	41,801	(732)	(2)
Provision for uncollectible accounts receivable	2,284	3,063	(779)	(25)
Legal fee expense	8,788	6,954	1,834	26
Legal settlements, net	(11,458)	(3,100)	(8,358)	**
Total operating expenses	98,805	106,127	(7,322)	(7)
Operating loss	(1,206)	(10,180)	(8,974)	88
Other income (expense):				
Interest	(245)	(208)	37	(18)
Other	95	194	99	51
Foreign currency (loss) gain	(936)	289	1,225	**
Loss before income taxes	$(2,292)	$(9,905)	$ (7,613)	(77)

**** not meaningful**

Consolidated Results:

The “2015 period” and the “2014 period” refer to the fiscal year ended July 31, 2015 and 2014, respectively.

Clinical laboratory services revenues for the 2015 period were $63.4 million compared to $58.7 million, an increase of $4.7 million or 8%. The increase in revenue from fiscal year 2014 to 2015 is mainly attributed to an increase in molecular testing related to volume and the increase in the average gross charge per accession.

Product revenues for the 2015 period were $31.7 million compared to $32.9 million in the 2014 period, a decrease of $1.2 million or 4%. The decrease was due to the negative impact of translating revenues denominated in the euro, pound sterling and Swiss franc which depreciated versus the US dollar in the 2015 period compared to the 2014 period ($0.9 million) and declines in sales of non-proprietary products ($0.3 million), primarily in markets other than the US.

Royalty and license fee income during the 2015 period was $2.5 million compared to $4.4 million in the 2014 period a decrease of $1.9 million or 43%. Royalties are primarily earned from the reported sales of Qiagen products subject to a license agreement. Qiagen has experienced declines in its US sales of HPV products which in turn reduces our royalty income. There are no direct expenses relating to royalty and licensing income.

The cost of clinical laboratory services during the 2015 period was $39.6 million as compared to $38.9 million in the 2014 period, an increase of $0.6 million or 2%.

The cost of product revenues during the 2015 period was $15.2 million compared to $15.3 million in the 2014 period, a decrease of $0.1 million or 1%. The gross profit margin was 52% in the 2015 period versus 53% in the 2014 period.

Research and development expenses were approximately $3.4 million during the 2015 period, compared to $3.1 million in the 2014 period, an increase of $0.2 million or 7%. The increase was attributed to an increase in payroll and material costs related to product development for the Life Sciences segment.

Selling, general and administrative expenses were approximately $41.1 million during the 2015 period and $41.8 million during the 2014 period, a decrease of $0.7 million or 2%. For the Enzo Life Sciences segment, selling, general and administrative decreased $1.2 million due to the positive effects from the business realignments occurring in fiscal 2014 resulting in lower compensation related costs and lower facility costs. Other segment selling, general and administrative increased $0.3 million, primarily due to compensation related costs and professional and other fees. The Clinical Lab segment selling, general and administrative increased $0.2 million primarily due to increases in compensation related expenses.

The provision for uncollectible accounts receivable, primarily related to the Clinical Labs segment, was $2.3 million for the 2015 period as compared to $3.1 million in the 2014 period, a decrease of $0.8 million or 25%. The decrease is primarily due to improved collection procedures at the Clinical Labs.

Legal fee expense was $8.8 million during the 2015 period compared to $7.0 million in the 2014 period, an increase of $1.8 million or 26% primarily due to increased legal fees and related costs associated with ongoing patent litigation.

Legal settlements, net was $(11.5) million in the 2015 period and $(3.1) in the 2014 period. During the 2015 period the Company as plaintiff finalized and executed settlement agreements with Luminex Corporation ($4.9 million, net), Siemens Healthcare Diagnostics ($6.4 million, net), and Molecular Probes ($0.2 million).

During the 2014 period the Company as plaintiff finalized and executed a settlement agreement with Affymetrix, Inc. in the amount of $(5.1) million. Also during the 2014 period, the Company reached a final agreement on the principal terms of a settlement with the U.S. Department of Justice relating to their investigation of an alleged failure to collect diagnosis codes from physicians who ordered tests through Enzo Clinical Labs. As a result, the Company recorded a charge of $2.0 million.

Interest expense was $0.2 million during the 2015 and 2014 periods due to interest incurred on the credit agreement entered into in 2013.

During the 2015 and the 2014 periods, the (loss) gain on foreign currency transactions was $(0.9) million and $0.3 million, respectively, an unfavorable change of $1.2 million. The Company has loans and receivables with its foreign subsidiaries which may be denominated in US dollars or a foreign currency. When re-measuring these amounts into the respective entities' functional currency, the Company recognizes a loss if those foreign currencies, including the Swiss Franc, British pound and Euro depreciate relative to the US dollar during the period and a gain if those foreign

currencies appreciate relative to the US dollar. During the 2015 period, those currencies depreciated between 6.4% and 18.3% relative to the US dollar. During the 2014 period, those currencies appreciated relative to the US dollar.

Segment Results:

Clinical Labs

The Clinical Labs segment's income (loss) before taxes was $0.5 million for 2015 period as compared to a loss of $(6.6) million in the 2014 period, an improvement year over year of $7.1 million. The 2014 period loss includes a $2.0 million charge for a legal settlement with the U.S. Department of Justice. Revenue from laboratory services for the 2015 period were $63.4 million compared to $58.7 in the 2014 period. The increase of $4.7 million is mainly attributed to an increase in molecular testing related to volume and the increase in the average gross charge per accession. Cost of sales during the 2015 period was $39.6 million as compared to $38.9 million in the 2014 period, an increase of $0.6 million. Clinical Lab gross profit margin was 38% in the 2015 period and 34% in the 2014 period. The provision for uncollectable accounts was $2.4 million as compared to $3.1 million; the decrease is primarily due to continued process review and improvement.

Life Sciences

The Life Sciences segment's income before taxes was $15.0 million for the 2015 period as compared to $10.8 million for the 2014 period, an improvement of $4.2 million over fiscal 2014. The 2015 and 2014 periods include $11.5 and $5.1 million, respectively for patent litigation settlement agreements previously described. Product revenues decreased $1.2 million or 4% in the 2015 period due to the negative impact of translating revenues denominated in foreign currencies into the US dollar ($0.9 million) and by declines in sales of non-proprietary products ($0.3 million), primarily in markets other than the US. The segment's gross profit was $19.0 million in the 2015 period, as compared $21.9 million in the 2014 period, a decrease of $2.9 million primarily due to a decrease in royalty and license fee income of $1.9 million and a gross margin decrease of $1.0 million on lower product revenues. The segment's other operating expenses, excluding legal and legal settlements, net, decreased approximately $1.0 million during the 2015 period due to cost reductions from headcount realignments and continued centralization of activities, particularly relating to selling, general and administrative. Due to the depreciation of foreign currencies versus the US dollar, including the Swiss Franc, British pound and Euro during the 2015 period, the foreign currency loss was $0.9 million compared to a $0.3 million gain in the 2014 period, resulting in an unfavorable change of $1.2 million in the 2015 period.

Therapeutics

Therapeutics loss before income taxes was approximately $0.7 million for the 2015 period as compared to $0.8 million in 2014 period due to lower activity

Other

The Other loss before taxes for the 2015 period was approximately $17.0 million as compared to $13.4 million for the 2014 period, an increase of $3.6 million primarily from the increase in legal fee expense and related costs associated with ongoing patent litigation.

Results of Operations

Fiscal year ended July 31, 2014 compared to July 31, 2013
(in 000s)

Comparative Financial Data for the Fiscal Years Ended July 31,

	2014	2013	Increase (Decrease)	% Change
Revenues:				
Clinical laboratory services	$58,689	$55,889	$ 2,800	5 %
Product revenues	32,850	32,526	324	1
Royalty and license fee income	4,408	5,292	(884)	(17)
Total revenues	95,947	93,707	2,240	2
Operating expenses:				
Cost of clinical laboratory services	38,948	38,251	697	2
Cost of product revenues	15,320	16,584	(1,264)	(8)
Research and development	3,141	3,889	(748)	(19)
Selling, general, and administrative	41,801	43,654	(1,853)	(4)
Provision for uncollectible accounts receivable	3,063	4,496	(1,433)	(32)
Legal fee expense	6,954	5,813	1,141	20
Legal settlements, net	(3,100)	—	(3,100)	**
Total operating expenses	106,127	112,687	(6,560)	(6)
Operating loss	(10,180)	(18,980)	(8,800)	(46)
Other income (expense):				
Interest	(208)	(54)	(154)	**
Other	194	5	189	**
Foreign currency gain (loss)	289	80	209	**
Loss before income taxes	$(9,905)	$(18,949)	$ (9,044)	(48)

**** not meaningful**

Consolidated Results:

The “2014 period” and the “2013 period” refer to the fiscal year ended July 31, 2014 and 2013, respectively.

Clinical laboratory services revenues for the 2014 period were $58.7 million compared to $55.9 million, an increase of $2.8 million or 5%. The increase was driven by growth in high value molecular testing of $6.1 million, which was partially offset by lower test volume versus 2013.

Product revenues for the 2014 period were $32.9 million compared to $32.5 million in the 2013 period, an increase of $0.4 million or 1% due to a continued increase in sales of our manufactured products which yield higher margins.

Royalty and license fee income during the 2014 period was $4.4 million compared to $5.3 million in the 2013 period a decrease of $0.9 million or 17%. Royalties are primarily earned from the reported sales of Qiagen products subject to a license agreement. There are no direct expenses relating to royalty and licensing income.

The cost of clinical laboratory services during the 2014 period was $38.9 million as compared to $38.3 million in the 2013 period, an increase of $0.6 million or 2%. The increase is the result of higher cost of molecular testing of $1.7 million, partially offset by lower reagent cost of $0.7 million and a reduction in royalty expense of $0.3 million.

The cost of product revenues during the 2014 period was $15.3 million compared to $16.6 million in the 2013 period, a decrease of $1.3 million or 8% and was positively impacted by an increase in sales of manufactured products, and the impact of reduced payroll, facility and other costs resulting from realignments which occurred during fiscal 2013.

Research and development expenses were approximately $3.2 million during the 2014 period, compared to $3.9 million in the 2013 period, a decrease of $0.7 million or 19%. The decrease was attributed to declines in payroll and other related costs, adjustment to obligations relating to clinical trial activity and lower material costs.

Selling, general and administrative expenses were approximately $41.8 million during the 2014 period and $43.7 million during the 2013 period, a decrease of $1.9 million or 4%. In Enzo Life Sciences segment, selling, general and administrative decreased $2.2 million due to the positive effects from the business realignments occurring in fiscal 2013 resulting in lower payroll and related costs, lower depreciation and amortization, and lower marketing costs. Other segment selling, general and administrative decreased $0.2 million, primarily due to lower salary and related costs and lower professional and other fees. The Clinical Lab segment selling, general and administrative increased $0.5 million primarily due to increases in payroll costs.

The provision for uncollectible accounts receivable, primarily related to the Clinical Labs segment, was $3.1 million for the 2014 period as compared to $4.5 million in the 2013 period, a decrease of $1.4 million or 32%. The decrease is primarily due to improved collection procedures and changes in the mix of payers at the Clinical Labs.

Legal fee expense was $6.9 million during the 2014 period compared to $5.8 million in the 2013 period, an increase of $1.1 million or 20% primarily due to fees incurred for legal settlements recorded in 2014.

Legal settlements, net was $(3.1) million in the 2014 period. The Company as plaintiff finalized and executed a settlement agreement with Affymetrix, Inc. to settle a patent litigation lawsuit in the amount of $5.1 million. Also during the 2014 period, the Company reached a final agreement on the principal terms of a settlement with the U.S. Department of Justice relating to their investigation of an alleged failure to collect diagnosis codes from physicians who ordered tests through Enzo Clinical Labs. As a result, the Company recorded a charge of $2.0 million. Both settlements are more fully described in Note 14 in the Notes to Consolidated Financial Statements.

Interest expense was $0.2 million during the 2014 compared to $0.1 million in the 2013 period due to interest incurred on the credit agreement entered into in the fourth quarter of 2013.

During the 2014 and the 2013 periods, the gain on foreign currency transactions was $0.3 million and $0.1 million, respectively. The Company has loans and receivables with its foreign subsidiaries denominated in US dollars and recognizes a gain if foreign currencies including the Swiss Franc, Euro and British pound strengthen relative to the US dollar during the period and recognizes a loss if those foreign currencies weaken relative to the US dollar. The gain in both periods was due to the strengthening of these foreign currencies relative to the US dollar.

Segment Results:

Clinical Labs

The Clinical Labs segment's loss before taxes was $6.6 million for 2014 period as compared to a loss of $7.1 million in the 2013 period, an improvement year over year of $0.5 million. The 2014 period loss includes a $2.0 million charge for a legal settlement with the U.S. Department of Justice. Revenue from laboratory services increased $2.8 million driven by growth in high value molecular testing of $6.1 million, which was partially offset by lower test volume versus 2013. Cost of sales increased $0.7 million as a result of higher cost of reference testing, which includes the cost of molecular testing of $0.8 million. Year over year selling and general administrative expense in support of the lab increased $0.5 million due to increases in payroll costs. The provision for uncollectible accounts receivable decreased $1.1 million due to improved collection procedures and changes in the mix of payers. Legal fees increased $0.4 million in support of the previously discussed legal settlement.

Life Sciences

The Life Sciences segment's income before taxes was $10.8 million for the 2014 period as compared to $3.1 million for the 2013 period, an improvement of $7.7 million over fiscal 2013. The 2014 period includes $5.1 million for a patent litigation settlement agreement with Affymetrix, Inc. Product revenues increased $0.3 million or 1% in the 2014 period due to a continued increase in sales of our manufactured products which yield high margins. Royalty and license fee income of $4.4 million represented a decrease of $0.9 million compared to the 2013 period and is primarily from royalties earned from sales of Qiagen products subject to a license agreement. The segment's gross profit was $21.9 million in the 2014 period, compared to $21.2 million in the 2013 period. Gross profit was positively impacted by the increase in manufactured product revenues, and the impact of reduced payroll, facility and other costs resulting from realignments which occurred during fiscal 2013. The segment's other operating expenses, excluding legal settlements, net, decreased approximately $1.6 million during the 2014 period due to cost reductions from headcount realignments and continued centralization of activities, particularly relating to selling, general and administrative. Due to the greater strengthening of foreign currencies versus the US dollar during the 2014 period compared to the 2013 period, the foreign currency gain was $0.3 million as compared to $0.1 million in the 2013 period.

