ENZO BIOCHEM INC
Form 10-K
October 13, 2016

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, 2016

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 $202,791,000 as of January 31, 2016.

The number of shares of the Company's common stock, $.01 par value, outstanding at October 1, 2016 was 46,267,619.

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 5, 2017 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 vertically integrated growth-oriented bioscience 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. Enzo's structure and business strategy represents the culmination of years of extensive planning and work. The Company now has the unique ability to offer low cost, high performance products and services in molecular diagnostics, which ideally positions it to capitalize on the reimbursement pressures facing diagnostic labs. 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 314 issued patents worldwide, and over 146 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, 2016, 2015 and 2014 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 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 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. Given our license in New York State, we are able to offer testing services to clinical laboratories and physicians in the majority of states nationwide.

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 115 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, 2016, 2015 and 2014 (in thousands and percentages):

Fiscal year ended July 31,	**2016**		**2015**		**2014**	
Clinical laboratory services	$70,915	69 %	$63,414	65 %	$58,689	61 %
Product revenues	30,337	30	31,690	32	32,850	34
Royalty and license fee income	1,521	1	2,495	3	4,408	5
Total	$102,773	100%	$97,599	100%	$95,947	100%

Markets

Clinical diagnostics

The U.S. 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
- on-going advancements in tools that accelerate these research and development activities.

Therapeutics

We believe our core technologies have broad diagnostic and therapeutic applications. We have focused our efforts on discovering how best to treat 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.

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.

In addition to selling these highly effective and compatible platforms and their assays, we are positioning ourselves as a reference lab for independent labs nationwide primarily by offering lower cost reference services.

Our commitment to utilize our proprietary technologies to develop clinically relevant diagnostics, while helping to relieve the cost pressures that independent laboratories are bearing is core to our strategy. It underscores the progress we are achieving in our strategy

of utilizing Enzo's integrated structure to produce diagnostic products and services relevant to today's dynamic and challenging healthcare marketplace.

By developing a broad technology base, Enzo has positioned the Company for a robust flow of products and services that will provide medically relevant, cost effective solutions easily adaptable to the workflow of the clinical laboratory, and that its ability to do so is based on several factors, including:

- The Company's integrated structure that enables it to internally develop and advance products seamlessly from innovation through commercialization validation via recent patent settlements of Enzo's intellectual property strength and ownership of basic patents that provide an economic advantage.
- In a steadily declining reimbursement environment the unique ability to deliver high performance, easily adaptable products and services that are also meaningfully cost effective for independent labs as well as Enzo's own clinical lab.
- Ample finances with which to execute and follow through on the Company's integrated strategy.

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:

- AMPIPROBE® – easily adaptable, affordable, real time DNA amplification and detection
- FLOWSCRIPT® – enhanced flow cytometry for signal cell analysis
- Enhanced Immunohistochemistry – moving Pathology to the next generation
- Enhanced Immunoassays – Pushing sensitivity to expand immunoassay applications

Enzo's proprietary platforms and the assays developed based on them can provide more sensitive diagnostic information at lower costs than many other tests currently marketed. The Company designs its products to be able to work with lower specimen volume which not only allows the laboratories to run more tests off of a single clinical specimen, but also may reduce the need for patients to submit additional samples, thus reducing unnecessary physician visits. The Company's newly approved assays are the forerunners of a comprehensive line of diagnostic products under development by Enzo to address the critical needs of clinical laboratories that are often locked into closed-system contracts with molecular diagnostic suppliers that, with ever-declining reimbursements, reduce or even eliminate operating margins.

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 in further evaluation 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 2016, we were issued 64 patents and expanded our patent estate in the area of nucleotides, amplification, labelling and detection, among others.

Product Development and Pipeline

Enzo is committed to delivering a robust line of products and services that will provide medically relevant, cost effective solutions that are easily adaptable to the workflow of clinical laboratories. The Company’s integrated Life Science-Clinical Lab structure continues to be instrumental in its ability to seamlessly develop and advance products from innovation and manufacturing in our life sciences group and validation and commercialization through our clinical laboratory.

The Company’s development pipeline includes an extensive line of assays for detection of numerous women’s health infectious agents as well as for the identification of other pathogens. The Company is also developing a proprietary line of products designed to aid pathologists in differentiating the characteristics of various tumors from biopsy specimens. The Company’s molecular-based products and services are targeted at a market currently estimated to be in excess of $3 billion annually.

During fiscal 2016 and most recently, we successfully gained New York State Department of Health approval of a number of key products based on Enzo's proprietary technology platforms. On November 17, 2015, we announced approval of AMPIPROBE® HCV Assay for the quantitative detection of Hepatitis C. This assay is based on the proprietary nucleic acid amplification and detection technology platform was the first in a line of products to be developed at Enzo to address the critical needs of the molecular diagnostics market and serves as validation of Enzo's unique business strategy and structure.

On June 7, 2016, we were granted conditional approval of AMPIPROBE® Candidiasis Assay. This multiplex assay is designed to identify the presence of five of the most common species of Candida from a single vaginal swab. Industry estimates put the number of tests performed for the identification of Candida at over 10 million per year in the US alone. It is also estimated that over 70% of women will develop a Candida infection during their reproductive lifetime. While an independent assay, it will also serve as a component of a comprehensive women's health panel currently under development.

On September 20, 2016, we were granted conditional approval of PLAQPRO™ Lp-PL$_2$A Assay. This is a biochemical activity assay designed to identify lipoprotein-associated phospholipase A2, a marker associated with the potential for coronary heart disease. The PLAQPRO™ Lp- PL$_2$A Assay can be useful as part of a cardiac testing panel for individuals at intermediate or high risk for developing coronary heart disease. Early identification of increased risk of developing coronary heart disease offers the opportunity to adjust patient lifestyles or utilize medical interventions to reduce risk. The assay was developed using the Company's strong expertise in assay development, antibody production, small molecule chemistry, and detection technology. This cardiac assay delivers improved consistency and is designed to work on open platform clinical analysis instruments. The open platform configuration is one of the several factors that contribute to its cost effectiveness, which is vital to today's clinical labs that are confronted by shrinking reimbursements.

These assays are an important addition to Enzo's expanding line of women's health products, while also helping to solidify Enzo's position as a leading full service women's health lab.

Products in the Company's development pipeline include an extensive line of assays for detection of numerous women's health infectious agents as well as for use in the identification of pathogens for other markets. The Company also reported that it expects to roll-out a line of products designed to aid pathologists in distinguishing the characteristics of various tumors from biopsy specimens using technology developed by Enzo scientists. The Company's molecular-based products are targeted at a market estimated to be in excess of $3 billion worth of laboratory service revenue.

Enzo is committed to delivering a robust line of products and services that will provide medically relevant, cost effective solutions that are easily adaptable to the workflow of clinical laboratories. The Company's integrated Life Science and Clinical Lab structure continues to be instrumental in its ability to seamlessly develop and advance products from innovation and manufacturing in our life sciences group and validation and commercialization through our clinical laboratory. Our product development activity and pipeline include the following products.

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Product / Test Description	Expected Availability(1)	Platform
HPV E6/E7 Detection	Available	FLOWSCRIPT® GENE EXPRESSION
HCV Viral Load	Available	AMPIPROBE® REAL-TIME AMPLIFICATION AND DETECTION
Cardiac Marker	Available	ENHANCED IMMUNOASSAY
Fertility Assay	Q1 2017	ENHANCED IMMUNOASSAY
Women's Health Panel	Q4 2016 – Q1 2017	AMPIPROBE® REAL-TIME AMPLIFICATION AND DETECTION
HBV Viral Load	2017	AMPIPROBE®REAL-TIME AMPLIFICATION AND DETECTION
HIV Viral Load	2017	AMPIPROBE® REAL-TIME AMPLIFICATION AND DETECTION
IHC Detection	Available	ENHANCED DETECTION
TH1/TH2	In development	FLOWSCRIPT® GENE EXPRESSION
Cancer AB Panel	In development	AMPIFLOW™ ENHANCED DETECTION LABEL
Cancer Marker Panel	In development	FLOWSCRIPT® GENE EXPRESSION

(1) There can be no assurances these products can be successfully developed or within these timeframes or available on these dates.

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/E7 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 lipoprotein receptor-related protein (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:

•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 immunomodulation 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.

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 and New Jersey 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 EnzoDirect to a physician office Electronic Medical Records (EMR) 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, 2016, 2015 and 2014, respectively, approximately 69%, 65% and 61% 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, 2016, 2015 and 2014 were approximately 16%, 19% 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 30%, 28% and 25% of the Clinical Labs segment's net revenue for the fiscal year ended July 31, 2016, 2015 and 2014, respectively.

At July 31, 2016 and 2015, approximately 71% and 68% 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.

•differences in medical policies established by 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 2014 by 0.75%, was unchanged in calendar 2015 and 2016. 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 (PAMA), which included substantial changes to the way in which clinical laboratory services will be paid under Medicare. Beginning in 2018, 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 final regulation to implement Medicare laboratory payment reform was released on June 17, 2016 by CMS. Since Enzo's clinical lab receives more than 50% of its total Medicare revenue from the Part B Clinical Laboratory Fee Schedule and the Physician Fee Schedule and receives more than $12,500 in Medicare revenues per year, we are considered an "applicable laboratory", and as such, must report private payor fee reimbursements for the period January 1, 2016 to June 30, 2016 to CMS by March 31, 2017. This data will be aggregated and utilized as the basis for the 2018 fee schedules that will be finalized in November 2017. At this time, 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 The Company successfully transitioned to ICD-10 on October1, 2015, with no disruption in business, and has not experienced increased accounts receivable as a result of timing of billing and payments related to the implementation.

Life Sciences

Enzo Life Sciences is a manufacturer of labeling and detection technologies from DNA to whole cell analysis. Enzo's products are backed by innovative technology platforms and a deep patent portfolio. With 40 years' experience, Enzo Life Sciences continues to provide integrated solutions for Life Sciences, Clinical Research, and Drug Development. Enzo Life Sciences offers a broad range of high-quality products to advance research including proteins, antibodies, peptides, small molecules, labeling probes, dyes, and kits. Enzo Life Sciences operates in a highly competitive and price-sensitive marketplace and is repositioning itself by narrowing its product mix to concentrate on improved profitability, while also adding staff who are more experienced in operations. We have become a specialized assay supplier as part of our integrated strategic plan to deliver highly efficient, cost effective diagnostics and assays for our own use and sale to independent labs. 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.

With a passion for genomics, Enzo was the first to develop non-radioactive labeling of nucleic acids. This technique was instrumental in the development of today's genomic analysis market. Our pioneering research in genetic modification medicine was the first to recognize that nucleic acids could be used as therapeutics. Our innovations in the detection of nucleic acids in solutions and solid matrices led to the development of technology platforms such as hybrid capture, as well as fluorescent and chromogenic *in situ* hybridization. Enzo remains at the forefront of target amplification technologies critical in the detection of infectious agents, cancer markers, and genotyping. Our work in the genomic space has resulted in technologies in gene expression and immune system regulation, which opened the door for the well-known molecular diagnostics assays used today.

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 maintains acquired brands including Alexis, Biomol International, Assay Designs, and Stressgen. Enzo strategically uses these brands to complete our product portfolio, allowing us to offer complete solutions to researchers in all fields. These brands are complementary to our core expertise in genomics and molecular biology. 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.

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 connect with over 40 specialty manufacturers and gain access to over 40,000 products.

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 manufacturing and distribution capability. 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, 2016, 2015 and 2014, the Company incurred costs of approximately $3.5 million, $3.4 million and, $3.1 million, respectively, for research and development activities. During fiscal 2016, 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 35 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 and New Jersey 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 2016 we owned or licensed 314 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 on-going 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 (PAMA), which included substantial changes to the way in which clinical laboratory services will be paid under Medicare. Beginning in 2018, 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 final regulation to implement Medicare laboratory payment reform was released on June 17, 2016 by CMS. Since Enzo's clinical lab receives more than 50% of its total Medicare revenue from the Part B Clinical Laboratory Fee Schedule and the Physician Fee Schedule and receives more than $12,500 in Medicare revenues per year, we are considered an "applicable laboratory", and as such, must report private payor fee reimbursements for the period January 1, 2016 to June 30, 2016 to CMS by March 31, 2017. This data will be aggregated and utilized as the basis for the 2018 fee schedules that will be finalized in November 2017. At this time, 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.

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 2016 reimbursement rates have remained constant with 2015 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 payer.

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 non-invasive, 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 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, 2016, we employed 446 full-time and 43 part-time employees. Of the full-time employees, 108 were engaged in research, development, manufacturing, and marketing of research products, 272 in performing testing, marketing and billing our clinical laboratories services and 66 in finance, information technology, administrative and executive functions. Our scientific staff, including 35 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

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.

Our strategy envisions, if an opportunistic target is identified, future growth from acquiring and integrating similar operations and/or product or services 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.

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 on-going 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.

Financial Risks

With the exception of 2016, 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.

Although for fiscal year 2016, we reported net income of $45.3 million, we incurred net losses of $2.3 million, and $10.0 million for the fiscal years ended July 31, 2015 and 2014, 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.

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, 2016 and 2015, goodwill and intangible assets represented approximately 11% and 20%, 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.

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.

Since each payer makes its own decision as to whether to establish a policy or enter into a contract to cover our tests, as well as the amount it will reimburse for a test, seeking these approvals is a time-consuming and costly process. In addition, the determination by a payer to cover and the amount it will reimburse for our tests will likely be made on an indication by indication basis. To date, we have obtained policy-level reimbursement approval or contractual reimbursement for some indications for our test from a small number of commercial third-party payers, and have not obtained coverage from Medicare or any state Medicaid program. Further, we believe that establishing adequate reimbursement from Medicare is an important factor in gaining adoption from healthcare providers. Our claims for reimbursement from commercial payers may be denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive, and may not result in payment. In cases where there is not a contracted rate for reimbursement, there is typically a greater co-insurance or co-payment requirement from the patient which may result in further delay or decreased likelihood of collection.

We expect to continue to focus substantial resources on increasing adoption of, and coverage and reimbursement for, our current tests and any future tests we may develop. We believe it may take several years to achieve coverage and adequate contracted reimbursement with a majority of third-party payers. However, we cannot predict whether, under what circumstances, or at what payment levels payers will reimburse for our tests. If we fail to establish and maintain broad adoption of, and coverage and reimbursement for, our tests, our ability to generate revenue could be harmed and our future prospects and our business could suffer.

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 on-going 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 on-going 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, biologics 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 9% of total revenues in fiscal 2016. 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, 2016 and 2015, we had $1.6 million and $3.0 million, respectively, in borrowings under our Revolving Loan and Security Agreement (“credit agreement”), which expires December 7, 2016. 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.

In addition, there can be no assurance that we can extend or negotiate an update to the Revolving Loan under favorable condition and satisfactory terms upon expiration in December 2016.

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 - 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, 2017, was extended through May 2020.

Note 3 - In July 2016, the lease was automatically extended through December 2018.

Note 4 - In March 2009 the lease 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. 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 was also be awarded starting November 7, 2012 until the total award is satisfied. The final award to the Company could have been reduced or 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. On February 22, 2016, the Connecticut District Court granted Applera's motion for summary judgment of non-infringement. The Company appealed that decision. 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 parties are waiting for the Court's ruling on claim construction. The Company and Enzo Life Sciences intend to vigorously press their remaining claims and contest the claims against them.

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. The final settlement covers the time period 2004-2014. During the three months ended January 31, 2016, the Company accrued an additional $1.5 million, due to the Company's achievement of certain financial milestones. As of July 31, 2016, the total liability for this settlement is $1.2 million, of which $0.4 million is included in other current liabilities and $0.8 million included in other liabilities.

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 attorney's charging lien for fees allegedly owed for past services rendered to the Company. On December 3, 2015, the Company entered into a Settlement Agreement with the former attorney pursuant to which the Company and the former attorney resolved their respective claims against each other. As of July 31, 2016, the Company received a total of approximately $7.0 million from the escrow referred to above in accordance with the terms of the Settlement Agreement. This settlement is included in the statement of operations under Legal settlements, net within the Life Science segment.

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 case against the Abbott defendants continues. The parties have not begun summary judgement briefing because the court has not set a briefing schedule. The court also has not set a trial date.

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 $6.7 million, net. 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 net settlement amount was included in other receivables in the consolidated balance sheet as of July 31, 2015 and was received in August 2015.

On October 9, 2015, the Company reached and finalized a settlement with Affymetrix, Inc. in the amount of $6.8 million, net in a patent infringement action brought by the Company. On January 4, 2016, the Company reached and finalized a settlement agreement with Agilent Technologies, Inc. in the amount of $6.1 million, net in a patent infringement action brought by the Company. Both cases were originally brought by the Company in the United States District Court for the District of Delaware. The settlements are included in the statement of operations under Legal settlements, net within the Life Science segment.

On May 16, 2016, the Company reached and finalized a settlement with Life Technologies Corporation in the amount of $24.3 million, net in an infringement action brought by the Company regarding its US Patents No. 6,992,180 and 7,064,197. On July 1, 2016, the Company reached and finalized a settlement with Illumina, Inc., in the amount of $14.5 million, net in an infringement action brought by the Company regarding US Patent No. 7,064,197. These cases were originally brought by the Company in the United States District Court for the District of Delaware. The settlements are included in the statement of operations under Legal settlements, net within the Life Science segment.

As of July 31, 2016, there are six pending cases originally brought by the Company in the United States District Court for the District of Delaware alleging patent infringements against various companies. There can be no assurance that the Company will be successful in these litigations. Even if the Company is not successful, management does not believe that there will be a significant adverse monetary impact on the Company.

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

June 30, 2015 and 2014. The results of operations for the three and six-month periods ended June 30, 2015 are not necessarily indicative of the results for a full-year period. These interim consolidated financial statements should be read in conjunction with the financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2014 filed with the Securities and Exchange Commission (the "SEC").

2. Inventories. Inventories at June 30, 2015 and December 31, 2014, consisted of the following (in thousands):

	June 30, 2015	December 31, 2014
Finished goods	$45,560	$50,000
Work-in-process	12,171	7,680
Raw materials	34,990	34,093
Total	$92,721	$91,773

3. Stock-Based Compensation. Stock-based compensation expense before income tax expense for the three and six-month periods ended June 30, 2015 and 2014, consisted of the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Cost of goods sold	$109	$46	$202	$89
Research and development	32	17	59	33
Selling, general, and administrative	424	261	824	541
Stock-based compensation expense before taxes	$565	$324	$1,085	$663

As of June 30, 2015, the total remaining unrecognized compensation cost related to non-vested stock options, net of expected forfeitures, was approximately $7.0 million and is expected to be recognized over a weighted average period of 3.7 years.