Therapeutics

Therapeutics loss before income taxes was approximately $0.8 million for the 2014 period as compared to $1.2 million in 2013 period due to lower personnel costs and an adjustment to prior estimated amounts.

Other

The Other loss before taxes for the 2014 period was approximately $13.4 million as compared to $13.6 million for the 2013 period, a decrease of $0.2 million due to lower payroll expenses incurred during the second half of the 2014 period and lower legal fees, partially offset by higher interest expense.

Liquidity and Capital Resources

At July 31, 2015, the Company had cash and cash equivalents of $18.1million of which $0.5 million was in foreign accounts, as compared to cash and cash equivalents of $17.5 million, of which $1.1 million was in foreign accounts at July 31, 2014. It is the Company's current intent to permanently reinvest these funds outside of the United States, and its current plans do not demonstrate a need to repatriate them to fund its United States operations. The Company had working capital of $22.5 million at July 31, 2015 compared to $15.8 million at July 31, 2014. The increase in working capital of $6.7 million was primarily due to the recognition of $11.5 million in income from Legal Settlements, net from patent litigation settlement agreements and from proceeds from issuances of common stock under the Controlled Equity Offering program of $6.7 million, partially offset by net changes in operating assets and liabilities.

At July 31, 2014, the Company had cash and cash equivalents of $17.5 million of which $1.1 million was in foreign accounts, as compared to cash and cash equivalents of $9.0 million, of which $1.5 million was in foreign accounts at July 31, 2013. The Company had working capital of $15.8 million at July 31, 2014 compared to $8.7 million at July 31, 2013. The increase in working capital of $7.1 million was primarily due to the increase in cash and cash equivalents as a result of the settlement agreement with Affymetrix, Inc. in the amount of $5.1 million and from proceeds from issuance of common stock under the Controlled Equity Offering program of $11.5 million, offset by the net loss and changes in net operating assets and liabilities.

Net cash used in operating activities in fiscal 2015 was approximately $3.7 million as compared to $1.7 million in fiscal 2014, an increase of approximately $2.0 million. The increase in net cash used in operating activities in the 2015 period versus the 2014 period was primarily due to a net change in operating assets and liabilities of $9.5 million, which includes the increase in other receivables of $6.7 million for the settlement agreement with Siemens Healthcare Diagnostics Inc., and a decrease in non-cash charges of $0.2 million, partially offset by the change in the net loss of $7.7 million. Net cash used in operating activities in fiscal 2014 was approximately $1.7 million as compared to $10.0 million in fiscal 2013, a decrease of approximately $8.3 million. The decrease in net cash used in operating activities

in the 2014 period versus the 2013 period was primarily due to a decrease in the net loss of $8.3 million; the decrease in non-cash charges of $1.5 million was offset by an increase in operating assets and liabilities of $1.5 million.

Net cash used in investing activities in fiscal 2015 was approximately $1.8 million as compared to $0.8 million in the year ago period, an increase of $1.0 million. The increase in the 2015 period is primarily due to increased capital expenditures. Net cash used in investing activities in fiscal 2014 was approximately $0.8 million as compared to $1.0 million in fiscal 2013, a decrease of $0.2 million, primarily due to lower capital expenditures.

Net cash provided by financing activities in fiscal 2015 was approximately $6.2 million as compared to $10.9 million in fiscal 2014. The decrease of $4.7 million was due to the decrease in proceeds from the issuance of common stock of $4.9 million partially offset by a decrease of $0.3 million in net payments under the Credit Agreement and installment loans and capital leases. Net cash provided by financing activities in fiscal 2014 was approximately $10.9 million as compared to $4.8 million in fiscal 2013. The increase of $6.1 million was due to the increase in proceeds from the issuance of common stock of $9.7 million offset by a decrease in net borrowings of $3.5 million under the Credit Agreement and an increase in payments of instalment loans and capital leases of $0.1 million.

On June 7, 2013, the Company entered into a secured Revolving Loan and Security Agreement (the “Credit Agreement”) among the Company and certain of its subsidiaries, with Enzo Therapeutics as a guarantor, and MidCap Financial Services, LLC (formerly Healthcare Finance Group, LLC). The Credit Agreement, which expires in December 2016, provides for borrowings against eligible US receivables, as defined, of the Clinical Labs and Life Sciences segments up to $8.0 million at defined eligibility percentages and provides for additional borrowings of $4.0 million for increased eligible assets. At July 31, 2015, 2014 and 2013, the borrowings under the Credit Agreement related to the Clinical Labs and Life Sciences receivables aggregated $3.0, $3.0 and $3.3 million, respectively, with an additional availability of $2.4 million as of July 31, 2015. As of July 31, 2013, the Company received a waiver from the Lender for non-compliance with a financial covenant and the lender modified various financial covenants relating to fiscal 2014. As of July 31, 2015, the Company is in compliance with the modified financial covenants. See Note 7 to the Consolidated Financial Statements for a further description of the Credit Agreement’s terms and financial covenants.

The Company continued to review all operating units to further reduce annual operating expenditures in fiscal 2015. While revenues and operating results at the Clinical Labs segment improved, revenues for the Life Sciences segment declined versus fiscal 2014. If revenues continue to decline, the segment may be required to record impairments of its intangible assets, which last occurred in fiscal 2012. The Company believes that its current cash and cash equivalents level, utilization of the Controlled Equity Offering program disclosed in Note 10 to the financial statements, which has resulted in net proceeds of $6.7 million and $11.5 million during the fiscal year ended July 31, 2015 and 2014, respectively, and available borrowings under the aforementioned Revolving Loan and Security Agreement disclosed in Note 7 to the financial statements are sufficient for its foreseeable liquidity and capital resource needs over the next twelve (12) months, although there can be no assurance that future events will not alter such view. Although there can be no assurances, in the event additional capital is required, the Company believes it has the ability to raise additional funds through equity offerings or other sources of funds. Our liquidity plans are subject to a number of risks and uncertainties, including those described in the Item 1A. “Risk Factors” section of this Form 10-K for the year ended July 31, 2015, some of which are outside our control. Macroeconomic conditions could limit our ability to successfully execute our business plans and therefore adversely affect our liquidity plans.

Effect of New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standard Update (“ASU”) No. 2014-09, *Revenue from Contracts with Customers: Topic 606*. ASU 2014-09 amends the guidance for revenue recognition to replace numerous, industry-specific requirements and converges areas under this topic with those of the International Financial Reporting Standards. ASU 2014-09 implements a five-step process for customer contract revenue recognition that focuses on transfer of control, as opposed to transfer of risk and rewards. The amendment also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenues and cash flows from contracts with customers. Other major provisions include the capitalization and amortization of certain contract costs, ensuring the time value of money is considered in the transaction price, and allowing estimates of variable consideration to be recognized before contingencies are resolved in certain circumstances. As of July 9, 2015, the FASB decided to delay the effective date of the new revenue standard by one year. The amendments in ASU 2014-09 are effective for reporting periods beginning after December 15, 2017, (the fiscal year ending July 31, 2019 for the Company) and early adoption is permitted for reporting periods beginning after December 15, 2016. Entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. We are currently assessing the impact the adoption of ASU 2014-09 will have on the Company’s combined consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern*. ASU 2014-15 will explicitly require management to assess an entity’s ability to continue as a going concern, and to provide related footnote disclosure in certain circumstances. The new standard will be effective for all entities in the first annual period ending after December 15, 2016. Earlier adoption is permitted. We are currently evaluating the impact of the adoption of ASU 2014-15.

In January 2015, the FASB issued ASU No. 2015-01, *Income Statement Extraordinary and Unusual Items.* The ASU eliminates the concept of extraordinary items from U.S. GAAP as part of its simplification initiative. The ASU does not affect disclosure guidance for events or transactions that are unusual in nature or infrequent in their occurrence. The update applies to all entities for fiscal years, and interim periods within those fiscal years, beginning after

December 15, 2015. We do not expect the adoption of this update to have a material impact in our consolidated financial statements.

In February 2015, the FASB issued ASU No. 2015-02, *Consolidation: Amendments to the Consolidation Analysis.* The amendments in the update affect reporting entities that are required to evaluate whether they should consolidate certain legal entities. All legal entities are subject to reevaluation under the revised consolidation model. The amendments in the Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2015. For all other entities, the effective date for fiscal years beginning after December 15, 2016, and for interim periods within fiscal years beginning after December 15, 2017. Early adoption is permitted. We do not expect the adoption of this update to have a material impact in our consolidated financial statements.

In April 2015, the FASB issued ASU No. 2015-03 *Interest – Imputation of Interest.* The ASU was issued as part of the Simplification Initiatives, to simplify presentation of debt issuance costs. The amendments in the update require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the amendments in this update. For public business entities, the amendments in the update are effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption of the amendments in this update is permitted for financial statements that have not been previously issued. We do not expect the adoption of this update to have a material impact in our consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, *Simplifying the Measurement of Inventory (Topic 330).* ASU 2015-11 changes the measurement principle for inventory from the lower of cost or market to lower of cost or net realizable value. The new standard is effective for our fiscal years and interim periods beginning after December 15, 2016. We do not expect the adoption of this update to have a material impact on our consolidated financial statements.

Contractual Obligations

The Company has entered into various real estate and equipment operating leases and has employment agreements with certain executive officers. The real estate lease for the Company's Farmingdale Clinical Lab and Research facility is with a related party. See Item 2, Properties, and Note 13 to the Consolidated Financial Statements for a further description of these various leases.

The following is a summary of future payments under the Company's contractual obligations as of July 31, 2015:

Payments Due by Period (In thousands)	**Total**	**Less than 1 year**	**1-3 years**	**4-5 years**	**More than 5 years**
Operating lease obligations	$27,374	$7,834	$12,098	$6,916	$526
Current and long term debt obligations	5,308	1,744	3,164	400	—
Employment agreements	2,271	1,048	1,223	—	—
Capital lease obligations	359	149	210	—	—
Total	$35,312	$10,775	$16,695	$7,316	$526

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

Off-Balance Sheet Arrangements

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

Critical Accounting Policies

General

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

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

Product revenues

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

Royalties

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

Revenues - Clinical laboratory services

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

The following table represents the Clinical Labs segment's net revenues and percentages by revenue category (in thousands):

	Year ended July 31, 2015		Year ended July 31, 2014		Year ended July 31, 2013	
Category	**Revenue**	**%**	**Revenue**	**%**	**Revenue**	**%**
Third-party payers	$35,631	56	$29,509	50	$26,014	47
Medicare	11,981	19	12,815	22	12,497	22
Patient self-pay	11,028	17	11,204	19	12,172	22
HMO's	4,774	8	5,161	9	5,206	9
Total	$63,414	100%	$58,689	100%	$55,889	100%

The Company provides services to certain patients covered by various third-party payers, including the Federal Medicare program. Laws and regulations governing Medicare are complex and subject to interpretation for which action for noncompliance includes fines, penalties and exclusion from the Medicare programs. See Item 3. Legal Proceedings.

Other than the Medicare program, one provider whose programs are included in the "Third-party payers" and "Health Maintenance Organizations" ("HMO's") categories represent approximately 28%, 25% and 22% of the Clinical Labs segment net revenue for the years ended July 31, 2015, 2014 and 2013 respectively.

Contractual Adjustment

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

Our clinical laboratory business is primarily dependent upon reimbursement from third-party payers, such as Medicare (which principally serves patients 65 and older) and insurers. We are subject to variances in reimbursement rates among different third-party payers, as well as constant changes of reimbursement rates. Changes that decrease reimbursement rates or coverage would negatively impact our revenues. The number of individuals covered under

managed care contracts or other similar arrangements has grown over the past several years and may continue to grow in the future. In addition, Medicare and other government healthcare programs continue to shift to managed care. These trends will continue to reduce our revenues.

During the years ended July 31, 2015, 2014 and 2013, the contractual adjustment percentages, determined using current and historical reimbursement statistics, were approximately 85%, 86% and 85%, respectively, of gross billings. The Company believes a decline in reimbursement rates or a shift to managed care, or similar arrangements may be offset by the positive impact of an increase in the number of tests we perform. However, there can be no assurance that we can increase the number of tests we perform or that if we do increase the number of tests we perform, that we can maintain that higher number of tests performed, or that an increase in the number of tests we perform would result in increased revenue.

The Company estimates (by using a sensitivity analysis) that each 1% point change in the contractual adjustment percentage could result in a change in clinical laboratory services revenues of approximately $4.3 million, $4.1 million, and $3.8 million, for the years ended July 31, 2015, 2014, and 2013, respectively, and a change in the net accounts receivable of approximately $0.5 million as of each of July 31, 2015, 2014 and 2013.

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

- an analysis of industry reimbursement trends;

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

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

- an analysis of current gross billings and receivables by payer.

Accounts Receivable and Allowance for Doubtful Accounts

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

The following is a table of the Company's net accounts receivable by segment. The Clinical Labs segment's net receivables are detailed by billing category and as a percent to its total net receivables. As of July 31, 2015 and 2014, approximately 68% and 60% respectively, of the Company's net accounts receivable relates to its Clinical Labs business, which operates in the New York, New Jersey and Eastern Pennsylvania medical communities. The Life Sciences segment's accounts receivable, of which $1.1 million or 28% and $1.2 million or 24% represents foreign receivables as of July 31, 2015 and 2014 respectively, includes royalty receivables of $0.1 million and $1.0 million, respectively, from Qiagen Corporation.

Net accounts receivable

	July 31, 2015		**July 31, 2014**	
	Total (in thousands)	**%**	**Total** (in thousands)	**%**
Clinical Labs (by billing category)				
Third party payers	$3,595	44	$3,499	46
Patient self-pay	3,213	39	2,193	29
Medicare	1,081	13	1,558	21
HMO's	305	4	280	4
Total Clinical Labs	8,194	100%	7,530	100%
Total Life Sciences	3,915		4,940	
Total accounts receivable – net	$12,109		$12,470	

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

	July 31, 2015	July 31, 2014
	(in thousands)	
Beginning balance	$2,142	$2,707
Provision for doubtful accounts	2,284	3,063
Write-offs, net	(2,640)	(3,628)
Ending balance	$1,786	$2,142

For the Clinical Labs segment, the allowance for doubtful accounts represents amounts that the Company does not expect to collect after the Company has exhausted its collection procedures. The Company estimates its allowance for doubtful accounts in the period the related services are billed and reduces the allowance in future accounting periods based on write-offs during those periods. It bases the estimate for the allowance on the evaluation of historical experience of accounts going to collections and the net amounts not received. Accounts going to collection include 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 our estimate of the uncollected portion of receivables from self-payers, including deductibles and copayments, which are subject to credit risk and patients' ability to pay. As of July 31, 2015 and 2014, the Company recategorizes to collections customers whose accounts receivable have been outstanding more than 210 days. The Company fully reserves through its contractual allowances amounts that have not been written off because the payer's filing date deadline has not occurred or the collection process has not been exhausted. The Company's collection experience on Medicare receivables beyond 210 days has been insignificant. The Company adjusts the historical collection analysis for recoveries, if any, on an ongoing basis.

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

in payer mix, decline in economic conditions or deterioration in aging of receivables), our estimates of net realizable value of receivables could be reduced by a material amount.

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

The allowance for doubtful accounts as a percentage of total accounts receivable at July 31, 2015 and 2014 was 12.9% and 14.7% respectively. During fiscal 2015, the contractual allowance applied to the Clinical Labs segment's patient self-pay revenues was increased based on collections trends, which has the effect of reducing the allowance for doubtful patient pay accounts receivable. We continue to improve our patient pay collection process by billing patients sooner and by giving past due accounts to collection agencies sooner. As a result of these factors, a smaller allowance was required at July 31, 2015 versus 2014.

The following table indicates the Clinical Labs aged gross receivables by payer group (in thousands), which is prior to adjustment to gross receivables for: 1) contractual adjustment, 2) fully reserved balances not yet written off, and 3) other revenue adjustments.

As of July 31, 2015	**Total Amount**	**%**	**Third Party Payers Amount**	**%**	**Medicare Amount**	**%**	**Self-pay Amount**	**%**	**HMO's Amount**	**%**
1-30 days	$ 28,157	53	$ 17,527	50	$ 4,048	52	$ 2,991	47	$ 3,591	95
31-60 days	6,650	13	4,109	12	802	10	1,718	27	21	1
61-90 days	4,191	8	2,313	7	578	7	1,276	20	24	1
91-120 days	3,651	7	2,534	7	604	8	474	7	39	1
121-150 days	2,856	5	2,426	7	399	5	(3)	—	34	1
Greater than 150 days*	7,187	14	5,878	17	1,329	18	(40)	(1)	20	1
Totals	$ 52,692	100%	$ 34,787	100%	$ 7,760	100%	$ 6,416	100%	$ 3,729	100%

As of July 31, 2014	**Total Amount**	**%**	**Third Party Payers Amount**	**%**	**Medicare Amount**	**%**	**Self-pay Amount**	**%**	**HMO's Amount**	**%**
1-30 days	$ 29,762	58	$ 17,786	55	$ 5,475	57	$ 2,871	48	$ 3,630	96
31-60 days	5,689	11	3,210	10	819	9	1,624	27	36	1
61-90 days	4,541	9	2,519	8	826	9	1,172	20	24	1
91-120 days	3,669	7	2,140	7	1,093	11	409	7	27	1
121-150 days	2,218	4	1,690	5	514	5	(3)	—	17	—
Greater than 150 days**	5,672	11	4,841	15	888	9	(109)	(2)	52	1
Totals	$ 51,551	100%	$ 32,186	100%	$ 9,615	100%	$ 5,964	100%	$ 3,786	100%

* Total includes $4,072 fully reserved over 210 days as of July 31, 2015.

** Total includes $2,788 fully reserved over 210 days as of July 31, 2014.

Income Taxes

The Company accounts for income taxes under the liability method of accounting for income taxes. Under the liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. The liability method requires that any tax benefits recognized for net operating loss carry forwards and other items be reduced by a valuation allowance where it is not more likely than not the benefits will be realized in the foreseeable future. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Under the liability method, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. It is the Company’s policy to provide for uncertain tax positions, if any, and the related interest and penalties based upon management’s assessment of whether a tax benefit is more likely than not to be sustained upon examination by tax authorities. To the extent the Company prevails in matters for which a liability for an unrecognized tax benefit is established or is required to pay amounts in excess of the liability, the Company’s effective tax rate in a given financial statement period may be affected.

Inventory

The Company values inventory at the lower of cost (first-in, first-out) or market. Work-in-process and finished goods inventories consist of material, labor, and manufacturing overhead. Write downs of inventories to market value are based on a review of inventory quantities on hand and estimated sales forecasts based on sales history and anticipated future demand. Unanticipated changes in demand could have a significant impact on the value of our inventory and require additional write downs of inventory which would impact our results of operations.

Goodwill and Intangible Assets

Goodwill represents the excess of the cost of an acquisition over the fair value of the net assets acquired. Intangible assets (exclusive of patents), arose primarily from acquisitions, and primarily consist of customer relationships, trademarks, licenses, and website and database content. Finite-lived intangible assets are amortized according to their estimated useful lives, which range from 4 to 15 years. Patents represent capitalized legal costs incurred in pursuing patent applications. When such applications result in an issued patent, the related capitalized costs are amortized over a ten year period or the life of the patent, whichever is shorter, using the straight-line method. The Company reviews its issued patents and pending patent applications, and if it determines to abandon a patent application or that an issued patent no longer has economic value, the unamortized balance in deferred patent costs relating to that patent is immediately expensed.

The Company tests goodwill and long-lived assets annually as of the first day of the fourth quarter, or more frequently if indicators of potential impairment exist. In assessing goodwill and long-lived assets for impairment, the Company has the option to first perform a qualitative assessment to determine whether the existence of events or circumstances leads to a determination that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If the Company determines that it is not more likely that not that the fair value of a reporting unit is less than its carrying amount, the Company is not required to perform any additional tests in assessing goodwill and long-lived assets for impairment. However, if the Company concludes otherwise or elects not to perform the qualitative assessment, then it is required to perform the first step of a two-step quantitative impairment review process. The first step of the quantitative impairment test requires the identification of the reporting units and comparison of the fair value of each of these reporting units to their respective carrying value. If the carrying value of the reporting unit is less than its fair value, no impairment exists and the second step is not performed. If the carrying value of the reporting unit is higher than its fair value, the second step must be performed to compute the amount of the goodwill impairment, if any. In the second step, the impairment is computed by comparing the implied fair value of the reporting unit goodwill with the carrying amount of that goodwill. If the carrying amount of the reporting unit goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized for the excess

During fiscal years 2015, 2014 and 2013, there was no impairment of Goodwill or Long-lived Assets.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

Foreign Currency Exchange Rate Risk

The financial reporting of our non-U.S. subsidiaries is denominated in currencies other than the U.S. dollar. Since the functional currency of our non-U.S. subsidiaries is the local currency, foreign currency translation adjustments are accumulated as a component of accumulated other comprehensive income in stockholders' equity. Assuming a hypothetical decline of 10% in the exchange rates of foreign currencies against the U.S. dollar at July 31, 2015, our assets and liabilities would decrease by $0.5 million and $0.1 million, respectively, and our net sales and net earnings (loss) would decrease by $1.0 million and $0.2 million, respectively, on an annual basis.

We also maintain intercompany balances and loans receivable with subsidiaries with different local currencies. These amounts are at risk of foreign exchange losses if exchange rates fluctuate. Assuming a hypothetical increase of 10% in the exchange rates of foreign currencies against the U.S. dollar at July 31, 2015, our pre-tax earnings (loss) would be unfavorably impacted by approximately $0.9 million on an annual basis.

Interest Rate Risk

We are exposed to interest rate risk with our variable rate Credit Agreement which bears interest at the three month LIBOR with a floor of 1.25% plus 4% per annum. A 300 basis point change in the LIBOR rate would impact our interest expense by $0.1 million. As of July 31, 2015, we have fixed interest rate financing on transportation and equipment leases.

Item 8. Financial Statements and Supplementary Data

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

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of July 31, 2015. This evaluation was carried out under the supervision and with participation of our Chief Executive Officer and Chief Financial Officer. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. Therefore, effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives.

Based upon our evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective at that reasonable assurance level as of July 31, 2015, and that information required to be disclosed in the reports that we file under the Exchange Act is recorded, processed, summarized and reported in a timely manner and is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during the fourth quarter ended July 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

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

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

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of management and our directors; and
- provide reasonable assurance regarding prevention and timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

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

Management assessed the effectiveness of our internal control over financial reporting based on criteria for effective internal control over financial reporting described in the 2013 Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on its assessment, management concluded that we maintained effective internal control over financial reporting as of July 31, 2015.

EisnerAmper LLP, our independent registered public accounting firm, has audited the effectiveness of the Company’s internal control over financial reporting as of July 31, 2015, as stated in their report, which is included herein.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Enzo Biochem, Inc.

We have audited Enzo Biochem, Inc. and subsidiaries' (the "Company") internal control over financial reporting as of July 31, 2015, based on criteria established in the 2013 *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, Enzo Biochem, Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of July 31, 2015, based on criteria established in the 2013 *Internal Control-Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Enzo Biochem, Inc. and subsidiaries as of July 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the years in the three-year period ended July 31, 2015, and our report dated October 13, 2015 expressed an unqualified opinion thereon.

/s/ EisnerAmper LLP

New York, New York

October 13, 2015

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Item 9B. Other Information

None

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required under this item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission on or before November 27, 2015 and is incorporated herein by reference.

Item 11. Executive Compensation

The information required under this item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission on or before November 27, 2015 and is incorporated herein by reference.

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

The information required under this item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission on or before November 27, 2015 and is incorporated herein by reference.

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

The information required under this item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission on or before November 27, 2015 and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required under this item will be set forth in the Company's proxy statement expected to be filed with the Securities and Exchange Commission on or before November 27, 2015 and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a)(1) Consolidated Financial Statements
Consolidated Balance Sheets - July 31, 2015 and 2014
Consolidated Statements of Operations - Years ended July 31, 2015, 2014 and 2013
Consolidated Statements of Comprehensive Income (Loss) - Years ended July 31, 2015, 2014 and 2013
Consolidated Statements of Stockholders' Equity - Years ended July 31, 2015, 2014 and 2013
Consolidated Statements of Cash Flows - Years ended July 31, 2015, 2014 and 2013
Notes to Consolidated Financial Statements

(2) Financial Statement Schedule

Schedule II - Valuation and Qualifying Accounts

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

(3) Exhibits

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

Exhibit No.	Description
3(a)	Certificate of Incorporation (1)
3(b)	Certificate of Incorporation, as amended on March 17, 1980. (1)
3(c)	Certificate of Amendment of the Certificate of Incorporation as amended on June 16, 1981. (2)
3(d)	Certificate of Amendment to the Certificate of Incorporation as of July 22, 1988. (3)
3(e)	Amended and restated Bylaws. (4)
10(a)	1994 Stock Option Plan. (5)
10 (b)	1999 Stock Option Plan. (6)
10 (c)	2005 Equity Compensation Incentive Plan (7)
10 (d)	2011 Incentive Plan (8)
10 (e)	Lease agreement with Pari Management (9)
10 (f)	Settlement and Release Agreement between the Company and Sigma Aldrich (10)
10 (g)	Stock Purchase Agreement By and Among Enzo Life Sciences, Inc., Axxora Life Sciences Inc., and the Stock holders, Option holders and Warrant holders (12)
10 (h)	Stock Asset Purchase Agreement By and Among Buyer Parties and Seller Parties with respect to the Biomol International and affiliate acquisition (13)
10 (i)	Asset Purchase Agreement By and Among Enzo Life Sciences, Acquisition, Inc. and Assay Designs, Inc.(14)
10 (j)	Amended and Restated Employment Agreement with Elazar Rabbani (15)
10 (k)	Amended and Restated Employment Agreement with Barry Weiner (15)
10 (l)	Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co,, as sales agent (16)
10 (m)	Revolving Loan and Security Agreement among the Enzo Biochem, Inc., Enzo Clinical Labs, Inc., Enzo Life Sciences, Inc., Axxora, LLC and Enzo Realty, LLC as borrowers, and Enzo Therapeutics, Inc. as a guarantor, and Healthcare Finance Group, LLC as Lender(17)
10 (n)	Settlement and Release Agreement between the Company and Affymetrix (18)
10 (o)	Settlement and Release Agreement between the Company and PerkinElmer (19)
10 (p)	Settlement and Release Agreement between the Company and U.S. Department of Justice (20)

10 (q)	Settlement and Release Agreement between the Company and Luminex Corporation (21)
10 (r)	Settlement and Release Agreement between the Company and Siemens Healthcare Diagnostics Inc. (22)
10(s)*	Amendment of Lease with Pari Management
14 (a)	Code of Ethics (11)
21*	List of subsidiaries of the Company
23.1*	Consent of Independent Registered Public Accounting Firm
31 (a)*	Certification of CEO Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

31 (b)*	Certification of CFO Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32 (a)*	Certification of CEO Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32 (b)*	Certification of CFO Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101. INS**	XBRL Instance Document
101. SCH**	XBRL Taxonomy Extension Schema Document
101. CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definitions Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

Notes to exhibits

* Filed herewith

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

(1) The exhibits were filed as exhibits to the Company's Registration Statement on Form S-18 (File No. 2-67359) and are incorporated herein by reference.

(2) This exhibit was filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended July 31, 1981 and is incorporated herein by reference.

(3) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 1989 and is incorporated herein by reference.

(4) This exhibit was filed with the Company's Current Report on Form 8-K May 8, 2008 and is incorporated herein by reference.