During the three and six-month periods ended June 30, 2015, we granted awards representing 150,000 and 596,800 shares of our common stock, respectively. During the three and six-month periods ended June 30, 2014, we granted awards representing 125,000 shares of our common stock. We use the Black-Scholes methodology to value the stock-based compensation expense for options. In applying the Black-Scholes methodology to the options granted during the six months ended June 30, 2015, the fair value of our stock-based awards granted was estimated using the following assumptions for the periods indicated below:

	Six Months Ended June 30, 2015	June 30, 2014
Risk-free interest rate	1.53% - 1.57%	1.97%
Expected option life in years	5.0	5.5
Expected dividend yield	—%	—%
Expected price volatility	34.00% - 35.11%	36.90%

For purposes of the foregoing analysis, the average risk-free interest rate is determined using the U.S. Treasury rate in effect as of the date of grant, based on the expected term of the stock option. The expected term of the stock options is determined using the

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historical exercise behavior of employees. The expected price volatility is determined using a weighted average of daily historical volatility of our stock price over the corresponding expected option life and implied volatility based on recent trends of the daily historical volatility. Compensation expense is recognized on a straight-line basis over the service period, which corresponds to the related vesting period.

4. Earnings Per Common Share (EPS). The computation of weighted average shares outstanding and the basic and diluted earnings per common share for the following periods consisted of the following (in thousands, except per share amounts):

	Three Months			Six Months		
	Net Income	Shares	Per Share Amount	Net Income	Shares	Per Share Amount
Period ended June 30, 2015:						
Basic EPS	$7,401	44,055	$0.17	$12,575	43,880	$0.29
Effect of dilutive stock options and warrants		462			452	
Diluted EPS	$7,401	44,517	$0.17	$12,575	44,332	$0.28
Stock options excluded from the calculation of common stock equivalents as the impact was anti-dilutive		529			456	
Period ended June 30, 2014:						
Basic EPS	$3,716	43,061	$0.09	$6,539	42,963	$0.15
Effect of dilutive stock options and warrants		249			309	
Diluted EPS	$3,716	43,310	$0.09	$6,539	43,272	$0.15
Stock options excluded from the calculation of common stock equivalents as the impact was anti-dilutive		1,173			1,434	

5. Acquisitions. On January 6, 2015, we amended a distribution and patent sublicense agreement with Catheter Connections, Inc. ("CathConn"), a Utah corporation, which we had originally entered into on August 21, 2012 for CathConn's MaleCap Solo technology. The amendment provides exclusive rights for other aspects of CathConn's DualCap disinfecting cap technology. We paid CathConn an additional $250,000 in January 2015. The purchase price was allocated to a distribution agreement for $250,000, which we intend to amortize over 10 years.

On August 8, 2014, we entered into a license agreement and a distribution agreement with a medical device company for the right to manufacture and sell certain percutaneous transluminal angioplasty balloon catheter products. As of December 31, 2014, we had paid $3.0 million and recorded an additional $1.0 million obligation to accrued liabilities in connection with these agreements. During the quarter ended March 31, 2015, we paid the $1.0 million that was accrued as of December 31, 2014. During the quarter ended June 30, 2015, we paid another $1.0 million and we had recorded an additional $1.5 million obligation to accrued liabilities as of June 30, 2015 with the completion of additional milestones under these two agreements. As of June 30, 2015, we had paid or accrued all obligations under these two agreements. We accounted for the transaction contemplated by the foregoing agreements as an asset purchase. Of the purchase price paid as of June 30, 2015, $200,000 was allocated to a distribution agreement asset, which we are amortizing over a period of 3 years, and $6.3 million was allocated to a license agreement asset, which

we intend to amortize over a period of 12 years.

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6. Segment Reporting. We report our operations in two operating segments: cardiovascular and endoscopy. Our cardiovascular segment consists of cardiology and radiology medical device products which assist in diagnosing and treating coronary artery disease, peripheral vascular disease and other non-vascular diseases and includes embolotherapeutic products and cardiac rhythm management and electrophysiology ("CRM/EP") devices. Our endoscopy segment consists of gastroenterology and pulmonology medical device products which assist in the palliative treatment of expanding esophageal, tracheobronchial and biliary strictures caused by malignant tumors. We evaluate the performance of our operating segments based on operating income (loss). Financial information relating to our reportable operating segments and reconciliations to the consolidated totals for the three and six-month periods ended June 30, 2015 and 2014, are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Revenues				
Cardiovascular	$132,789	$124,669	$257,552	$239,576
Endoscopy	5,293	4,196	10,107	8,525
Total revenues	138,082	128,865	267,659	248,101
Operating income				
Cardiovascular	11,258	7,300	19,327	13,696
Endoscopy	984	84	1,619	177
Total operating income	12,242	7,384	20,946	13,873

7. Recent Accounting Pronouncements. In April 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2015-03, Simplifying the Presentation of Debt Issuance Costs, which requires debt issuance costs to be presented in the balance sheet as a direct deduction from the associated debt liability. The standard is effective for our financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted for financial statements that have not been previously issued. The new guidance will be applied on a retrospective basis. We do not presently anticipate that the adoption of this standard will have a material impact on our financial statements.

In August 2014, the FASB issued ASU 2014-15, which requires management to assess, at each annual and interim reporting period, the entity's ability to continue as a going concern within one year after the date that the financial statements are issued and provide related disclosures. The guidance is effective for the year ending December 31, 2016, with early adoption permitted. We do not presently anticipate that the adoption of this standard will have a material impact on our financial statements.

In May 2014, the FASB issued authoritative guidance amending the FASB Accounting Standards Codification and creating a new Topic 606, Revenue from Contracts with Customers. The new guidance clarifies the principles for recognizing revenue and develops a common revenue standard for U.S. GAAP applicable to revenue transactions. This guidance provides that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The existing industry guidance will be eliminated when the new guidance becomes effective and annual disclosures will be substantially revised. Additional disclosures will also be required under the new standard. In July 2015, the FASB approved a proposal that extended the required implementation date one year to the first quarter of 2018 but also would permit companies to adopt the standard at the original effective date of 2017. Implementation may be either through retrospective application to each period from the first quarter of 2016 or with a cumulative effect adjustment upon adoption in 2018. We are assessing the impact this new standard is anticipated to have on our consolidated financial statements.

8. Income Taxes. Our overall effective tax rate for the three months ended June 30, 2015 was 29.7%, compared to 26.9% for the three months ended June 30, 2014. For the six months ended June 30, 2015, our effective tax rate was 30.1%, compared to 27.1% for the six months ended June 30, 2014. The increase in the effective tax rate for both periods, when compared to the prior-year periods, was due primarily to the impact of certain tax benefits recognized during the second quarter of 2014.

9. Long-term Debt. We entered into an Amended and Restated Credit Agreement, dated December 19, 2012, with the lenders who are or may become party thereto (collectively, the "Lenders") and Wells Fargo Bank, National Association ("Wells Fargo"), as administrative agent for the Lenders, which was amended on October 4, 2013 by a First Amendment to the Amended and Restated Credit Agreement by and among Merit, certain subsidiaries of Merit, the Lenders and Wells Fargo as administrative agent for the Lenders (as amended, the "Credit Agreement"). Pursuant to the terms of the Credit Agreement, the Lenders have agreed to make revolving credit loans up to an aggregate amount of $215 million. The Lenders also made a term loan in the amount of $100 million, repayable in quarterly installments in the amounts provided in the Credit Agreement until the maturity date of

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December 19, 2017, at which time the term and revolving credit loans, together with accrued interest thereon, will be due and payable. In addition, certain mandatory prepayments are required to be made upon the occurrence of certain events described in the Credit Agreement. Wells Fargo has agreed, upon satisfaction of certain conditions, to make swingline loans from time to time through the maturity date in amounts equal to the difference between the amounts actually loaned by the Lenders and the aggregate revolving credit commitment. The Credit Agreement is collateralized by substantially all of our assets. At any time prior to the maturity date, we may repay any amounts owing under all revolving credit loans, term loans, and all swingline loans in whole or in part, subject to certain minimum thresholds, without premium or penalty, other than breakage costs.

The term loan and any revolving credit loans made under the Credit Agreement bear interest, at our election, at either (i) the base rate (described below) plus 0.25% (subject to adjustment if the Consolidated Total Leverage Ratio, as defined in the Credit Agreement, is at or greater than 2.25 to 1), (ii) the London Inter-Bank Offered Rate ("LIBOR") Market Index Rate (as defined in the Credit Agreement) plus 1.25% (subject to adjustment if the Consolidated Total Leverage Ratio, as defined in the Credit Agreement, is at or greater than 2.25 to 1), or (iii) the LIBOR Rate (as defined in the Credit Agreement) plus 1.25% (subject to adjustment if the Consolidated Total Leverage Ratio, as defined in the Credit Agreement, is at or greater than 2.25 to 1). Initially, the term loan and revolving credit loans under the Credit Agreement bear interest, at our election, at either (x) the base rate plus 1.00%, (y) the LIBOR Market Index Rate, plus 2.00%, or (z) the LIBOR Rate plus 2.00%. Swingline loans bear interest at the LIBOR Market Index Rate plus 1.25% (subject to adjustment if the Consolidated Total Leverage Ratio, as defined in the Credit Agreement, is at or greater than 2.25 to 1). Initially, swingline loans bear interest at the LIBOR Market Index Rate plus 2.00%. Interest on each loan featuring the base rate or the LIBOR Market Index Rate is due and payable on the last business day of each calendar month; interest on each loan featuring the LIBOR Rate is due and payable on the last day of each interest period selected by us when selecting the LIBOR Rate as the benchmark for interest calculation. For purposes of the Credit Agreement, the base rate means the highest of (i) the prime rate (as announced by Wells Fargo), (ii) the federal funds rate plus 0.50%, and (iii) LIBOR for an interest period of one month plus 1.00%. Our obligations under the Credit Agreement and all loans made thereunder are fully secured by a security interest in our assets pursuant to a separate collateral agreement entered into in conjunction with the Credit Agreement.