(5) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 1995 and is incorporated herein by reference.

(6) This exhibit was filed with the Company's Registration Statement on Form S-8 (333-87153) and is incorporated herein by reference.

(7) This exhibit was filed as an exhibit to the Company's Proxy Statement of Schedule 14A filed on January 19, 2006 and is incorporated herein by reference.

(8) This exhibit was filed as appendix B to the Company's Definitive Proxy Statement on Schedule 14A, which was filed with the Securities and Exchange Commission on November 16, 2010 and is incorporated herein by reference.

(9) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 2006 and is incorporated herein by reference.

(10) This exhibit was filed with the Company's Current Report on Form 8-K on September 21, 2006 and is incorporated herein by reference.

(11) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 2003 and is incorporated here by reference.

(12) This exhibit was filed with the Company's Current Report on Form 8-K May 30, 2007 and is incorporated herein by reference.

(13) This exhibit was filed with the Company's Current Report on Form 8-K May 8, 2008 and is incorporated herein by reference.

(14) This exhibit was filed with the Company's Current Report on Form 8-K March 13, 2009 and is incorporated herein by reference.

(15)

This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 2010 and is incorporated herein by reference.

(16) This exhibit was filed with the Company's Current Report on Form 8-K on March 28, 2013 and incorporated herein by reference.

(17) This exhibit was filed with the Company's Current Report on Form 10-K for the year ended July 31, 2013 and incorporated herein by reference.

(18) This exhibit was filed with the Company's Current Report on Form 8-K on April 24, 2014 and incorporated herein by reference

(19) This exhibit was filed with the Company's Current Report on Form 8-K on June 23, 2014 and incorporated herein by reference.

(20) This exhibit was filed with the Company's Current Report on Form 10-K for the year ended July 31, 2014.

(21) This exhibit was filed with the Company's Current Report on Form 8-K on July 7, 2015 and incorporated herein by reference.

(22) This exhibit was filed with the Company's Current Report on Form 8-K on July 22, 2015 and incorporated herein by reference.

SIGNATURES

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

ENZO BIOCHEM, INC.

Date: October 13, 2015 By: /s/ Elazar Rabbani Ph.D.
Chairman of the Board

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

By: /s/ Elazar Rabbani Ph.D. October 13, 2015

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

By: /s/ Barry W. Weiner October 13, 2015

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

By: /s/ Bernard L. Kasten MD October 13, 2015

Bernard Kasten, Director

By: /s/ Gregory M. Bortz

Gregory M. Bortz, Director

October 13, 2015

By: /s/ Dov Perlysky

Dov Perlysky, Director

October 13, 2015

FORM 10-K, ITEM 15(a) (1) and (2)

ENZO BIOCHEM, INC.

LIST OF CONSOLIDATED FINANCIAL STATEMENTS AND

FINANCIAL STATEMENT SCHEDULE

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

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

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Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying consolidated balance sheets of Enzo Biochem, Inc. and subsidiaries (the "Company") as of July 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the years in the three-year period ended July 31, 2015. The financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Enzo Biochem, Inc. and subsidiaries as of July 31, 2015 and 2014, and the consolidated results of their operations and their cash flows for each of the years in the three-year period ended July 31, 2015 in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Enzo Biochem, Inc. and subsidiaries' internal control over financial reporting as of July 31, 2015, based on criteria established in the 2013 *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), and our report dated October 13, 2015 expressed an unqualified opinion thereon.

In connection with our audits of the consolidated financial statements referred to above, we also audited Schedule II - Valuation and Qualifying Accounts for each of the years in the three-year period ended July 31, 2015. In our opinion, this financial schedule, when considered in relation to the consolidated financial statements taken as a whole, presents fairly, in all material respects, the information stated therein.

/s/ EisnerAmper LLP

New York, New York

October 13, 2015

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ENZO BIOCHEM, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)

	July 31, 2015	July 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$18,109	$17,455
Accounts receivable, net of allowance for doubtful accounts of $1,786 in 2015 and $2,142 in 2014	12,109	12,470
Other receivables	6,650	—
Inventories	7,396	8,690
Prepaid expenses	2,222	2,121
Total current assets	46,486	40,736
Property, plant, and equipment, net	7,948	7,730
Goodwill	7,452	7,452
Intangible assets, net	6,155	8,108
Other	353	385
Total assets	$68,394	$64,411
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Loan payable	$3,013	$3,013
Accounts payable - trade	8,762	8,245
Accrued liabilities	11,297	12,917
Other current liabilities	886	790
Total current liabilities	23,958	24,965
Deferred taxes	37	183
Other liabilities	1,793	2,313
Total liabilities	$25,788	$27,461
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, $.01 par value; authorized 25,000,000 shares; no shares issued or outstanding	—	—
Common Stock, $.01 par value; authorized 75,000,000 shares; shares issued and outstanding: 46,062,065 at July 31, 2015 and 44,239,183 at July 31, 2014	461	443

Additional paid-in capital	324,966	317,160
Accumulated deficit	(284,682)	(282,397)
Accumulated other comprehensive income	1,861	1,744
Total stockholders' equity	42,606	36,950
Total liabilities and stockholders' equity	$68,394	$64,411

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

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ENZO BIOCHEM, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Years ended July 31,		
	2015	2014	2013
Revenues:			
Clinical laboratory services	$63,414	$58,689	$55,889
Product revenues	31,690	32,850	32,526
Royalty and license fee income	2,495	4,408	5,292
Total revenues	97,599	95,947	93,707
Operating expenses:			
Cost of clinical laboratory services	39,589	38,948	38,251
Cost of product revenues	15,183	15,320	16,584
Research and development	3,350	3,141	3,889
Selling, general, and administrative	41,069	41,801	43,654
Provision for uncollectible accounts receivable	2,284	3,063	4,496
Legal fee expense	8,788	6,954	5,813
Legal settlements, net	(11,458)	(3,100)	—
Total operating expenses	98,805	106,127	112,687
Operating loss	(1,206)	(10,180)	(18,980)
Other income (expense):			
Interest	(245)	(208)	(54)
Other	95	194	5
Foreign exchange (loss) gain	(936)	289	80
Loss before income taxes	(2,292)	(9,905)	(18,949)
Benefit (provision) for income taxes	7	(72)	712
Net loss	$(2,285)	$(9,977)	$(18,237)
Net loss per common share:			
Basic and diluted	$(0.05)	$(0.23)	$(0.46)
Weighted average common shares outstanding:			
Basic and diluted	45,355	42,561	39,607

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

ENZO BIOCHEM, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(in thousands)

	Years Ended July 31,		
	2015	2014	2013
Net loss	$(2,285)	$(9,977)	$(18,237)
Other comprehensive income (loss):			
Foreign currency translation adjustments	117	(114)	253
Comprehensive loss	$(2,168)	$(10,091)	$(17,984)

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

ENZO BIOCHEM, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

Years ended July 31, 2015, 2014, and 2013

(in thousands, except share data)

	Common Stock Shares Issued	Treasury Stock Shares	Common Stock Amount	Additional Paid-in Capital	Treasury Stock Amount	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
Balance at July 31, 2012	39,495,475	216,556	395	304,358	(3,074)	(254,183)	1,605	49,101
Net (loss) for the year ended July 31, 2013	—	—	—	—	—	(18,237)	—	(18,237)
Vesting of restricted stock	157,784	—	2	—	—	—	—	2
Share-based compensation charges	—	—	—	545	—	—	—	545
Net proceeds from Issuance of common stock (net of expenses of $224)	906,715	—	9	1,816	—	—	—	1,825
Issuance of treasury stock for employee 401(k) plan match	—	(216,556)	—	(2,458)	3,074	—	—	616
Issuance of common stock for employee 401(k) plan match	9,419	—	—	27	—	—	—	27
Foreign currency translation adjustments	—	—	—	—	—	—	253	253
Balance at July 31, 2013	40,569,393	—	406	304,288	—	(272,420)	1,858	34,132
Net (loss) for the year ended July 31, 2014	—	—	—	—	—	(9,977)	—	(9,977)
Vesting of restricted stock	82,968	—	1	—	—	—	—	1
Share-based compensation charges	—	—	—	594	—	—	—	594
Net proceeds from Issuance of common stock (net of	3,421,176	—	34	11,508	—	—	—	11,542

expenses of $357)								
Issuance of options in lieu of payment of cash bonuses	—	—	—	136	—	—	—	136
Issuance of common stock for employee 401(k) plan match	165,646	—	2	634	—	—	—	636
Foreign currency translation adjustments	—	—	—		—	—	(114)	(114)
Balance at July 31, 2014	44,239,183	—	$ 443	$ 317,160	$ —	$ (282,397)	$ 1,744	$ 36,950
Net (loss) for the year ended July 31, 2015	—	—	—	—	—	(2,285)	—	(2,285)
Vesting of restricted stock	19,418	—	—	—	—	—	—	—
Share-based compensation charges	—	—	—	429	—	—	—	429
Net proceeds from Issuance of common stock (net of expenses of $207)	1,588,480	—	16	6,672	—	—	—	6,688
Issuance of options in lieu of payment of cash bonuses	—	—	—	45	—	—	—	45
Issuance of common stock for employee 401(k) plan match	214,984	—	2	660	—	—	—	662
Foreign currency translation adjustments	—	—	—		—	—	117	117
Balance at July 31, 2015	46,062,065	—	$ 461	$ 324,966	$ —	$ (284,682)	$ 1,861	$ 42,606

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

ENZO BIOCHEM, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Years ended July 31,		
	2015	2014	2013
Cash flows from operating activities:			
Net loss	$(2,285)	$(9,977)	$(18,237)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of property, plant and equipment	2,019	2,131	2,615
Amortization of intangible assets	1,770	1,840	1,990
Provision for uncollectible accounts receivable	2,284	3,063	4,496
Deferred income tax (benefit)	(104)	(18)	(759)
Share-based compensation charges	429	594	545
Share-based 401(k) employer match expense	662	636	643
Foreign exchange (gain) loss	664	(304)	(127)
Changes in operating assets and liabilities:			
Accounts receivable	(2,003)	(3,224)	(2,606)
Other receivables - settlements	(6,650)	—	—
Inventories	1,151	159	60
Prepaid expenses	(108)	336	(97)
Accounts payable - trade	394	(226)	(514)
Accrued liabilities, other current liabilities and other liabilities	(1,923)	3,293	1,975
Total adjustments	(1,415)	8,280	8,221
Net cash used in operating activities	(3,700)	(1,697)	(10,016)
Cash flows from investing activities:			
Capital expenditures	(1,783)	(838)	(988)
Decrease in security deposits and other	31	5	17
Net cash used in investing activities	(1,752)	(833)	(971)
Cash flows from financing activities:			
Net proceeds from issuance of common stock	6,688	11,542	1,825
Proceeds from borrowings under Credit Agreement	88,632	78,814	13,360
Repayments under Credit Agreement	(88,632)	(79,065)	(10,096)
Installment loan payments	(463)	(374)	(274)
Net cash provided by financing activities	6,225	10,917	4,815
Effect of exchange rate changes on cash and cash equivalents	(119)	61	103
Increase (decrease) in cash and cash equivalents	654	8,448	(6,069)
Cash and cash equivalents - beginning of year	17,455	9,007	15,076
Cash and cash equivalents - end of year	$18,109	$17,455	$9,007

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

ENZO BIOCHEM, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

July 31, 2015

(Dollars in thousands except share data)

Note 1 - Summary of significant accounting policies

Nature of business

Enzo Biochem, Inc. (the "Company") is an integrated life science and biotechnology company engaged in research, development, manufacturing and marketing of diagnostic and research products based on genetic engineering, biotechnology and molecular biology. These products are designed for the diagnosis of and/or screening for infectious diseases, cancers, genetic defects and other medically pertinent diagnostic information and are distributed in the United States and internationally. The Company is conducting research and development activities in the development of therapeutic products based on the Company's technology platform of genetic modulation and immune modulation. The Company also operates a clinical laboratory that offers and provides molecular and esoteric diagnostic medical testing services in the New York, New Jersey and Eastern Pennsylvania medical communities. The Company operates in three segments (see Note 15).

Principles of consolidation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("U.S. GAAP") and include the accounts of the Company and its wholly-owned subsidiaries, Enzo Clinical Labs, Inc., Enzo Life Sciences, Inc. (and its wholly-owned foreign subsidiaries), Enzo Therapeutics, Inc. and Enzo Realty LLC ("Realty"). All intercompany transactions and balances have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying footnotes. Actual results could differ from those estimates.

Foreign Currency Translation/Transactions

The Company has determined that the functional currency for its foreign subsidiaries is the local currency. For financial reporting purposes, assets and liabilities denominated in foreign currencies are translated at current exchange rates and profit and loss accounts are translated at weighted average exchange rates. Resulting translation gains and losses are included as a separate component of stockholders' equity as accumulated other comprehensive income or loss. Gains or losses resulting from transactions entered into in other than the functional currency are recorded as foreign exchange gains and losses in the consolidated statements of operations.

Cash and cash equivalents

Cash and cash equivalents consist of demand deposits with banks and highly liquid money market funds. At July 31, 2015 and 2014, the Company had cash and cash equivalents in foreign bank accounts of $0.5 million and $1.1 million, respectively.

Fair Values of Financial Instruments

The recorded amounts of the Company's cash and equivalents, receivables, loan payable, accounts payable and accrued liabilities approximate their fair values principally because of the short-term nature of these items.

Concentration of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of cash and cash equivalents and accounts receivable.

The Company believes the fair value of the aforementioned financial instruments approximates the cost due to the immediate or short-term nature of these items.

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

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ENZO BIOCHEM, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

July 31, 2015

(Dollars in thousands except share data)

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

Accrual for Self-Funded Medical

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

Revenue Recognition - Product revenues

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

Royalties

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

Clinical laboratory services

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

The following table summarizes the Clinical Lab segment's net revenues and revenue percentages by revenue category:

	Years Ended July 31,					
	2015		**2014**		**2013**	
Revenue category	**Amount**	**%**	**Amount**	**%**	**Amount**	**%**
Third-party payers	$35,631	56	$ 29,509	50	$ 26,014	47
Medicare	11,981	19	12,815	22	12,497	22
Patient self-pay	11,028	17	11,204	19	12,172	22
HMO's	4,774	8	5,161	9	5,206	9
Total	$63,414	100%	$58,689	100%	$55,889	100%

The Company provides services to certain patients covered by various third-party payers, including the Federal Medicare program. Laws and regulations governing Medicare are complex and subject to interpretation for which action for noncompliance includes fines, penalties and exclusion from the Medicare programs (See Note 14).

Other than the Medicare program, one provider whose programs are included in the "Third-party payers" and "Health Maintenance Organizations" ("HMO's") categories represent approximately 28%, 25% and 22% of the Clinical Labs segment net revenue for the years ended July 31, 2015, 2014 and 2013 respectively.

ENZO BIOCHEM, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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Contractual Adjustment

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

During the years ended July 31, 2015, 2014 and 2013, the contractual adjustment percentages, determined using current and historical reimbursement statistics, were approximately 85%, 86% and 85%, respectively, of gross billings.

Accounts Receivable and Allowance for Doubtful Accounts

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

For the Clinical Labs segment, the allowance for doubtful accounts represents amounts that the Company does not expect to collect after the Company has exhausted its collection procedures. The Company estimates its allowance for doubtful accounts in the period the related services are billed and reduces the allowance in future accounting periods based on write-offs during those periods. It bases the estimate for the allowance on the evaluation of historical experience of accounts going to collections and the net amounts not received. Accounts going to collection include 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 our estimate of the uncollected portion of receivables from self-payers, including deductibles and copayments, which are subject to credit risk and patients'

ability to pay. As of July 31, 2015 and 2014, the Company recategorizes to collections customers whose accounts receivable have been outstanding more than 210 days. The Company fully reserves through its contractual allowances amounts that have not been written off because the payer's filing date deadline has not occurred or the collection process has not been exhausted. The Company's collection experience on Medicare receivables beyond 210 days has been insignificant. The Company adjusts the historical collection analysis for recoveries, if any, on an ongoing basis.

As of July 31, 2015 and 2014, the Company determined an allowance for doubtful accounts for customers whose accounts receivable have been outstanding less than 210 days and either fully reserved (principally Medicare) or wrote off 100% of accounts receivable over 210 days, as it determined based on historical trends that these accounts were unlikely to be collected. Amounts fully reserved have not been written off because the payer's filing date deadline has not occurred or the collection process has not been exhausted. The Company adjusts the historical collection analysis for recoveries, if any, on an ongoing basis.

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

The allowance for doubtful accounts as a percentage of total accounts receivable at July 31, 2015 and 2014 was 12.9% and 14.7% respectively. During fiscal 2015, the contractual allowance applied to the Clinical Labs segment's patient self-pay revenues was increased based on collections trends, which has the effect of reducing the allowance for doubtful patient pay accounts receivable. We continue to improve our patient pay collection process by billing patients sooner and by giving past due accounts to collection agencies sooner. As a result of these factors, a smaller allowance was required at July 31, 2015 versus 2014.

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(Dollars in thousands except share data)

The Clinical Labs segment's net receivables are detailed by billing category and as a percent to its total net receivables. At July 31, 2015 and 2014, approximately 68% and 60%, respectively, of the Company's net accounts receivable relates to its Clinical Labs business, which operates in the New York, New Jersey, and Eastern Pennsylvania medical communities.

The Life Sciences segment's accounts receivable includes royalties receivable of $0.1 million and $1.0 million, as of July 31, 2015 and 2014, respectively, due from QIAGEN Gaithersburg Inc. ("Qiagen") (see Note 12).

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

	July 31, 2015		July 31, 2014	
Net accounts receivable by segment	**Amount**	**%**	**Amount**	**%**
Clinical Labs (by billing category)				
Third party payers	$3,595	44	$3,499	46
Patient self-pay	3,213	39	2,193	29
Medicare	1,081	13	1,558	21
HMO's	305	4	280	4
Total Clinical Labs	8,194	100%	7,530	100%
Total Life Sciences	3,915		4,940	
Total accounts receivable – net	$12,109		$12,470	

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

	July 31, 2015	July 31, 2014
Beginning balance	$2,142	$2,707
Provision for doubtful accounts	2,284	3,063
Write-offs	(2,640)	(3,628)
Ending balance	$1,786	$2,142

The Company's Life Sciences segment other receivables from a legal settlement was $6,650 as of July 31, 2015.

Inventories

The Company values inventory at the lower of cost (first-in, first-out) or market. Work-in-process and finished goods inventories consist of material, labor, and manufacturing overhead. Write downs of inventories to market value are based on a review of inventory quantities on hand and estimated sales forecasts based on sales history and anticipated future demand. Unanticipated changes in demand could have a significant impact on the value of our inventory and require additional write downs of inventory which would impact our results of operations.

Property, plant and equipment

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

Goodwill and Intangible Assets

Goodwill represents the excess of the cost of an acquisition over the fair value of the net assets acquired.

Intangible assets (exclusive of patents), arose primarily from acquisitions, and primarily consist of customer relationships, trademarks, licenses, and website and database content. Finite-lived intangible assets are amortized according to their estimated useful lives, which range from 4 to 15 years. Indefinite-lived intangibles are not amortized and are evaluated each reporting period to determine whether

ENZO BIOCHEM, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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(Dollars in thousands except share data)

events and circumstances continue to support their having an indefinite life. Indefinite-lived intangibles found to no longer have an indefinite life are evaluated for impairment and are then amortized over their remaining useful life as finite-lived intangible assets. Patents represent capitalized legal costs incurred in pursuing patent applications. When such applications result in an issued patent, the related capitalized costs are amortized over a ten year period or the life of the patent, whichever is shorter, using the straight-line method.

The Company reviews its issued patents and pending patent applications, and if it determines to abandon a patent application or that an issued patent no longer has economic value, the unamortized balance in deferred patent costs relating to that patent is immediately expensed.

Impairment testing for Goodwill and Long-Lived Assets

The Company tests goodwill annually as of the first day of the fourth quarter, or more frequently if indicators of potential impairment exist. In assessing goodwill for impairment, the Company has the option to first perform a qualitative assessment to determine whether the existence of events or circumstances leads to a determination that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If the Company determines that it is not more likely that not that the fair value of a reporting unit is less than its carrying amount, the Company is not required to perform any additional tests in assessing goodwill for impairment. If the Company concludes otherwise or elects not to perform the qualitative assessment, then it is required to perform the first step of a two-step quantitative impairment review process. The first step of the quantitative impairment test requires the identification of the reporting units and comparison of the fair value of each of these reporting units to their respective carrying value. If the carrying value of the reporting unit is less than its fair value, no impairment exists and the second step is not performed. If the carrying value of the reporting unit is higher than its fair value, the second step must be performed to compute the amount of the goodwill impairment, if any. In the second step, the impairment is computed by comparing the implied fair value of the reporting unit goodwill with the carrying amount of that goodwill. If the carrying amount of the reporting unit goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized for the excess. The Company performed a qualitative assessment in 2015 and 2014, and a quantitative assessment in 2013 and concluded there were no goodwill impairments.

The Company reviews the recoverability of the carrying value of long-lived assets (including intangible assets with finite lives) for impairment annually as of the first day of the fourth quarter, or more frequently if indicators of potential impairment exist. Should indicators of impairment exist, the carrying values of the assets are evaluated in relation to the operating performance and future undiscounted cash flows of the underlying business. The net book

value of an asset is adjusted to fair value if its expected future undiscounted cash flow is less than its book value. There were no long-lived asset impairments in 2015, 2014 or 2013.

Comprehensive loss

Comprehensive loss consists of the Company's consolidated net loss and foreign currency translation adjustments. Foreign currency translation adjustments included in comprehensive loss were not tax effected as investments in international affiliates are deemed to be permanent. Accumulated other comprehensive income is a separate component of stockholders' equity and consists of the cumulative foreign currency translation adjustments.

Shipping and Handling Costs

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

Research and Development

Research and development costs are charged to expense as incurred.

Advertising

All costs associated with advertising are expensed as incurred. Advertising expense, included in selling, general and administrative expense, approximated $556, $440 and $302 for the years ended July 31, 2015, 2014 and 2013, respectively.

ENZO BIOCHEM, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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(Dollars in thousands except share data)

Income Taxes

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

Under the liability method, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

It is the Company’s policy to provide for uncertain tax positions and the related interest and penalties based upon management’s assessment of whether a tax benefit is more likely than not to be sustained upon examination by tax authorities. At July 31, 2015, the Company believes it has appropriately accounted for any unrecognized tax benefits. To the extent the Company prevails in matters for which a liability for an unrecognized tax benefit is established or is required to pay amounts in excess of the liability, the Company’s effective tax rate in a given financial statement period may be affected.

Segment Reporting

The Company separately reports information about each operating segment that engages in business activities from which the segment may earn revenues and incur expenses, whose separate operating results are regularly reviewed by the chief operating decision maker regarding allocation of resources and performance assessment and which exceed specific quantitative thresholds related to revenue and profit or loss. The Company’s operating activities are reported in three segments (see Note 15).

Net income (loss) per share

Basic net income (loss) per share represents net income (loss) divided by the weighted average number of common shares outstanding during the period. The dilutive effect of potential common shares, consisting of outstanding stock options and unvested restricted stock, is determined using the treasury stock method. Diluted weighted average shares outstanding for fiscal 2015, 2014 and 2013 do not include the potential common shares from stock options and unvested restricted stock because to do so would have been antidilutive and as such is the same as basic weighted average shares outstanding for 2015, 2014 and 2013. The number of potential common shares ("in the money options") and unvested restricted stock excluded from the calculation of diluted earnings per share for the years ended July 31, 2015, 2014, and 2013 was 403,000, 1,016,000 and 125,000, respectively.

For the years ended July 31, 2015, 2014 and 2013, the effect of approximately 977,000, 182,000 and 727,000 respectively, of outstanding "out of the money" options to purchase common shares were excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. The following table sets forth the computation of basic and diluted net loss per share for the years ended July 31:

	2015	**2014**	**2013**
Net loss	$(2,285)	$(9,977)	$(18,237)
Weighted-average common shares outstanding - basic	45,355	42,561	39,607
Add: effect of dilutive stock options and restricted stock	—	—	—
Weighted-average common shares outstanding - diluted	45,355	42,561	39,607
Net income (loss) per share – basic and diluted	$(0.05)	$(0.23)	$(0.46)

Share-Based Compensation

The Company records compensation expense associated with stock options and restricted stock based upon the fair value of stock based awards as measured at the grant date. The Company determines the award values using the Black Scholes option pricing model.

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(Dollars in thousands except share data)

The expense is recorded by amortizing the fair values on a straight line basis over the vesting period, adjusted for estimated forfeitures.

For the years ended July 31, 2015, 2014 and 2013, share-based compensation expense relating to the fair value of stock options, restricted shares and restricted stock units was approximately $429, $594, and $545, respectively (see Note 10). No excess tax benefits were recognized for the year ended July 31, 2015, 2014 and 2013.

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

	2015	2014	2013
Cost of clinical laboratory services	$5	$9	$10
Research and development	2	1	2
Selling, general and administrative	422	584	533
	$429	$594	$545

As of July 31, 2015, there was $555 of total unrecognized compensation cost related to non-vested share-based payment arrangements granted under the Company’s incentive stock plans, which will be recognized over a weighted average remaining life of approximately fifteen months.

Effect of new accounting pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standard Update (“ASU”) No. 2014-09, *Revenue from Contracts with Customers: Topic 606*. ASU 2014-09 amends the guidance for revenue recognition to replace numerous, industry-specific requirements and converges areas under this topic with those of the International Financial Reporting Standards. ASU 2014-09 implements a five-step process for customer contract revenue recognition that focuses on transfer of control, as opposed to transfer of risk and rewards. The amendment also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenues and cash flows from contracts with customers. Other major provisions include the capitalization and amortization of certain contract costs, ensuring the time value of money is considered in the transaction price, and allowing estimates of variable

consideration to be recognized before contingencies are resolved in certain circumstances. As of July 9, 2015, the FASB decided to delay the effective date of the new revenue standard by one year. The amendments in ASU 2014-09 are effective for reporting periods beginning after December 15, 2017, (the fiscal year ending July 31, 2019 for the Company) and early adoption is permitted for reporting periods beginning after December 15, 2016. Entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. We are currently assessing the impact the adoption of ASU 2014-09 will have on the Company's combined consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. ASU 2014-15 will explicitly require management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosure in certain circumstances. The new standard will be effective for all entities in the first annual period ending after December 15, 2016. Earlier adoption is permitted. We are currently evaluating the impact of the adoption of ASU 2014-15.

In January 2015, the FASB issued ASU No. 2015-01, *Income Statement Extraordinary and Unusual Items.* The ASU eliminates the concept of extraordinary items from U.S. GAAP as part of its simplification initiative. The ASU does not affect disclosure guidance for events or transactions that are unusual in nature or infrequent in their occurrence. The update applies to all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. We do not expect the adoption of this update to have a material impact in our consolidated financial statements.

In February 2015, the FASB issued ASU No. 2015-02, *Consolidation: Amendments to the Consolidation Analysis.* The amendments in the update affect reporting entities that are required to evaluate whether they should consolidate certain legal entities. All legal entities are subject to reevaluation under the revised consolidation model. The amendments in the update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2015. For all other entities, the effective date for fiscal years beginning after December 15, 2016, and for interim periods within fiscal years beginning after December 15, 2017. Early adoption is permitted. We do not expect the adoption of this update to have a material impact in our consolidated financial statements.

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In April 2015, the FASB issued ASU No. 2015-03 *Interest – Imputation of Interest.* The ASU was issued as part of the Simplification Initiatives, to simplify presentation of debt issuance costs. The amendments in the update require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the amendments in this update. For public business entities, the amendments in the update are effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption of the amendments in this update is permitted for financial statements that have not been previously issued. We do not expect the adoption of this update to have a material impact in our consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, *Simplifying the Measurement of Inventory (Topic 330).* ASU 2015-11 changes the measurement principle for inventory from the lower of cost or market to lower of cost or net realizable value. The new standard is effective for our fiscal years and interim periods beginning after December 15, 2016. We do not expect the adoption of this update to have a material impact on our consolidated financial statements.