The Credit Agreement contains covenants, representations and warranties and other terms customary for revolving credit loans of this nature. In this regard, the Credit Agreement requires us to not, among other things, (a) permit the Consolidated Total Leverage Ratio (as defined in the Credit Agreement) to be greater than 4.75 to 1 through the end of 2013, no more than 4.00 to 1 as of the fiscal quarter ending March 31, 2014, no more than 3.75 to 1 as of the fiscal quarter ending June 30, 2014, no more than 3.50 to 1 as of the fiscal quarter ending September 30, 2014, no more than 3.25 to 1 as of the fiscal quarter ending December 31, 2014, no more than 3.00 to 1 as of any fiscal quarter ending during 2015, no more than 2.75 to 1 as of any fiscal quarter ending during 2016, and no more than 2.50 to 1 as of any fiscal quarter ending thereafter; (b) for any period of four consecutive fiscal quarters, permit the ratio of Consolidated EBITDA (as defined in the Credit Agreement and subject to certain adjustments) to Consolidated Fixed Charges (as defined in the Credit Agreement) to be less than 1.75 to 1; (c) subject to certain adjustments, permit Consolidated Net Income (as defined in the Credit Agreement) for certain periods to be less than $0; or (d) subject to certain conditions and adjustments, permit the aggregate amount of all Facility Capital Expenditures (as defined in the Credit Agreement) in any fiscal year beginning in 2013 to exceed $30 million. Additionally, the Credit Agreement contains various negative covenants with which we must comply, including, but not limited to, limitations respecting: the incurrence of indebtedness, the creation of liens or pledges on our assets, mergers or similar combinations or liquidations, asset dispositions, the repurchase or redemption of equity interests or debt, the issuance of equity, the payment of dividends and certain distributions, the entry into related party transactions and other provisions customary in similar types of agreements. As of June 30, 2015, we were in compliance with all covenants set forth in the Credit Agreement.

We had originally entered into an unsecured credit agreement, dated September 30, 2010, with certain lenders who were or became party thereto and Wells Fargo, as administrative agent for the lenders. Pursuant to the terms of that credit agreement, the lenders agreed to make revolving credit loans up to an aggregate amount of $175 million. Wells Fargo also agreed to make swingline loans from time to time through the maturity date of September 10, 2015 in amounts equal to the difference between the amount actually loaned by the lenders and the aggregate credit agreement. The unsecured credit agreement was amended and restated as of December 19, 2012, as the Credit Agreement.

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In summary, principal balances under our long-term debt as of June 30, 2015 and December 31, 2014, consisted of the following (in thousands):

	June 30, 2015	December 31, 2014
Term loan	$69,962	$82,500
Revolving credit loans	139,812	141,990
Total long-term debt	209,774	224,490
Less current portion	10,000	10,000
Long-term portion	$199,774	$214,490

Future minimum principal payments on our long-term debt as of June 30, 2015, are as follows (in thousands):

Years Ending December 31	Future Minimum Principal Payments
2015	$5,000
2016	10,000
2017	194,774
Total future minimum principal payments	$209,774

As of June 30, 2015, we had outstanding borrowings of approximately $209.8 million under the Credit Agreement, with available borrowings of approximately $35.2 million, based on the leverage ratio in the terms of the Credit Agreement. Our interest rate as of June 30, 2015 was a fixed rate of 2.98% on $137.5 million as a result of an interest rate swap (see Note 10), a variable floating rate of 1.94% on $67.8 million and a variable floating rate of 2.04% on approximately $4.5 million. Our interest rate as of December 31, 2014 was a fixed rate of 2.98% on $140.0 million as a result of an interest rate swap, variable floating rate of 2.17% on $84.3 million and a variable floating rate of 2.26% on approximately $174,000.

10. Derivatives.

Interest Rate Swap. On December 19, 2012, we entered into a pay-fixed, receive-variable interest rate swap having an initial notional amount of $150 million with Wells Fargo to fix the one-month LIBOR rate at 0.98%. The variable portion of the interest rate swap is tied to the one-month LIBOR rate (the benchmark interest rate). The interest rates under both the interest rate swap and the underlying debt reset, the swap is settled with the counterparty, and interest is paid, on a monthly basis. The notional amount of the interest rate swap is reduced quarterly by 50% of the minimum principal payment due under the terms of the Credit Agreement. The interest rate swap is scheduled to expire on December 19, 2017.

At June 30, 2015, our interest rate swap qualified as a cash flow hedge. The fair value of our interest rate swap at June 30, 2015 was a liability of approximately $227,000, which was offset by approximately $88,000 in deferred taxes. The fair value of our interest rate swap at December 31, 2014 was an asset of approximately $573,000, which was offset by approximately $223,000 in deferred taxes.

During the three and six-month periods ended June 30, 2015 and 2014, the amounts reclassified from accumulated other comprehensive income to earnings due to hedge effectiveness were included in interest expense in the accompanying consolidated statements of income and were not material.

Foreign Currency Forward Contracts. On May 29, 2015, we forecasted a net exposure for June 30, 2015 (representing the difference between Euro and GBP-denominated receivables and Euro-denominated payables) of approximately 543,000 Euros and 83,000 GBPs. In order to partially offset such risks, on May 29, 2015, we entered into a 30-day forward contract for the Euro and GBP with a notional amount of approximately 543,000 Euros and notional amount

of 83,000 GBPs.

We enter into similar transactions at various times during the year to partially offset exchange rate risks we bear throughout the year. These contracts are marked to market at the end of each month. The effect on our consolidated statements of income for the three and six-month periods ended June 30, 2015 and 2014 of all forward contracts, and the fair value of our open positions at June 30, 2015, were not material.

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11. Fair Value Measurements. Our financial assets and (liabilities) carried at fair value measured on a recurring basis as of June 30, 2015 and December 31, 2014, consisted of the following (in thousands):

Description	Total Fair Value at June 30, 2015	Fair Value Measurements Using Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant Unobservable inputs (Level 3)
Interest rate swap (1)	$(227)	$—	$(227)	$—

Description	Total Fair Value at December 31, 2014	Fair Value Measurements Using Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant Unobservable inputs (Level 3)
Interest rate swap (1)	$573	$—	$573	$—

(1) The fair value of the interest rate swap is determined based on forward yield curves.

Certain of our business combinations involve the potential for the payment of future contingent consideration, generally based on a percentage of future product sales or upon attaining specified future revenue milestones. The contingent consideration liability is re-measured at the estimated fair value at each reporting period with the change in fair value recognized within operating expenses in the accompanying consolidated statements of income. We measure the initial liability and re-measure the liability on a recurring basis using Level 3 inputs as defined under authoritative guidance for fair value measurements. Changes in the fair value of our contingent consideration liability during the three and six-month periods ended June 30, 2015 and 2014, consisted of the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Beginning balance	$1,842	$2,513	$1,886	$2,526
Fair value adjustments recorded to income during the period	121	8	243	19
Contingent payments made	(14)	(14)	(180)	(38)
Ending balance	$1,949	$2,507	$1,949	$2,507

The recurring Level 3 measurement of our contingent consideration liability includes the following significant unobservable inputs at June 30, 2015 (amount in thousands):

Contingent consideration liability	Fair value at June 30, 2015	Valuation technique	Unobservable inputs	Range
Revenue-based payments	$1,803	Discounted cash flow	Discount rate	1% - 14%
			Probability of milestone payment	15% - 100%
			Projected year of payments	2015-2028
Other payments	$146	Discounted cash flow	Discount rate	5%
			Probability of milestone payment	100%

Projected year of payments	2015-2016

The contingent consideration liability is re-measured to fair value each reporting period using projected revenues, discount rates, probabilities of payment, and projected payment dates. Projected contingent payment amounts are discounted back to the current period using a discounted cash flow model. Projected revenues are based on our most recent internal operational budgets and long-

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range strategic plans. Increases (decreases) in discount rates and the time to payment may result in lower (higher) fair value measurements. A decrease in the probability of any milestone payment may result in lower fair value measurements. An increase (decrease) in either the discount rate or the time to payment, in isolation, may result in a significantly lower (higher) fair value measurement.

Our determination of the fair value of the contingent consideration liability could change in future periods based upon our ongoing evaluation of these significant unobservable inputs. We intend to record any such change in fair value to operating expenses in our consolidated statements of income. As of June 30, 2015, approximately $756,000 was included in other long-term obligations and $1.2 million was included in accrued expenses in our consolidated balance sheet. As of December 31, 2014, approximately $803,000 was included in other long-term obligations and $1.1 million was included in accrued expenses in our consolidated balance sheet. The cash paid to settle the contingent consideration liability recognized at fair value as of the acquisition date (including measurement-period adjustments) has been reflected as a cash outflow from financing activities in the accompanying consolidated statements of cash flows.