Note 2 - Goodwill and intangible assets

Goodwill

The Company’s net carrying amount of goodwill is in the Clinical Labs segment as of July 31, 2015 and 2014 is $7,452.

Intangible assets

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

	Gross	**Net**

		Accumulated Amortization	
July 31, 2013	$28,214	$ (18,271)	$9,943
Amortization expense	—	(1,840)	(1,840)
Foreign currency translation	264	(259)	5
July 31, 2014	$28,478	$ (20,370)	$8,108
Amortization expense	—	(1,770)	(1,770)
Foreign currency translation	(640)	457	(183)
July 31, 2015	$27,838	$ (21,683)	$6,155

Intangible assets, all finite-lived, consist of the following:

	July 31, 2015			July 31, 2014		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Patents	$11,028	$ (10,871)	$157	$11,027	$ (10,775)	$252
Customer relationships	12,243	(7,398)	4,845	12,602	(6,565)	6,037
Website and acquired content	1,020	(1,020)	—	1,037	(1,037)	—
Licensed technology and other	518	(441)	77	537	(434)	103
Trademarks	3,029	(1,953)	1,076	3,275	(1,559)	1,716
Total	$27,838	$ (21,683)	$6,155	$28,478	$ (20,370)	$8,108

At July 31, 2015 information with respect to the intangibles acquired is as follows:

	Useful life assigned	Weighted average remaining useful life
Customer relationships	8-15 years	5 years
Trademarks	5 years	2 years
Other intangibles	10 years	4 years

At July 31, 2015, the weighted average remaining useful life of intangible assets was approximately four years.

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

2016	$1,620
2017	1,508
2018	1,141
2019	827
2020	512

Amortization expense for the years ended July 31, 2015, 2014, and 2013 was $1,770 $1,840, and $1,990, respectively.

Note 3 - Supplemental disclosure for statement of cash flows

In the years ended July 31, 2015, 2014, and 2013, income taxes paid by the Company approximated $115, $44, and $46 respectively**.**

In the years ended July 31, 2015, 2014, and 2013, interest paid by the Company approximated $206, $208, and $69 respectively.

During fiscal 2015, 2014 and 2013, the Company financed $346, $392 and $365, respectively, in machinery and transportation equipment under installment loans.

During fiscal 2015, the Company entered into a capital lease agreements with a cost basis of $155. During fiscal 2014, the Company did not enter into any capital lease agreements. During fiscal 2013, the Company entered into a capital lease for machinery and equipment with a cost basis of $765.

During fiscal 2015 and 2014, the Company recorded $45 and $136, respectively, in additional paid in capital and reduced accrued liabilities by the same amount for options issued in lieu of cash payment of certain incentive compensation awards.

Note 4 - Inventories

Inventories consisted of the following at July 31:

	2015	2014
Raw materials	$1,013	$1,092
Work in process	2,002	2,460
Finished products	4,381	5,138
	$7,396	$8,690

Note 5 - Property, plant, and equipment

At July 31, 2015 and 2014 property, plant, and equipment consist of:

	2015	2014
Building and building improvements	$4,854	$4,834
Machinery and equipment (includes asset under capital lease - see Note 9)	7,397	7,125
Office furniture and computer equipment	18,289	16,834
Leasehold improvements	4,958	4,835
	35,498	33,628
Accumulated depreciation and amortization	(28,262)	(26,610)
	7,236	7,018
Land and land improvements	712	712
	$7,948	$7,730

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Note 6 - Income taxes

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

	2015	2014	2013
Current (provision) benefit:			
Federal	$—	$—	$—
State and local	(72)	(68)	(46)
Foreign	(25)	(22)	(1)
Deferred benefit	104	18	759
Benefit (provision) for income taxes	$7	$(72)	$712

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

	2015	2014
Deferred tax assets:		
Federal tax carryforward losses	$35,411	$35,352
Provision for uncollectible accounts receivable	685	753
State and local tax carry forward losses	2,661	2,604
Accrued royalties	144	144
Stock compensation	99	190
Depreciation	618	618
Research and development and other tax credit carryforwards	1,134	1,085
Foreign tax carryforward losses	1,476	1,207
Intangibles	2,951	2,970
Inventory	2,558	2,194
Accrued expenses	2,627	3,103
Unrealized foreign exchange	98	—
Other, net	18	15
Deferred tax assets	50,480	50,235

Deferred tax liabilities:

Deferred patent costs	(152)	(135)
Prepaid expenses	(676)	(671)
Unrealized foreign exchange	—	(118)
Other, net	(31)	(29)
Deferred tax liabilities	(859)	(953)
Net deferred tax assets (liabilities) before valuation allowance	49,621	49,282
Less: valuation allowance	(49,658)	(49,465)
Net deferred tax liabilities	$(37)	$(183)

At July 31, 2015, net deferred tax liabilities consist primarily of identifiable intangible assets and cumulative tax deductions in excess of book expenses recognized by foreign subsidiaries.

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

	2015	**2014**
Deferred taxes:		
Current	$ —	$—
Non-current	37	183
	$ 37	$183

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The Company recorded a valuation allowance during the year ended July 31, 2015 and 2014 equal to domestic and certain foreign net deferred tax assets. The Company believes that the valuation allowance is necessary as it is not more likely than not that the deferred tax assets will be realized in the foreseeable future based on positive and negative evidence available at this time. This conclusion was reached because of uncertainties relating to future taxable income, in terms of both its timing and its sufficiency, which would enable the Company to realize the deferred tax assets. For fiscal year 2015 and 2014 the change in the valuation allowance was $0.2 million and $1.8 million, respectively.

As of July 31, 2015, the Company had U.S. federal net operating loss carryforwards of approximately $104.1 million. The U.S. federal tax loss carryforwards, if not fully utilized, expire between 2018 and 2035. Utilization is dependent on generating sufficient taxable income prior to expiration of the tax loss carryforwards. In addition, the Company has research and development tax credit carryforwards of approximately $1.0 million which expire between 2025 and 2035. As of July 31, 2015, the Company had foreign loss carryforwards of approximately $8.8 million.

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

	2015	2014	2013
United States operations	$(615)	$(8,702)	$(15,419)
International operations	(1,677)	(1,203)	(3,530)
Loss before taxes	$(2,292)	$(9,905)	$(18,949)

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

	2015	2014	2013
Federal statutory rate	34.0 %	34.0 %	34.0 %
Penalties and other expenses not deductible for income tax return purposes	(18.6)	(6.6)	(0.9)
State income taxes, net of benefit of federal tax deduction	(0.5)	0.2	2.5
Change in valuation allowance	(15.2)	(16.5)	(32.7)
State tax law change	—	(12.3)	—

Other	0.6		0.5		(0.9	)
	0.3	%	(0.7	)%	3.8	%

U.S. federal income taxes have not been provided on approximately $46 of undistributed earnings at the Company's foreign subsidiaries at July 31, 2015, because it is the Company's intent to keep the earnings reinvested. As of July 31, 2015, the Company has no liabilities for uncertain tax positions. It is the Company's policy to record interest and penalties as a component of tax expense. The Company files income tax returns in the U.S. Federal jurisdiction, various U.S. state jurisdictions and several foreign jurisdictions.

Note 7 - Loan Payable

On June 7, 2013, the Company entered into a secured Revolving Loan and Security Agreement (the "Credit Agreement") among the Company and certain of its subsidiaries, with Enzo Therapeutics as a guarantor, and MidCap Financial LLC. (formerly Healthcare Finance Group, LLC). The Credit Agreement, which expires in December 2016, provides for borrowings against eligible US receivables, as defined, of the Clinical Lab and Life Science segments up to $8.0 million at defined eligibility percentages and provides for additional borrowings of $4.0 million for increased eligible assets. Debt issuance costs of $281 are being amortized over the life of the Credit Agreement. If the amount of borrowings outstanding under the revolving credit facility exceeds the borrowing base then in effect, or the Lender requires a reserve, the Company will be required to repay such borrowings in an amount sufficient to eliminate such excess. Interest on advances, payable monthly, is based on the three month LIBOR rate, with a floor of 1.25% plus an applicable margin of 4.0%, In the event of any default, the interest rate may be increased 3.0% over the current rate. The facility also carries a non-utilization fee of 0.50% per annum, payable monthly, on the unused portion of the credit line. The Credit Agreement requires a minimum borrowing of $2.0 million. At July 31, 2015 and 2014, the borrowings under the Credit Agreement related to the Clinical Labs and Life Sciences receivables aggregated $3.0 million, with an additional availability of $2.4 million at July 31, 2015.

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The Company's obligations under the Credit Agreement are secured by primarily all the unencumbered U.S. assets of the Company, excluding buildings and intellectual property which the Lender has a negative pledge, and the capital stock of subsidiaries. The Credit Agreement includes customary affirmative and negative covenants and events of default and requires maximum levels of cash usage and minimum levels of liquidity, as defined, and provides for increased liquidity levels if operating results are not achieved. Negative covenants include among others, limitations on additional debt, liens, loans or investments, distributions, asset sales and affiliate transactions. Events of default include, non-payment of principal and interest on debt outstanding, non-performance of covenants, material change in business, breach of representations, bankruptcy and insolvency, material judgments and changes in control. In July 31, 2013, the lender modified various financial covenants relating to fiscal 2014. As of July 31, 2015 and 2014, the Company is in compliance with the financial covenants.

The Credit Agreement includes customary affirmative and negative covenants and events of default. The terms of the debt covenants include:

- The minimum balance the Company must borrow at any time is $2.0 million. At July 31, 2015, the loan balance was approximately $3.0 million.

- The Company must maintain a Minimum Liquidity, as defined in the Credit Agreement, of not less than $3.0 million. At July 31, 2015, the Company's Minimum Liquidity was $11.5 million.

- The quarterly Cash Burn, as defined in the Credit Agreement, must be greater than zero. During the three months ended July 31, 2015, the Cash Burn was positive in the amount of $0.3 million.

Based on its current level of Minimum Liquidity and Cash Burn, the Company believes it will continue to be in compliance with the financial covenants in future periods; however there are no assurances of such compliance. Based on our ability to comply with financial covenants in the past, our ability to obtain covenant waivers previously, and our expected future performance, we believe we would be able to cure a non-compliance event and obtain a Lender waiver. The Company currently believes that the Lender would be willing to negotiate and provide waivers to the Company in the event of non-compliance with covenants, although there can be no assurances. In addition, the Company believes the effects of non-compliance with the covenants would not have a material effect on our financial condition and liquidity due to cash provided by operating cash flows and funds available under the Company's Controlled Equity Offering program.

Note 8 - Accrued Liabilities, Other Current Liabilities and Other Liabilities

At July 31 accrued liabilities consist of:

	2015	2014
Legal	$4,183	$4,721
Payroll, benefits, severance and commissions	3,907	4,959
Professional fees	678	638
Research and development	300	400
Other	2,229	2,199
	$11,297	$12,917

Self-Insured Medical Plan

The Company self-funds medical insurance coverage for certain of its U.S. based employees. The risk to the Company is being limited through the use of individual and aggregate stop loss insurance. As of July 31, 2015 and 2014, the Company has established a reserve of $0.3 million and $0.2 million, respectively, which is included in accrued liabilities, for claims that have been reported but not paid and incurred but not reported. The reserve is based upon the Company’s historical payment trends, claim history and current estimates.

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Note 9 - Other liabilities

At July 31 Other liabilities consist of:

	2015	2014
Accrued legal settlement – see Note 14	$1,220	$1,600
Capital lease obligation	210	344
Installment loans	363	369
	$1,793	$2,313

The capital lease obligation and installment loans are for machinery and equipment used in the Clinical Labs segment. Amortization of the assets recorded under the capital lease is included in depreciation expense. At July 31, 2015, the accumulated amortization on the capital lease was $534.

Future minimum lease and loan payments are as follows:

	Capital lease	**Installment loans**
2016	$ 149	$ 331
2017	195	267
2018	15	96
Payments net of interest	359	694
Less: current portion	(149)	(331)
Other liabilities - net	$ 210	$ 363

The weighted average interest rate on our short term borrowings during fiscal 2015 was 2.7%. The weighted average interest rate on our short term borrowings during fiscal 2014 was 2.87%.

Note 10 - Stockholders’ equity

Controlled Equity Offering

On March 28, 2013, the Company entered into a Controlled Equity Offering[SM] Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as sales agent ("Cantor"). Under the Sales Agreement, the Company may offer and sell, from time to time, through Cantor, shares of the Company's common stock, par value $0.01 per share (the "Common Stock"), having an aggregate offering price of up to $20.0 million (the "Shares"). The Company will pay Cantor a commission of 3.0% of the aggregate gross proceeds received under the Sale Agreement. The Company is not obligated to make any sales of the Shares under the Sales Agreement. The offering of Shares pursuant to the Sales Agreement will terminate upon the earlier of (a) the sale of all of the Shares subject to the Sales Agreement or (b) the termination of the Sales Agreement by Cantor or the Company, as permitted therein. The Shares were initially issued pursuant to the Company's Registration Statement which was declared effective on August 5, 2010 and the prospectus supplement, dated March 28, 2013, and more recently under a current registration statement declared effective August 13, 2013 and the prospectus supplement dated August 1, 2013, filed by the Company with the Securities and Exchange Commission.

On December 31, 2014, the Sales Agreement was amended in order for the Company to offer and sell, through Cantor, acting as agent, additional shares of Common Stock having an aggregate offering price of $20.0 million. In connection with the amendment to the Sales Agreement, the Company also filed with the SEC a prospectus supplement dated December 31, 2014.

For the year ended July 31, 2015, the Company sold an aggregate of 1,588,480 shares of common stock under the Sales Agreement at an average price of $4.34 per share and received proceeds of approximately $6.7 million, net of expenses of $207. For the year ended July 31, 2014, the Company sold an aggregate of 3,421,176 shares of common stock under the Sales Agreement at an average price of $3.48 per share and received proceeds of approximately $11.5 million, net of expenses of $357.