During the three and six-month periods ended June 30, 2015, we had losses of approximately $0 and $14,000, respectively, compared to $85,000 and $119,000 for the three and six-month periods ended June 30, 2014, respectively, related to the measurement of non-financial assets at fair value on a nonrecurring basis subsequent to their initial recognition.

The carrying amount of cash and cash equivalents, receivables, and trade payables approximates fair value because of the immediate, short-term maturity of these financial instruments. The carrying amount of long-term debt approximates fair value, as determined by borrowing rates estimated to be available to us for debt with similar terms and conditions. The fair value of assets and liabilities whose carrying value approximates fair value is determined using Level 2 inputs, with the exception of cash and cash equivalents (Level 1).

12. Goodwill and Intangible Assets. The changes in the carrying amount of goodwill for the six months ended June 30, 2015 are as follows (in thousands):

	2015
Goodwill balance at January 1	184,464
Effect of foreign exchange	(41)
Goodwill balance at June 30	$184,423

There were no changes in the carrying amount of goodwill for the six months ended June 30, 2014.

As of June 30, 2015, we had recorded $8.3 million of accumulated goodwill impairment charges. All of the goodwill balance as of June 30, 2015 and December 31, 2014 related to our cardiovascular segment.

Other intangible assets at June 30, 2015 and December 31, 2014, consisted of the following (in thousands):

	June 30, 2015		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents	$11,060	$(2,374)	$8,686
Distribution agreements	5,626	(2,558)	3,068
License agreements	11,396	(2,122)	9,274
Trademarks	7,267	(2,313)	4,954

Covenants not to compete	1,029	(755)	274
Customer lists	20,405	(14,104)	6,301
Royalty agreements	267	(267)	—
Total	$57,050	$(24,493)	$32,557

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	December 31, 2014		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents	$10,199	$(2,196)	$8,003
Distribution agreements	5,376	(2,285)	3,091
License agreements	8,995	(1,823)	7,172
Trademarks	7,298	(2,079)	5,219
Covenants not to compete	1,029	(636)	393
Customer lists	20,452	(13,194)	7,258
Royalty agreements	267	(267)	—
Total	$53,616	$(22,480)	$31,136

Aggregate amortization expense for the three and six-month periods ended June 30, 2015 was approximately $3.7 million and $7.3 million, respectively, and approximately $3.7 million and $7.4 million for the three and six-month periods ending June 30, 2014, respectively.

Estimated amortization expense for the developed technology and other intangible assets for the next five years consists of the following as of June 30, 2015 (in thousands):

Year Ending December 31	
Remaining 2015	$7,757
2016	14,728
2017	14,116
2018	13,782
2019	13,479

13. Commitments and Contingencies. In the ordinary course of business, we are involved in various claims and litigation matters. These claims and litigation matters may include actions involving product liability, intellectual property, contractual, and employment matters. We do not believe that any such actions are likely to be, individually or in the aggregate, material to our business, financial condition, results of operations or liquidity. However, in the event of unexpected further developments, it is possible that the ultimate resolution of these matters, or other similar matters, if unfavorable, may be materially adverse to our business, financial condition, results of operations or liquidity. Legal costs for these matters such as outside counsel fees and expenses are charged to expense in the period incurred.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Disclosure Regarding Forward-Looking Statements

This Report includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). All statements in this Report, other than statements of historical fact, are forward-looking statements for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of our management for future operations, any statements concerning proposed new products or services, any statements regarding the integration, development or commercialization of the business or assets acquired from other parties, any statements regarding future economic conditions or performance, and any statements of assumptions underlying any of the foregoing. All forward-looking statements included in this Report are made as of the date hereof and are based

on information available to us as of such date. We assume no obligation to update any forward-looking statement. In some cases, forward-looking statements can be identified by the use of terminology such as “may,” “will,” “expects,” “plans,” “anticipates,” “intends,” “believes,” “estimates,” “potential,” or “continue,” or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that any such expectation or any forward-looking statement will prove to be correct. Our actual results will vary, and may vary materially, from those projected or assumed in the forward-looking statements. Our financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including risks relating to product recalls and product liability claims; potential restrictions on our liquidity or our ability to operate our business by our current debt agreement, and the consequences of any default under that

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agreement; possible infringement of our technology or the assertion that our technology infringes the rights of other parties; the potential imposition of fines, penalties, or other adverse consequences if our employees or agents violate the U.S. Foreign Corrupt Practices Act or other laws or regulations; expenditures relating to research, development, testing and regulatory approval or clearance of our products and the risk that such products may not be developed successfully or approved for commercial use; greater governmental scrutiny and regulation of the medical device industry; reforms to the 510(k) process administered by the U.S. Food and Drug Administration (the "FDA"); laws targeting fraud and abuse in the healthcare industry; potential for significant adverse changes in, or our failure to comply with, governing regulations; increases in the price of commodity components; negative changes in economic and industry conditions in the United States and other countries; termination or interruption of relationships with our suppliers, or failure of such suppliers to perform; our potential inability to successfully manage growth through acquisitions, including the inability to commercialize technology acquired through recent, proposed or future acquisitions; fluctuations in Euro and GBP exchange rates; our need to generate sufficient cash flow to fund our debt obligations, capital expenditures, and ongoing operations; concentration of our revenues among a few products and procedures; development of new products and technology that could render our existing products obsolete; market acceptance of new products; volatility in the market price of our common stock; modification or limitation of governmental or private insurance reimbursement policies; changes in health care markets related to health care reform initiatives; failures to comply with applicable environmental laws; changes in key personnel; work stoppage or transportation risks; uncertainties associated with potential healthcare policy changes which may have a material adverse effect on Merit; introduction of products in a timely fashion; price and product competition; availability of labor and materials; cost increases; fluctuations in and obsolescence of inventory; and other factors referred to in our Annual Report on Form 10-K for the year ended December 31, 2014 and other materials filed with the Securities and Exchange Commission. All subsequent forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by these cautionary statements. Actual results will differ, and may differ materially, from anticipated results. Financial estimates are subject to change and are not intended to be relied upon as predictions of future operating results, and we assume no obligation to update or disclose revisions to those estimates. Additional factors that may have a direct bearing on our operating results are discussed in Part I, Item 1A “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2014.

OVERVIEW

The following discussion and analysis of our financial condition and results of operation should be read in conjunction with the consolidated financial statements and related condensed notes thereto, which are included in Part I of this Report.

We design, develop, manufacture and market single-use medical products for interventional and diagnostic procedures. For financial reporting purposes, we report our operations in two operating segments: cardiovascular and endoscopy. Our cardiovascular segment consists of cardiology and radiology devices, which assist in diagnosing and treating coronary arterial disease, peripheral vascular disease and other non-vascular diseases, and includes our embolotherapeutic products and CRM/EP devices. Our endoscopy segment consists of gastroenterology and pulmonology devices which assist in the palliative treatment of expanding esophageal, tracheobronchial and biliary strictures caused by malignant tumors.

For the three-month period ended June 30, 2015, we reported record sales of approximately $138.1 million, up approximately $9.2 million, or 7.2%, from sales for the three months ended June 30, 2014 of approximately $128.9 million. For the six-month period ended June 30, 2015, we reported record sales of approximately $267.7 million, up approximately $19.6 million, or 7.9%, compared to sales of approximately $248.1 million for the first six months of 2014.

Gross profit as a percentage of sales increased to 44.1% for the three-month period ended June 30, 2015, from 43.2% for the three-month period ended June 30, 2014. Gross profit as a percentage of sales remained constant at 43.4% for the six-month period ended June 30, 2015 compared to 43.4% for the six-month period ended June 30, 2014. The increase in gross profit for the quarter ended June 30, 2015 was primarily related to a decrease in Euro-based

manufacturing expenses due to the strengthening of the U.S. Dollar against the Euro.

Net income for the three months ended June 30, 2015 was approximately $7.4 million, or $0.17 per diluted share, up 99% compared to net income of approximately $3.7 million, or $0.09 per diluted share, for the three months ended June 30, 2014. The increase in net income for the three-month period ended June 30, 2015 was attributable primarily to increased sales, lower operating expenses as a percentage of sales and higher gross profit as a percentage of sales.

Net income for the six-month period ended June 30, 2015 was approximately $12.6 million, or $0.28 per diluted share, up 92% compared to net income of approximately $6.5 million, or $0.15 per diluted share, for the corresponding period of 2014. The increase in net income for the six-month period ended June 30, 2015 was attributable primarily to increased sales and lower operating expenses as a percentage of sales.

Our new facility in Tijuana, Mexico began production in early July. The first products being produced in this facility were moved from an independent third party contract manufacturer in Tijuana, Mexico. We made arrangements with the contract manufacturer to hire approximately 170 of the manufacturer's employees who are currently manufacturing our products. The employees hired

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included production operators and supervisors and quality and engineering personnel. We believe this arrangement will help us maintain the quality and production volumes of the products that are currently being produced in Mexico and will aid in our ability to transfer additional product lines from our other existing production facilities to our Tijuana facility. In connection with the termination of our agreement with our contract manufacturer, we paid a one-time termination fee of $800,000, which was recorded in selling, general and administrative costs. In addition to this termination fee, we anticipate approximately $1.5 to $2.5 million of operating expenses will be treated as selling, general and administrative costs, as opposed to cost of sales, during a transition period as we begin operation of our Tijuana, Mexico production facility. As we move additional product lines to our new Tijuana facility from other existing production facilities over the next three years, we expect to see our overall gross profit and earnings improve. We anticipate that much of the expected improvement in gross margins and earnings we have forecasted will not be achieved until we are efficiently utilizing the Tijuana facility to produce product. It is anticipated that this utilization could occur sometime between the end of 2016 and the beginning of 2017.

In April 2015, we began to move the production lines from our West Jordan, Utah manufacturing site to our other existing manufacturing facilities. We plan to move additional production lines from our West Jordan site to our Tijuana facility in the third and fourth quarters of 2015. We believe the West Jordan manufacturing site, which is currently under an operating lease, should be vacated by the end of 2015.

During the three and six-month periods ended June 30, 2015, we benefited from the strengthening of the U.S. Dollar against the Euro, as the result of our natural hedge. This natural hedge is the result of having more cost of sales and operating expenses (European manufacturing facilities, European distribution site and EMEA direct and distributor sales efforts) denominated in Euros than our Euro-denominated sales. The improvement in the U.S. Dollar against the Euro decreased our Euro-denominated sales and cost of sales in the three-month period ended June 30, 2015 by approximately $3.4 million and $3.2 million, respectively, and by approximately $5.8 million and $4.4 million, respectively, for the six-month period ended June 30, 2015. The overall effect on gross profits of the strengthening of the U.S. Dollar against the Euro for the second quarter of 2015 was an improvement of 0.88%. Our operating expenses for the three and six-month periods ended June 30, 2015 also benefited from the strengthening of the U.S. Dollar against the Euro, with a decrease in operating expenses of approximately $1.9 million and $3.6 million, respectively.

We reduced our long-term debt by approximately $14.7 million in the six months ended June 30, 2015 to approximately $199.8 million. Our debt to Consolidated EBITDA (as defined in our Amended and Restated Credit Agreement, dated December 19, 2012, with the lenders who are or may become party thereto (collectively, the "Lenders") and Wells Fargo Bank, National Association ("Wells Fargo"), as administrative agent for the Lenders, which was amended on October 4, 2013 by a First Amendment to the Amended and Restated Credit Agreement by and among Merit, certain subsidiaries of Merit, the Lenders and Wells Fargo as administrative agent for the Lenders (as amended, the "Credit Agreement") and subject to certain adjustments) ratio decreased to 2.42 on June 30, 2015, down from 2.62 on March 31, 2015, 2.86 on December 31, 2014 and 3.24 on September 30, 2014.

RESULTS OF OPERATIONS

The following table sets forth certain operational data as a percentage of sales for the three and six-month periods ended June 30, 2015 and 2014, as indicated:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Net sales	100%	100%	100%	100%
Gross profit	44.1%	43.2%	43.4%	43.4%
Selling, general, and administrative expenses	28.5%	30.0%	28.5%	30.4%
Research and development expenses	6.7%	7.5%	7.1%	7.4%
Income from operations	8.9%	5.7%	7.8%	5.6%
Other (expense) - net	(1.2)%	(1.8)%	(1.1)%	(2.0)%

Income before income taxes	7.6%	3.9%	6.7%	3.6%
Net income	5.4%	2.9%	4.7%	2.6%

Sales. Sales for the three months ended June 30, 2015 increased by 7.2%, or approximately $9.2 million, compared to the corresponding period of 2014. Sales for the six months ended June 30, 2015 increased by 7.9%, or approximately $19.6 million, compared to the corresponding period of 2014. Listed below are the sales by product category within each business segment for the three and six-month periods ended June 30, 2015 and 2014 (in thousands):

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		Three Months Ended June 30,			Six Months Ended June 30,	
	% Change	2015	2014	% Change	2015	2014
Cardiovascular						
Stand-alone devices	9.0%	$39,496	$36,231	8.1%	76,674	$70,958
Custom kits and procedure trays	3.7%	30,067	28,981	6.6%	57,753	54,198
Catheters	11.5%	24,139	21,648	14.1%	47,596	41,730
Inflation devices	(0.9)%	18,701	18,880	3.6%	37,391	36,109
Embolization devices	6.3%	11,603	10,914	7.6%	21,995	20,433
CRM/EP	9.6%	8,783	8,015	—%	16,143	16,148
Total	6.5%	132,789	124,669	7.5%	257,552	239,576
Endoscopy						
Endoscopy devices	26.1%	5,293	4,196	18.6%	10,107	8,525
Total	7.2%	$138,082	$128,865	7.9%	$267,659	$248,101

Our cardiovascular sales grew 6.5% for the three months ended June 30, 2015 and 7.5% for the six months ended June 30, 2015, when compared to the corresponding periods of 2014. This improvement was largely the result of increased sales of catheters (particularly our Prelude® introducer sheath product line, micro catheter product line, guiding catheter product line, ProGuide™ dialysis catheter product line) our stand-alone devices (particularly our diagnostic guide wire product line, tubing product line and hydrophilic guide wire product line) and our procedure trays.

Our endoscopy sales increased 26.1% for the three months ended June 30, 2015 and 18.6% for the six months ended June 30, 2015, when compared to the corresponding periods of 2014. The increase was primarily related to an increase in sales of our AEROmini® fully covered tracheobronchial stent and EndoMAXX™ fully covered esophageal stent.

Gross Profit. Gross profit as a percentage of sales increased to 44.1% for the three-month period ended June 30, 2015, from 43.2% for the three-month period ended June 30, 2014. Gross profit as a percentage of sales remained constant at 43.4% for the six-month period ended June 30, 2015 compared to 43.4% for the six-month period ended June 30, 2014. The increase in gross profit for the quarter ended June 30, 2015 was primarily related to a decrease in Euro-based manufacturing expenses due to the strengthening of the U.S. Dollar against the Euro.

Operating Expenses. Selling, general, and administrative ("SG&A") expenses were 28.5% as a percentage of sales for the three-month period ended June 30, 2015, compared to 30.0% as a percentage of sales for the three-month period ended June 30, 2014. Selling, general, and administrative expenses were 28.5% as a percentage of sales for the six-month period ended June 30, 2015, compared to 30.4% as a percentage of sales for the six-month period ended June 30, 2014. The decrease in SG&A expenses as a percentage of sales for both periods was primarily related to increased sales as well as a decrease in our Euro-based SG&A expenses due to the strengthening of the U.S. Dollar against the Euro of approximately $1.7 million and $3.1 million, for the three and six-month periods ended June 30, 2015, respectively, when compared to the comparable periods for 2014.

Research and Development Expenses. Research and development ("R&D") expenses were 6.7% of sales for the three months ended June 30, 2015, compared with 7.5% of sales for the three months ended June 30, 2014. Research and development expenses were 7.1% of sales for the six months ended June 30, 2015, compared with 7.4% of sales for the six months ended June 30, 2014. The decrease in R&D expenses as a percentage of sales in each period of 2015 was primarily the result of higher sales and expenses that were relatively flat compared to the comparable periods in 2014, in addition to decreases in Merit’s Euro-based R&D expenses due to the strengthening of the U.S. Dollar against

the Euro.

Operating Income. The following table sets forth our operating income by business segment for the three and six-month periods ended June 30, 2015 and 2014 (in thousands):

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	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Operating Income				
Cardiovascular	$11,258	$7,300	$19,327	$13,696
Endoscopy	984	84	1,619	177
Total operating income	$12,242	$7,384	$20,946	$13,873

Cardiovascular Operating Income. During the three months ended June 30, 2015, we reported income from operations of approximately $11.3 million from our cardiovascular business segment, compared to income from operations of approximately $7.3 million for the corresponding period of 2014. During the six months ended June 30, 2015, we reported income from operations of approximately $19.3 million from our cardiovascular business segment, compared to income from operations of approximately $13.7 million for the corresponding period of 2014. The increase in income from operations was primarily attributable to higher sales and lower operating expenses as a percentage of sales.

Endoscopy Operating Income. During the three months ended June 30, 2015, we reported income from operations of approximately $984,000 from our endoscopy business segment, compared to income from operations of approximately $84,000 for the corresponding period of 2014. During the six months ended June 30, 2015, we reported income from operations of approximately $1.6 million from our endoscopy business segment, compared to income from operations of approximately $177,000 for the corresponding period of 2014. The increase in operating income was primarily the result of higher sales and gross profits, as well as lower selling, general, and administrative expenses as a percentage of sales.

Other Expense - Net. Other expense, net, for the three months ended June 30, 2015 was approximately $1.7 million, compared to other expense, net, of approximately $2.3 million for the three months ended June 30, 2014. Other expense, net, for the six months ended June 30, 2015 was approximately $3.0 million, compared to other expense, net, of approximately $4.9 million for the six months ended June 30, 2014. The decrease in other expense for both periods was principally the result of decreased interest expense related to a lower average outstanding debt balance and a lower interest rate.

Income Taxes. Our overall effective tax rate for the three months ended June 30, 2015 was 29.7% compared to 26.9% for the three months ended June 30, 2014. For the six months ended June 30, 2015, our effective tax rate was 30.1%, compared to 27.1% for the six months ended June 30, 2014. The increase in the effective tax rate for both periods, when compared to the prior-year periods, was due primarily to the impact of certain tax benefits recognized during the second quarter of 2014.

Net Income. During the second quarter of 2015, we reported net income of approximately $7.4 million, an increase of 99.2% from net income of approximately $3.7 million for the second quarter of 2014. For the six months ended June 30, 2015, we reported net income of approximately $12.6 million, an increase of approximately 92.3% from net income of approximately $6.5 million for the corresponding period of 2014. The increase in net income was primarily affected by increased sales, lower operating expenses as a percentage of sales and lower interest expense, and was partially offset by a higher effective income tax rate.