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Common stock

In fiscal 2015, the Company issued 214,984 shares of common for its employees' 401(k) matching contributions obligation. The Company recorded an expense of $662 for the match, representing the fair value of the shares at the date of issuance.

In fiscal 2014, the Company issued 165,646 shares of common for its employees' 401(k) matching contributions obligation. The Company recorded an expense of $636 for the match, representing the fair value of the shares at the date of issuance.

In fiscal 2013, the Company issued 9,419 shares of common stock for its employees' 401(k) matching contributions obligation. The Company recorded an expense of $27 for the match representing the fair value of the shares at the date of issuance.

Treasury stock

In fiscal 2013, the Company issued 216,556 shares from treasury stock to match a portion of its employees' 401(k) contributions. The Company recorded an expense of $616 for the match, reducing treasury stock by $3,074 for the average acquisition cost of such shares and adjusting additional paid in capital by $2,458.

Incentive stock plans

The Company has an incentive stock option and restricted (non-vested) stock award plan (the "2005 Plan"), under which the Company may grant options and restricted stock (non-vested) awards for up to 1,000,000 common shares under the 2005 Plan. No additional awards may be granted under the 2005 Plan. On January 14, 2011, the Company's stockholders approved the adoption of the 2011 Incentive Plan (the "2011 Plan") which provides for the issuance of equity awards, including among others, options, restricted stock and restricted stock units for up to 3,000,000

Common Shares. The exercise price of options granted under the 2011 Plan, and consistent with other Plans, is equal to or greater than fair market value of the Common Stock on the date of grant. Unless terminated earlier by the Board of Directors, the 2011 Plan will terminate at the earliest of; (a) such time as no shares of Common Stock remain available for issuance under the 2011 Plan or (b) tenth anniversary of the effective date of the 2011 Plan. Awards outstanding upon expiration of the 2011 Plan shall remain in effect until they have been exercised, terminated, or have expired. As of July 31, 2015, there were approximately 1,301,000 shares available for grant under the 2011 Plan.

The Company estimates the fair value of each stock option award on the measurement date using a Black-Scholes option pricing model. The fair value of awards is amortized to expense on a straight line basis over the requisite service period. The Company expenses restricted stock awards based on vesting requirements, primarily time elapsed.

Options granted pursuant to the plans may be either incentive stock options or non-statutory options The 2011 Plan provides for the issuance of stock options, restricted stock and restricted stock unit awards which generally vest over a two to four year period. A summary of the activity pursuant to the Company's stock option plans for the years ended July 31, 2015, 2014, and 2013 is as follows:

	2015		2014		2013	
	Options	Weighted-Average Exercise Price	Options	Weighted-Average Exercise Price	Options	Weighted-Average Exercise Price
Outstanding at beginning of year	1,155,910	$ 5.03	726,645	$ 10.39	736,490	$ 14.50
New Grants	383,873	$ 3.55	665,117	$ 2.77	336,817	$ 2.88
Expired	(181,679)	$ 16.84	(236,852)	$ 15.80	(346,662)	$ 11.82
Outstanding at end of year	1,358,104	$ 3.04	1,155,910	$ 5.03	726,645	$ 10.39
Exercisable at end of year	782,688	$ 2.88	399,262	$ 7.66	389,828	$ 16.88
Weighted average fair value of options granted during year		$ 1.36		$ 0.90		$ 1.22

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The intrinsic value of stock option awards that vested during the fiscal year represents the value of the Company's closing stock price on the last trading day of the fiscal year in excess of the exercise price multiplied by the number of options that vested. Total intrinsic value of options that vested and were exercisable during the fiscal years ended July 31, 2015, 2014, and 2013 was $97, $425 and $0, respectively. The intrinsic value of options outstanding at July 31, 2015, 2014, and 2013 was $154, $1,915 and $0, respectively.

On January 21, 2015, the Company awarded 293,373 options to two senior officers and the board of directors with an exercise price of $3.40 and a five year term, which vest annually over two years. The fair value of the options granted was $1.27 per share. The assumptions used to fair value this option award were as follows: expected life of 3.25 years, expected volatility 52.25%, a risk free interest rate of 0.93% and no dividend yield. As of July 31, 2015, none of these options were vested. Further on January 21, 2015, the Company awarded 40,000 options to executive officers with an exercise price of $3.40 and a five year term, which vest annually over three years. The fair value of the options granted was $1.39 per share. The assumptions used to fair value this option award were as follows: expected life of 3.5 years, expected volatility 55.63%, a risk free interest rate of 1.00% and no dividend yield. As of July 31, 2015, none of these options were vested.

On December 10, 2014, the Company awarded 50,500 options to employees with an exercise price of $4.66 and a five year term, which vest annually over three years. The fair value of the options granted was $1.894 per share. The assumption used to fair value this option award were as follows: expected life of 3.5 years, expected volatility 55.16%, a risk free interest rate of 1.15% and no dividend yield. As of July 31, 2015 none of these options were vested.

On January 17, 2014, the Company awarded 267,797 options to two senior officers and the board of directors with an exercise price of $2.70 and a five year term, which vest annually over two years. The fair value of the options granted was $1.05 per share. The assumptions used to fair value this option award were as follows: expected life of 3.25 years, expected volatility 54.78%, a risk free interest rate of 0.90% and no dividend yield. As of July 31, 2015, approximately 133,900 of these options were vested. Further on January 17, 2014, the Company awarded 95,729 options to executive officers with an exercise price of $2.70 and a five year term, which vest annually over three years. The fair value of the options granted was $1.10 per share. The assumptions used to fair value this option award were as follows: expected life of 3.5 years, expected volatility 55.45%, a risk free interest rate of 1.00% and no dividend yield. As of July 31, 2015, approximately 55,600 of these options were vested, including approximately 42,000 which became fully vested upon termination and 12,000 of which were forfeited.

On February 3, 2014, the Company awarded 20,000 options to an executive officer with an exercise price of $2.75 and a five year term, which vest annually over three years. The fair value of the options granted was $1.11 per share. The assumptions used to fair value this option award were as follows: expected life of 3.5 years, expected volatility 55.07%, risk free interest rate of 0.84% and no dividend yield. As of July 31, 2015, approximately 6,600 of these options were vested.

On November 26, 2013, the Company awarded 271,591 options to two senior officers with an exercise price of $3.00 and a four year term, which vest over one year. The award satisfies $0.2 million of their fiscal 2013 incentive compensation award liability in lieu of cash. The fair value of the options granted was $0.66 per share. The assumptions used to fair value this option award were as follows: expected life of 2.5 years, expected volatility 54.79%, risk free interest rate of 0.42% and no dividend yield. As of July 31, 2015, all of these options were vested.

On January 17, 2013, the Company awarded 336,817 options to directors and certain officers with an exercise price of $2.88 and a five year term, of which 247,672 options vest over two years and 89,145 vest over three years. The weighted average assumptions used to fair value this option award were as follows: expected life of 3.3 years, expected volatility 60.8%, risk free interest rate of 0.45% and no dividend yield. As of July 31, 2015, approximately 307,000 of these options were vested.

The following table summarizes information for stock options outstanding at July 31, 2015:

	Options outstanding and exercisable		
Range of Exercise prices	Shares	Weighted-Average Remaining Contractual Life in Years	Weighted-Aveage Exercise Price
$2.53 – $3.00	978,232	2.02	$ 2.84
$3.40 - $4.66	379,872	0.47	$ 3.55
	1,358,104		

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Restricted Stock Awards

During fiscal 2015, 2014 and 2013, the compensation committee of the Company's board of directors approved grants of restricted stock and restricted stock unit awards (the "Awards") to certain officers and certain employees under the 2011 or 2005 Plans. The Awards vest upon the recipient's continued employment service rateably over either two, three or four years. Share-based compensation expense is based on the fair value of the award as measured on the grant date and is recorded over the vesting period on a straight-line basis. The Awards will be forfeited if the recipient ceases to be employed by the Company, as defined in the Plans' terms. The Awards settle in shares of the Company's common stock on a one-for-one basis.

The following table summarizes the activity pursuant to restricted stock awards for the years ended July 31,

	2015		2014		2013	
	Awards	Weighted-Average Award Price	Awards	Weighted-Average Award Price	Awards	Weighted-Average Award Price
Outstanding at beginning of year	42,502	$ 5.74	125,133	$ 3.45	257,583	$ 3.58
Awarded	4,250	$ 4.75	11,500	$ 4.77	39,000	$ 1.77
Vested	(19,418)	$ (2.83)	(82,971)	$ (2.70)	(157,783)	$ (3.23)
Forfeited	(5,833)	$ (3.22)	(11,160)	$ (1.70)	(13,667)	$ (3.59)
Outstanding (non-vested) at end of year	21,501	$ 8.84	42,502	$ 5.74	125,133	$ 3.45
Weighted average market value of awards granted during year		$ 4.75		$ 4.77		$ 1.77

The fair value of the awards that vested during the years ended July 31, 2015, 2014 and 2013 was $79, $253 and $411, respectively.

Note 11 - Employee benefit plan

The Company has a qualified Salary Reduction Profit Sharing Plan (the "Plan") for eligible U.S. employees under Section 401(k) of the Internal Revenue Code. The Plan provides for voluntary employee contributions through salary reduction and voluntary employer contributions at the discretion of the Company. For the years ended July 31, 2015, 2014, and 2013, the Company authorized employer matched contributions of 50% of the employees' contribution up to 10% of the employees' compensation, payable in Enzo Biochem, Inc. common stock. The share-based 401(k) employer matched contribution was approximately $662, $636, and $643 in fiscal years 2015, 2014, and 2013, respectively.

The Company's Swiss operations provide a pension plan named the Enzo Life Sciences (ELS) AG Vertrag - Nr. 2/401144, (the "Swiss Plan") under the Swiss government's social security system for Swiss employees. The current required minimum saving contribution is 13% for employees over age 25 and minimum annual investment return is 2%. Employees are required to contribute based on a formula and the Company's Swiss operations make contributions of at least 50% of the employee contribution. The status of the Swiss Plan, which is substantially funded as of December 31, 2014, the latest plan year end, is as follows:

As of December 31,	2014	2013	2012
Total Assets	$2,132	$2,531	$2,965
Accumulated Benefit Obligation	$2,421	$2,697	$3,064
Funded status	88 %	94 %	97 %

Fiscal Year ended July 31,	2014	2013	2012
Contributions	$279	$467	$521

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The Swiss Plan's contract expires December 31, 2019 and currently the Company has no plans to change the current funding or plan design. No events have occurred that would impact the Swiss Plan status.

Note 12 - Royalty and other income

The Company has a license agreement with Qiagen that began in 2005, whereby the Company earns quarterly running royalties on the net sales of Qiagen products subject to the license until the expiration of the patent on April 24, 2018. During the years ended July 31, 2015, 2014 and 2013, the Company recorded royalty income under the agreement of approximately $2,495, $4,408 and $5,144, respectively, which is included in the Life Sciences segment.

Note 13 - Commitments

Leases

The Company leases equipment, office and laboratory space under several non-cancellable operating leases that expire between September 2014 and May 2023. Certain leases include renewal options and rent escalation clauses. An entity owned by certain executive officers/directors of the Company owns the building that the Company leases as its main facility for laboratory operations and certain research operations. In March 2005, the Company amended and extended the lease for 12 years. In addition to the minimum annual rentals of space, the lease is subject to annual increases, based on the consumer price index. Annual increases are limited to 3% per year. Rent expense for this lease, inclusive of real estate taxes, approximated $1,623, $1,649 and $1,605 during fiscal years 2015, 2014 and 2013, respectively. Total rent expense incurred by the Company during fiscal 2015, 2014 and 2013 for all its facilities was approximately $4,504, $4,488 and $4,354, respectively.

Minimum future annual rentals under all non-cancellable operating leases, net of sublease rental income of $322, as of July 31, 2015, are as follows:

Years ended July 31,	
2016	7,834
2017	6,965
2018	5,133
2019	4,426
2020	2,490
Thereafter	526
	$27,374

Employment Agreements

The Company has employment agreements with certain officers that are cancellable at any time but provide for severance pay in the event an officer is terminated by the Company without cause, as defined in the agreements. Unless cancelled earlier or with notice as defined, the agreement automatically renews for two years. Aggregate minimum compensation commitments, exclusive of any severance provisions as of July 31, 2015 is $2,271.

Note 14 – Contingencies

On June 7, 2004, the Company and Enzo Life Sciences, Inc., filed suit in the United States District Court for the District of Connecticut against Applera Corporation and its wholly-owned subsidiary Tropix, Inc., which became Life Technologies, Inc. (NASDAQ:LIFE) and was acquired by Thermo Fisher Scientific, Inc. (NYSE:TMO) on February 3, 2014. The complaint alleged infringement of six patents relating to DNA sequencing systems, labeled nucleotide products, and other technology. Yale University is the owner of four of the patents and the Company is the exclusive licensee. These four patents are commonly referred to as the “Ward” patents. On November 12, 2012, a jury in New Haven found that one of these patents (United States Patent No. 5,449,667) was infringed and not proven invalid. The jury awarded $48.5 million for this infringement. On January 6, 2014, the judge awarded prejudgment interest of approximately $12.5 million and additional post-interest on the full amount will also be awarded starting

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November 7, 2012 until the total award is satisfied. The final award to Enzo could be reduced or be subject to possible claims from third parties. On March 16, 2015, the Court of Appeals for the Federal Circuit vacated that judgment in a decision remanding the matter to the district court for further proceedings. Enzo has moved for reconsideration of that decision by the panel and for en banc rehearing by the full Court. There can be no assurance that the Company will be successful in this litigation. Even if the Company is not successful, management does not believe that there will be a significant adverse monetary impact on the Company.