LIQUIDITY AND CAPITAL RESOURCES

Our working capital as of June 30, 2015 and December 31, 2014 was $113.0 million and $116.9 million respectively. The decrease in working capital as of June 30, 2015 was primarily the result of decreases in trade and other receivables and increases in accrued expenses, which were partially offset by a decrease in trade payables and an increase in cash. As of June 30, 2015, we had a current ratio of 2.42 to 1.

At June 30, 2015 and December 31, 2014, we had cash and cash equivalents of approximately $12.1 million and $7.4 million respectively, of which approximately $11.8 million and $6.6 million, respectively, were held by foreign subsidiaries. For each of our foreign subsidiaries, we make an assertion as to whether the earnings are intended to be

repatriated to the United States or held by the foreign subsidiary for permanent reinvestment. The cash held by our foreign subsidiaries for permanent reinvestment is generally used to fund the operating activities of our foreign subsidiaries and for further investment in foreign operations. We have accrued a deferred tax liability on our consolidated financial statements for the portion of our foreign earnings that are available to be repatriated to the United States.

In addition, cash held by our subsidiary in China is subject to local laws and regulations that require government approval for the transfer of such funds to entities located outside of China. As of June 30, 2015 and December 31, 2014, we had cash and cash equivalents of approximately $9.1 million and $5.2 million, respectively, held by our subsidiary in China.

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During the six months ended June 30, 2015, our inventory balances increased by approximately $0.9 million, from $91.8 million at December 31, 2014 to $92.7 million at June 30, 2015. The trailing twelve-month inventory turns for the period ended June 30, 2015 improved to 3.30, compared to 3.23 for the period ended June 30, 2014.

Pursuant to the terms of the Credit Agreement, the Lenders have agreed to make revolving credit loans up to an aggregate amount of $215 million. The Lenders also made a term loan in the amount of $100 million, repayable in quarterly installments in the amounts provided in the Credit Agreement until the maturity date of December 19, 2017, at which time the term and revolving credit loans, together with accrued interest thereon, will be due and payable. In addition, certain mandatory prepayments are required to be made upon the occurrence of certain events described in the Credit Agreement. Wells Fargo has agreed, upon satisfaction of certain conditions, to make swingline loans from time to time through the maturity date in amounts equal to the difference between the amounts actually loaned by the Lenders and the aggregate revolving credit commitment. The Credit Agreement is collateralized by substantially all of our assets. At any time prior to the maturity date, we may repay any amounts owing under all revolving credit loans, term loans, and all swingline loans in whole or in part, subject to certain minimum thresholds, without premium or penalty, other than breakage costs.

The term loan and any revolving credit loans made under the Credit Agreement bear interest, at our election, at either (i) the base rate (described below) plus 0.25% (subject to adjustment if the Consolidated Total Leverage Ratio, as defined in the Credit Agreement, is at or greater than 2.25 to 1), (ii) the London Inter-Bank Offered Rate ("LIBOR") Market Index Rate (as defined in the Credit Agreement) plus 1.25% (subject to adjustment if the Consolidated Total Leverage Ratio, as defined in the Credit Agreement, is at or greater than 2.25 to 1), or (iii) the LIBOR Rate (as defined in the Credit Agreement) plus 1.25% (subject to adjustment if the Consolidated Total Leverage Ratio, as defined in the Credit Agreement, is at or greater than 2.25 to 1). Initially, the term loan and revolving credit loans under the Credit Agreement bear interest, at our election, at either (x) the base rate plus 1.00%, (y) the LIBOR Market Index Rate, plus 2.00%, or (z) the LIBOR Rate plus 2.00%. Swingline loans bear interest at the LIBOR Market Index Rate plus 1.25% (subject to adjustment if the Consolidated Total Leverage Ratio, as defined in the Credit Agreement, is at or greater than 2.25 to 1). Initially, swingline loans bear interest at the LIBOR Market Index Rate plus 2.00%. Interest on each loan featuring the base rate or the LIBOR Market Index Rate is due and payable on the last business day of each calendar month; interest on each loan featuring the LIBOR Rate is due and payable on the last day of each interest period selected by us when selecting the LIBOR Rate as the benchmark for interest calculation. For purposes of the Credit Agreement, the base rate means the highest of (i) the prime rate (as announced by Wells Fargo), (ii) the federal funds rate plus 0.50%, and (iii) LIBOR for an interest period of one month plus 1.00%. Our obligations under the Credit Agreement and all loans made thereunder are fully secured by a security interest in our assets pursuant to a separate collateral agreement entered into in conjunction with the Credit Agreement.

The Credit Agreement contains customary covenants, representations and warranties and other terms customary for revolving credit loans of this nature. In this regard, the Credit Agreement requires us to not, among other things, (a) permit the Consolidated Total Leverage Ratio (as defined in the Credit Agreement) to be greater than 4.75 to 1 through the end of 2013, no more than 4.00 to 1 as of the fiscal quarter ending March 31, 2014, no more than 3.75 to 1 as of the fiscal quarter ending June 30, 2014, no more than 3.50 to 1 as of the fiscal quarter ending September 30, 2014, no more than 3.25 to 1 as of the fiscal quarter ending December 31, 2014, no more than 3.00 to 1 as of any fiscal quarter ending during 2015, no more than 2.75 to 1 as of any fiscal quarter ending during 2016, and no more than 2.50 to 1 as of any fiscal quarter ending thereafter; (b) for any period of four consecutive fiscal quarters, permit the ratio of Consolidated EBITDA (as defined in the Credit Agreement and subject to certain adjustments) to Consolidated Fixed Charges (as defined in the Credit Agreement) to be less than 1.75 to 1; (c) subject to certain adjustments, permit Consolidated Net Income (as defined in the Credit Agreement) for certain periods to be less than $0; or (d) subject to certain conditions and adjustments, permit the aggregate amount of all Facility Capital Expenditures (as defined in the Credit Agreement) in any fiscal year beginning in 2013 to exceed $30 million. Additionally, the Credit Agreement contains various negative covenants with which we must comply, including, but not limited to, limitations respecting: the incurrence of indebtedness, the creation of liens or pledges on our assets, mergers or similar combinations or liquidations, asset dispositions, the repurchase or redemption of equity interests or debt, the issuance of equity, the payment of dividends and certain distributions, the entry into related party

transactions and other provisions customary in similar types of agreements. As of June 30, 2015, we were in compliance with all covenants set forth in the Credit Agreement.

As of June 30, 2015, we had available borrowings under the Credit Agreement of approximately $35.2 million. Our interest rate as of June 30, 2015 was a fixed rate of 2.98% on $137.5 million as a result of an interest rate swap (see Note 10), a variable floating rate of 1.94% on $67.8 million and a variable floating rate of 2.04% on approximately $4.5 million. Our Total Leverage Ratio under the Credit Agreement for the quarter ended June 30, 2015, was 2.42 to 1. As a result of the quarterly adjustment of our Total Leverage Ratio, as contemplated by the Credit Agreement, the base interest rate on our term loan and amounts outstanding on our revolving credit loans is scheduled to drop 0.25% to 1.50%, from the current base rate of 1.75%, on August 24, 2015. The new base rate of 1.50% is scheduled to remain in effect until November 24, 2015, at which time the Credit Agreement provides for a new base rate to be determined.

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Capital expenditures for property and equipment were approximately $25.4 million and $18.7 million, respectively, for the six-month periods ended June 30, 2015 and 2014, an increase of $6.7 million.

We currently believe that our existing cash balances, anticipated future cash flows from operations, borrowings under the Credit Agreement (approximately $35.2 million of borrowing availability as of June 30, 2015), and potential equipment financing will be adequate to fund our current and currently planned future operations for the next twelve months and the foreseeable future. In the event we pursue and complete significant transactions or acquisitions in the future, additional funds will likely be required to meet our strategic needs, which may require us to raise additional funds in the debt or equity markets.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The SEC has requested that all registrants address their most critical accounting policies. The SEC has indicated that a "critical accounting policy" is one which is both important to the representation of the registrant's financial condition and results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. We base our estimates on past experience and on various other assumptions our management believes to be reasonable under the circumstances, the results of which form the basis for making judgments about carrying values of assets and liabilities that are not readily apparent from other sources. Actual results will differ, and may differ materially from these estimates under different assumptions or conditions. Additionally, changes in accounting estimates could occur in the future from period to period. Our management has discussed the development and selection of our most critical financial estimates with the audit committee of our Board of Directors. The following paragraphs identify our most critical accounting policies:

Inventory Obsolescence. Our management reviews on a quarterly basis inventory quantities on hand for unmarketable and/or slow-moving products that may expire prior to being sold. This review includes quantities on hand for both raw materials and finished goods. Based on this review, we provide adjustments for any slow-moving finished good products or raw materials that we believe will expire prior to being sold or used to produce a finished good and any products that are unmarketable. This review of inventory quantities for unmarketable and/or slow moving products is based on forecasted product demand prior to expiration lives.

Forecasted unit demand is derived from our historical experience of product sales and production raw material usage. If market conditions become less favorable than those projected by our management, additional inventory write-downs may be required. During the years ended December 31, 2014, 2013 and 2012, we recorded obsolescence expense of approximately $2.3 million, $2.7 million, and $2.3 million, respectively, and wrote off approximately $2.4 million, $2.8 million, and $1.5 million, respectively. Based on this historical trend, we believe that our inventory balances as of June 30, 2015 have been accurately adjusted for any unmarketable and/or slow moving products that may expire prior to being sold.