As of August 1, 2014 the Company was engaged in litigation in the United States District Court for the Southern District of New York against Roche Diagnostic GmbH and its related company Roche Molecular Systems, Inc. ("Roche"), as declaratory judgment defendant. This case was commenced in May 2004. Roche seeks a declaratory judgment of non-breach of contract and patent invalidity against the Company. Roche has also asserted tort claims against the Company. The Company has asserted breach of contract and patent infringement causes of action against Roche. There has been extensive discovery in the case. In 2011, Roche moved for summary judgment of non-infringement regarding the Company's patent claims. In 2012, the motion was granted in part and denied in part. In December 2012, Roche moved for summary judgment on the Company's non-patent claims. Additional discovery was taken and the Company responded to the motions in May 2013. On December 6, 2013, the Court granted in part and denied in part Roche's summary judgment motion. On October 22, 2014, the Court ordered that damages discovery concerning the Company's remaining contract and patent claims and Roche's claims should be completed by January 30, 2015, and expert discovery should be completed following the Court's not-yet-issued claim construction ruling concerning the Company's patent infringement claim against Roche. Roche dropped its tort claims during damages discovery. On April 28, 2015, the Court heard oral argument on claim construction issues. On May 8, 2015, Roche and the Company jointly moved the Court to extend the schedule for damages discovery until May 29, 2015, and the Court granted that motion. The litigation in the United States District Court for the Southern District of New York between the Company and Molecular Probes, Inc. terminated on May 11, 2015, with a settlement in favor of the Company in the amount of $170. The Company's former counsel, Greenberg Traurig LLP, is also engaged in litigation against the Company in the United States District Court for the Southern District of New York concerning Greenberg Traurig's request for a charging lien against another matter relating to its representation of the Company in the Roche and other cases.

On April 22, 2014, the Company as plaintiff finalized and executed a settlement agreement with Affymetrix, Inc. to settle a patent litigation lawsuit (the "Agreement") in the amount of $5.1 million. Under terms of the Agreement, Affymetrix paid to the Company $4.3 million and paid to the Company's attorneys $0.8 million, which is included in legal fees in the statements of operations for the year ended July 31, 2014. The amount of the settlement is included in the statement of operations under Legal settlements, net within the Life Science segment.

On June 20, 2014, the Company, as plaintiff finalized and executed a settlement agreement with PerkinElmer, Inc., and PerkinElmer Health Sciences, Inc. (formerly known as PerkinElmer Life Sciences, Inc.) (together, "PerkinElmer"), with respect to an action between the Company and PerkinElmer before the U.S. District Court, Southern District of New York, Case No 03-CV-3817. PerkinElmer paid $7.0 million in escrow pursuant to the agreement because of a former counsel's motion requesting a charging lien for fees allegedly owed for past services rendered to the Company. Because the settlement proceeds are held in escrow, and the amount the Company will ultimately receive is indeterminable, it did not include the settlement or any additional amounts which may be payable to the attorney in the financial statements as of and for the fiscal years ended July 31, 2015 and 2014.

As previously disclosed, in 2012, the Company received a Subpoena Duces Tecum (the "Subpoena") from the Department of Health and Human Services, Office of Inspector General ("OIG"). The Subpoena was issued as part of an investigation being conducted by the US Attorney's Office for the Eastern District of New York in conjunction with the OIG. While a number of potential issues were raised initially by the government, the investigation came to focus primarily on an alleged failure to collect diagnosis codes from physicians who ordered tests through Enzo Clinical Labs. The time period initially covered by the investigation was from 2004 through 2011. In response to the Subpoena, the Company cooperated with the government. On September 22, 2014, the Company and the U.S. Department of Justice reached a settlement agreement to resolve this matter, in substantive form as disclosed in the Company's fiscal quarter ended April 30, 2014. During the quarter ended April, 30, 2014, the Company recorded a charge of $2.0 million in the statement of operations under legal settlements, net within the Clinical Labs segment. The settlement amount will be paid with interest over a five-year period. As of July 31, 2015, the Company carried a balance of $0.4 million as other current liabilities and $1.2 million as a non-current liability. Under certain circumstances, the Company may be required to accelerate payments and/or pay up to an additional $1.5 million based upon (i) a favorable recovery and collection related to the judgment in the Life Technologies matter discussed above, (ii) receipt of additional capital greater than $10.0 million in a fiscal year (in that case, the

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Company is required to pay 20% of any amount over $10.0 million plus interest, or (iii) sale of the Company. The final settlement covers the time period 2004-2014.

As a result of the settlements with Affymetrix and the US Department of Justice, noted above, the Company recorded $3.1 million as legal settlements, net during the fiscal year ended July 31, 2014.

On July 2, 2015, the Company as Plaintiff executed a settlement agreement with Luminex Corporation with respect to an action between the Company and Abbott Laboratories and Abbott Molecular, Inc (Defendants) and Luminex Corporation (Intervening Defendant) before the United States District Court for the District of Delaware for alleged patent infringement. Luminex paid the Company a total of $7.1 million as consideration for this agreement and the dismissal of the litigation against Luminex. The amount of the settlement, net of attorney's fees is included in the statement of operations under Legal settlements, net within the Life Science segment.

On July 20, 2015, the Company as a Plaintiff finalized and executed a settlement agreement with Siemens Healthcare Diagnostics Inc. ("Siemens") to settle a patent litigation lawsuit before the U.S. District Court for the District of Delaware in the amount of $9.5 million. Under terms of the agreement, Siemens will also pay the Company additional royalties of $1.0 million per annum on sales of its molecular products manufactured and/or sold in the United States during the its fiscal years 2015 through 2019 if sales of such products exceed a contractual amount. The amount of the settlement, net of attorney's fees is included in the statement of operations under Legal settlements, net within the Life Sciences segment. The net settlement amount is included in other receivables in the consolidated balance sheet as of July 31, 2015 and was received in August 2015.

As a result of the settlements during fiscal 2015 noted above, the Company recorded $11.5 million as legal settlements, net during the fiscal year ended July 31, 2015.

On October 9, 2015, the Company reached and finalized a settlement with Affymetrix, Inc. in the amount of $10 million in an infringement action brought by the Company regarding its US Patent no. 7,064,197. The case was originally brought by the Company in the United States District Court for the District of Delaware. This settlement will be recorded in the first quarter of fiscal year 2016.

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

Note 15 - Segment reporting

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

Legal fee expense incurred to defend the Company's intellectual property, which may result in settlements recognized in another segment and other general corporate matters are considered a component of the Other segment. Legal fee expense specific to other segments' activities have been allocated to those segments.

Legal settlements, net, represent activities for which royalties would have been received in the Company's Life Sciences segment and expenses related to an investigation within the Clinical Labs segment.

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

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

Year ended July 31, 2015

	Clinical Labs	Life Sciences	Therapeutics	Other	Consolidated
Revenues:					
Clinical laboratory services	$63,414	—	—	—	$ 63,414
Product revenues	—	$31,690	—	—	31,690
Royalty and license fee income	—	2,495	—	—	2,495
Total revenues	63,414	34,185	—	—	97,599
Operating expenses:					
Cost of clinical laboratory services	39,589	—	—	—	39,589
Cost of product revenues	—	15,183	—	—	15,183
Research and development	—	2,608	$ 742	—	3,350
Selling, general and administrative	20,666	12,168	—	$8,235	41,069
Provision for uncollectible accounts receivable	2,418	(134)	—	—	2,284
Legal fee expense	196	(67)	—	8,659	8,788
Legal settlements, net	—	(11,458)	—	—	(11,458)
Total operating expenses	62,869	18,300	742	16,894	98,805
Operating income (loss)	545	15,885	(742)	(16,894)	(1,206)
Other income (expense)					
Interest	(86)	10	—	(169)	(245)
Other	28	9	—	58	95
Foreign exchange gain	—	(936)	—	—	(936)
Income (loss) before taxes	$487	$14,968	$ (742)	$(17,005)	$ (2,292)
Depreciation and amortization included above	$1,443	$2,254	$ 3	$89	$ 3,789
Share-based compensation included in above:					
Cost of clinical laboratory services	$5	$—	—	—	$ 5
Research and development	—	2	—	—	2
Selling, general and administrative	43	15	—	$364	422
Total	$48	$17	—	$364	$ 429

Capital expenditures	$1,557	$226	—	—	$ 1,783

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

Year ended July 31, 2014

	Clinical Labs	Life Sciences	Therapeutics	Other	Consolidated
Revenues:					
Clinical laboratory services	$58,689	—	—	—	$ 58,689
Product revenues	—	$ 32,850	—	—	32,850
Royalty and license fee income	—	4,408	—	—	4,408
Total revenues	58,689	37,258	—	—	95,947
Operating expenses:					
Cost of clinical laboratory services	38,948	—	—	—	38,948
Cost of product revenues	—	15,320	—	—	15,320
Research and development	14	2,350	$ 777	—	3,141
Selling, general and administrative	20,460	13,374	—	$7,967	41,801
Provision for uncollectible accounts receivable	3,115	(52)	—	—	3,063
Legal fee expense	736	940	—	5,278	6,954
Legal settlements, net	2,000	(5,100)			(3,100)
Total operating expenses	65,273	26,832	777	13,245	106,127
Operating (loss) income	(6,584)	10,426	(777)	(13,245)	(10,180)
Other income (expense)					
Interest	(43)	9	—	(174)	(208)
Other	56	95	—	43	194
Foreign exchange gain	—	289	—	—	289
(Loss) income before income taxes	$(6,571)	$ 10,819	$ (777)	$(13,376)	$ (9,905)
Depreciation and amortization included above	$1,415	$ 2,455	$ 7	$94	$ 3,971
Share-based compensation included in above:					
Cost of clinical laboratory services	$8	$ 1	—	—	$ 9
Research and development	—	1	—	—	1
Selling, general and administrative	36	6	—	$542	584
Total	$44	$ 8	—	$542	$ 594

Capital expenditures	$643	$195	—	—	$838

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

Year ended July 31, 2013

	Clinical Labs	Life Sciences	Therapeutics	Other	Consolidated
Revenues:					
Clinical laboratory services	$55,889	—	—	—	$ 55,889
Product revenues	—	$ 32,526	—	—	32,526
Royalty and license fee income	—	5,292	—	—	5,292
Total revenues	55,889	37,818	—	—	93,707
Operating expenses:					
Cost of clinical laboratory services	38,251	—	—	—	38,251
Cost of product revenues	—	16,584	—	—	16,584
Research and development	294	2,356	$ 1,239	—	3,889
Selling, general and administrative	19,942	15,511	—	$8,201	43,654
Provision for uncollectible accounts receivable	4,232	264	—	—	4,496
Legal fee expense	316	57	—	5,440	5,813
Total operating expenses	63,035	34,772	1,239	13,641	112,687
Operating (loss) income	(7,146)	3,046	(1,239)	(13,641)	(18,980)
Other income (expense)					
Interest	(46)	13	—	(21)	(54)
Other	49	(71)	—	27	5
Foreign exchange gain	—	80	—	—	80
(Loss) income before income taxes	$(7,143)	$ 3,066	$ (1,239)	$(13,635)	$ (18,949)
Depreciation and amortization included above	$1,377	$ 3,102	$ 22	$104	$ 4,605
Share-based compensation included in above:					
Cost of clinical laboratory services	$9	1	—	—	$ 10
Research and development	—	$ 2	—	—	2
Selling, general and administrative	36	10	—	$487	533
Total	$45	$ 13	—	$487	$ 545

Capital expenditures	$757	$231	—	—	$988

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Geographic financial information is as follows:

Net sales to unaffiliated customers:	2015	2014	2013
United States	$87,875	$84,389	$80,559
Switzerland	3,131	4,130	5,499
United Kingdom	1,904	2,023	2,324
Other international countries	4,689	5,405	5,325
Total	$97,599	$95,947	$93,707

Long-lived assets at July 31,	2015	2014	2013
United States	$19,799	$20,854	$23,136
Switzerland	1,224	1,629	1,984
United Kingdom	357	462	491
Other international countries	175	345	401
Total	$21,555	$23,290	$26,012

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

	2015	2014	2013
United States	$24,461	$25,700	$24,669
Foreign countries	9,724	11,558	13,149
	$34,185	$37,258	$37,818

Note 16 - Summary of Selected Quarterly Financial Data (unaudited)

The following table contains statement of operations information for each quarter of the years ended July 31, 2015 and 2014. The Company believes that the following information reflects all normal recurring adjustments necessary for a fair presentation of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

Unaudited quarterly financial data for fiscal 2015 and 2014 is summarized as follows:

	Quarter Ended			
Fiscal 2015	October 31, 2014	January 31, 2015	April 30, 2015	July 31, 2015
Total revenues	$24,824	$23,092	$23,986	$25,697
Gross profit	10,999	10,028	10,483	11,317
(Loss) income before income taxes	(3,606)	(4,206)	(3,003)	8,523
Net (loss) income	(3,729)	(4,091)	(2,907)	8,442
Basic and diluted (loss) income per common share	$(0.08)	$(0.09)	$(0.06)	$0.18

	Quarter Ended			
Fiscal 2014	October 31, 2013	January 31, 2014	April 30, 2014	July 31, 2014
Total revenues	$24,134	$22,928	$23,978	$24,907
Gross profit	10,579	9,771	10,394	10,935
Loss before income taxes	(2,725)	(3,570)	(448)	(3,162)
Net loss	(2,787)	(3,566)	(455)	(3,169)
Basic and diluted loss per common share	$(0.07)	$(0.09)	$(0.01)	$(0.07)

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SCHEDULE II

VALUATION AND QUALIFYING ACCOUNTS
Years ended July 31, 2015, 2014 and 2013
(in thousands)

Year ended July 31,	Description	Balance at Beginning of period	Charged to costs and expenses	**Charged to other accounts**	Deductions		Balance at end of period
2015	Allowance for doubtful accounts receivable	2,142	2,284		2,640	(1)	1,786
2014	Allowance for doubtful accounts receivable	2,707	3,063		3,628	(1)	2,142
2013	Allowance for doubtful accounts receivable	3,273	4,496		5,062	(1)	2,707
2015	Deferred tax valuation allowance	49,465	193				49,658
2014	Deferred tax valuation allowance	47,623	1,842				49,465
2013	Deferred tax valuation allowance	41,261	6,362				47,623

(1) Write-off of uncollectible accounts receivable.
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