Allowance for Doubtful Accounts. A majority of our receivables are with hospitals which, over our history, have demonstrated favorable collection rates. Therefore, we have experienced relatively minimal bad debts from hospital customers. In limited circumstances, we have written off bad debts as the result of the termination of our business relationships with foreign distributors. The most significant write-offs over our history have come from U.S. custom procedure tray manufacturers who bundle our products in surgical trays.

We maintain allowances for doubtful accounts relating to estimated losses resulting from the inability of our customers to make required payments. These allowances are based upon historical experience and a review of individual customer balances. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.

Stock-Based Compensation. We measure stock-based compensation cost at the grant date based on the value of the award and recognize the cost as an expense over the term of the vesting period. Judgment is required in estimating the

fair value of share-based awards granted and their expected forfeiture rate. If actual results differ significantly from these estimates, stock-based compensation expense and our results of operations could be materially impacted.

Income Taxes. Under our accounting policies, we initially recognize a tax position in our financial statements when it becomes more likely than not that the position will be sustained upon examination by the tax authorities. Such tax positions are initially and subsequently measured as the largest amount of tax positions that has a greater than 50% likelihood of being realized upon ultimate settlement with the tax authorities assuming full knowledge of the position and all relevant facts. Although we believe our provisions for unrecognized tax positions are reasonable, we can make no assurance that the final tax outcome of these matters will not be different from that which we have reflected in our income tax provisions and accruals. The tax law is subject to varied interpretations, and we have taken positions related to certain matters where the law is subject to interpretation. Such differences

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could have a material impact on our income tax provisions and operating results in the period(s) in which we make such determination.

Goodwill and Intangible Assets Impairment and Contingent Consideration. We test our goodwill balances for impairment as of July 1 of each year, or whenever impairment indicators arise. We utilize several reporting units in evaluating goodwill for impairment. We assess the estimated fair value of reporting units based on discounted future cash flows. If the carrying amount of a reporting unit exceeds the fair value of the reporting unit, an impairment charge is recognized in an amount equal to the excess of the carrying amount of the reporting unit goodwill over implied fair value of that goodwill. This analysis requires significant judgment, including estimation of future cash flows and the length of time they will occur, which is based on internal forecasts, and a determination of a discount rate based on our weighted average cost of capital. During our annual test of goodwill balances in 2014, which was completed during the third quarter of 2014, we determined that the fair value of each reporting unit with goodwill exceeded the carrying amount.

We evaluate the recoverability of intangible assets whenever events or changes in circumstances indicate that an asset's carrying amount may not be recoverable. This analysis requires similar significant judgments as those discussed above regarding goodwill, except that undiscounted cash flows are compared to the carrying amount of intangible assets to determine if impairment exists. All of our intangible assets are subject to amortization.

Contingent consideration is an obligation by the buyer to transfer additional assets or equity interests to the former owner upon reaching certain performance targets. Certain of our business combinations involve the potential for the payment of future contingent consideration, generally based on a percentage of future product sales or upon attaining specified future revenue milestones. In connection with a business combination, any contingent consideration is recorded on the acquisition date based upon the consideration expected to be transferred in the future. We utilize a discounted cash flow method, which includes a probability factor for milestone payments, in valuing the contingent consideration liability. We re-measure the estimated liability each quarter and record changes in the estimated fair value through operating expense in our consolidated statements of income. Significant increases or decreases in our estimates could result in changes to the estimated fair value of our contingent consideration liability, as the result of changes in the timing and amount of revenue estimates, as well as changes in the discount rate or periods.

During the year ended December 31, 2014, we reduced the amount of the contingent consideration liability related to the Ostial PRO® Stent Positioning System, which we acquired in January 2012, by approximately $874,000. Under the terms of the Asset Purchase Agreement we executed with Ostial Solutions, LLC ("Ostial"), we are obligated to make contingent purchase price payments based on a percentage of future sales of products utilizing the Ostial PRO Stent Positioning System. The adjustment to the contingent consideration liability triggered a review of the intangible assets we acquired from Ostial, which resulted in an intangible asset write-down of approximately $1.1 million related to those assets. These adjustments reduced operating income for the year ended December 31, 2014 by approximately $228,000, or approximately $141,000 net of tax. The reduction of the Ostial contingent consideration liability and the impairment of the Ostial intangible assets was the result of our assessment that we are not likely to generate the level of revenues from sales of the Ostial PRO Stent Positioning System that we anticipated at the acquisition date.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our principal market risk relates to changes in the value of the Euro, the Chinese Yuan, and the Great British Pound ("GBP") relative to the value of the U.S. Dollar. We also have less significant market risks relating to the Hong Kong Dollar and the Swedish and Danish Kroner. Our consolidated financial statements are denominated in, and our principal currency is, the U.S. Dollar. For the three-month period ended June 30, 2015, a portion of our revenues (approximately $28.0 million, representing approximately 20% of our aggregate revenues), was attributable to sales that were denominated in foreign currencies. All other international sales were denominated in U.S. Dollars. Certain of our expenses for the three-month period ended June 30, 2015 were also denominated in foreign currencies, which partially offset risks associated with fluctuations of exchange rates between foreign currencies and the U.S. Dollar. During the three-month period ended June 30, 2015, fluctuations in the exchange rate between foreign currencies and the U.S. Dollar resulted in a decrease in our gross revenues of approximately $3.4 million, or 2.5%, and an increase of 0.88% in gross profit, primarily as a result of a decrease in Irish manufacturing operating costs and raw materials denominated in Euros. Our Euro-denominated revenue represents our largest single currency risk. However, our Euro-denominated expenses associated with our European operations (manufacturing sites, a distribution facility and sales representatives) provide a natural hedge. Accordingly, changes in the Euro, and in particular a strengthening of the U.S. Dollar against the Euro, will generally have a positive effect our net income. We anticipate that a strengthening U.S. Dollar against the Euro of 10% would increase our net income by approximately $1.0 million. Conversely, a weakening U.S. Dollar against the Euro of 10% would have a negative impact on our net income of $1.0 million.

On May 29, 2015, we forecasted a net exposure for June 30, 2015 (representing the difference between Euro and GBP-denominated receivables and Euro-denominated payables) of approximately 543,000 Euros and 83,000 GBPs. In order to partially offset such risks, on May 29, 2015, we entered into a 30-day forward contract for the Euro and GBP with a notional amount of approximately 543,000 Euros and notional amount of 83,000 GBPs. We enter into similar transactions at various times during the year to partially offset exchange rate risks we bear throughout the year. These contracts are marked to market at the end of each month. The effect on our consolidated statements of income for the six months ended June 30, 2015 and 2014 of all forward contracts, and the fair value of our open positions as of June 30, 2015, were not material.

As discussed in Note 9 to our consolidated financial statements, as of June 30, 2015, we had outstanding borrowings of approximately $209.8 million under the Credit Agreement. Accordingly, our earnings and after-tax cash flow are affected by changes in interest rates. As part of our efforts to mitigate interest rate risk, on December 19, 2012, we entered into a LIBOR-based interest rate swap agreement having an initial notional amount of $150 million with Wells Fargo to fix the one-month LIBOR rate at 0.98%. This instrument is intended to reduce our exposure to interest rate fluctuations and was not entered into for speculative purposes. Excluding the amount that is subject to a fixed rate under the interest rate swap and assuming the current level of borrowings remained the same, it is estimated that our interest expense and income before income taxes would change by approximately $723,000 annually for each one percentage point change in the average interest rate under these borrowings.

In the event of an adverse change in interest rates, our management would likely take actions to mitigate our exposure. However, due to the uncertainty of the actions that would be taken and their possible effects, additional analysis is not possible at this time. Further, such analysis would not consider the effects of the change in the level of overall economic activity that could exist in such an environment.

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ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of June 30, 2015. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Based on that evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our 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

During the quarter ended June 30, 2015, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934).

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PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

See Note 13 “Commitments and Contingencies” set forth in the notes to our condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report.

ITEM 1A. RISK FACTORS

In addition to other information set forth in this Report, readers should carefully consider the factors discussed in Part I, Item 1A. "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2014, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially and adversely affect our business, financial condition and/or operating results.

ITEM 6. EXHIBITS

Exhibit No.	Description
10.1	Third Amendment to the Merit Medical Systems, Inc. 2006 Long-Term Incentive Plan
10.2	Fourth Amendment to the Merit Medical Systems, Inc. 1996 Employee Stock Purchase Plan
10.3	Separation Agreement and Release of All Claims of Martin Stephens effective April 14, 2015
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following financial information from the quarterly report on Form 10-Q of Merit Medical Systems, Inc. for the quarter ended June 30, 2015, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Statements of Income, (ii) Consolidated Balance Sheets, (iii) Consolidated Statements of Comprehensive Income, (iv) Consolidated Statements of Cash Flows, and (v) Notes to the Consolidated Financial Statements

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SIGNATURES

Pursuant to the requirements 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.

MERIT MEDICAL SYSTEMS, INC.
REGISTRANT

Date: August 7, 2015

/s/ FRED P. LAMPROPOULOS
FRED P. LAMPROPOULOS
PRESIDENT AND CHIEF EXECUTIVE OFFICER

Date: August 7, 2015

/s/ KENT W. STANGER
KENT W. STANGER
CHIEF FINANCIAL OFFICER