

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549**

FORM 10-K

(Mark one)

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

For the fiscal year ended July 31, 2021

or

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

For the transition period from _____ to _____

Commission File Number 001-09974

ENZO BIOCHEM, INC.

(Exact name of registrant as specified in its charter)

New York

13-2866202

(State or other jurisdiction of
incorporation or organization)

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

527 Madison Ave.
New York, New York

10022

(Address of principal executive offices)

(Zip Code)

(212) 583-0100

(Registrant's telephone number, including area code)

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

| Title of Each Class | Trading Symbol | Name of Each Exchange on Which Registered |
|-------------------------------|----------------|---|
| Common Stock, \$.01 par value | ENZ | The New York Stock Exchange |

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

Yes No

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

Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

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

Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company Emerging company growth

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

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

The aggregate market value of the registrant's voting stock held by non-affiliates of the registrant was approximately \$126,324,000 as of January 31, 2021.

The number of shares of the Company's common stock, \$.01 par value, outstanding at October 11, 2021 was 48,471,771.

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 6, 2022 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 an integrated diagnostics, clinical lab, and life sciences company focused on delivering and applying advanced technology capabilities to produce affordable reliable products and services that enable our customers to meet their clinical needs. Through a connection with the market, we provide advanced biotechnology solutions to the global community as affordable and flexible quality products and services. We develop, manufacture and sell our proprietary technology solutions and platforms to clinical laboratories, specialty clinics, researchers and physicians globally. Enzo’s structure and business strategy represent the culmination of years of extensive planning and work. The Company has the unique ability to offer low cost, high performance products and services for diagnostic testing, which ideally positions us 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 develops low cost diagnostic platform products and related services. Our platform development includes automation-compatible reagent systems and associated products for sample collection and processing through analysis. We develop affordable products and services to improve healthcare, one of the greatest challenges today. Enzo combines over 40 years of expertise in technology development with assay development capabilities and diagnostic testing services to create high performance, cost-effective, and open assay solutions. The ability to combine these assets in one company is unique. With our strong intellectual property portfolio integrated with assay development know-how, production, distribution, validation and services capabilities, we have enabled sustainable products and services for a market that is facing increasing pressure in costs and reimbursement.

Enzo technology solutions and platforms and unique operational structure are designed to reduce overall healthcare costs for both government and private insurers. Our proprietary technology platforms reduces our customers’ need for multiple, specialized instruments, and offer a variety of high 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 GENFLEX R platform is a high-throughput, automated, and scalable instrument for processing molecular diagnostics tests within a clinical production setting. While initially focused on COVID-19 and Women’s Health assays, it can lead to the development of an entire line of molecular products that can allow laboratories to offer a complete menu of services for this \$7 billion plus growing market at a cost that allows them to enjoy an acceptable margin. These products include testing sample collection, molecular, and antibody tests, as well as instrumentation, all on a global basis. Our solutions provide tools to physicians, clinicians and other healthcare 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, comprised of 472 issued patents worldwide and over 64 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 which have been augmented by previous acquisitions of a number of related companies. Financial information by geographic area and business segments for the years ended July 31, 2021, 2020 and 2019 is located in Note 17 in the Notes to Consolidated Financial Statements.

Below are brief descriptions of each of our operating segments:

Enzo Clinical Lab 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 Clinical Laboratory Improvement Amendments of 1988 (“CLIA”) certified and College of American Pathologists (“CAP”) accredited 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 and 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, New Jersey and Connecticut, two free standing “STAT” or rapid response laboratories in New York City and Connecticut, an in-house logistics department, and an information technology department. Under our license in New York State, we are able to offer testing services to clinical laboratories and physicians nationwide.

Enzo Life Sciences manufactures, develops and markets products and tools for 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 also the life sciences markets 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 100 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 utilized by customers worldwide. The following table summarizes the sources of revenues for the fiscal years ended July 31, 2021, 2020 and 2019 (in thousands except percentages):

| Fiscal year ended July 31, | 2021 | | 2020 | | 2019 | |
|------------------------------|------------|------|-----------|------|-----------|------|
| Clinical laboratory services | \$ 86,984 | 74% | \$ 47,964 | 63% | \$ 51,115 | 63% |
| Product revenues | 30,747 | 26 | 26,561 | 35 | 30,055 | 37 |
| Grant income | — | — | 1,496 | 2 | — | — |
| Total | \$ 117,731 | 100% | \$ 76,021 | 100% | \$ 81,170 | 100% |

Markets

Clinical diagnostics

The U.S. clinical diagnostics market has been reported by industry sources to be greater than \$25 billion per year nationally and over \$60 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 bodily fluid based approaches.

Many of these tests employ traditional technologies such as cell culture technologies.

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

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

Molecular diagnostics have many advantages over traditional technologies. Since gene-based diagnostics focus on the identification of diseases at the molecular 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 diagnostics industry, growing at more than twice the rate of traditional diagnostics. Contributing to this growth are, among other factors:

- the increasing number of diagnostic tests being developed from discoveries in genomic research;
- advances in formats and other technologies that automate and accelerate gene-based diagnostic testing;
- growing emphasis by the healthcare 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

There is a large and growing global demand by biomedical and pharmaceutical companies 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 and 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 into disease and potential therapeutic solutions. These techniques use instruments such as DNA sequencing and genotyping equipment, microarrays, fluorescent microscopes, high content screening platforms, flow cytometers and plate readers. Common among these instruments is the need for reagents that allow the identification, quantification and characterization of 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 genomics 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 growth or metabolic control and immune-mediated diseases, including autoimmune diseases and cancers. Although the causes of disorders such as Crohn's disease, autoimmune uveitis and non-alcoholic steatohepatitis (NASH) remain unknown, various features suggest immune system involvement in their pathogenesis.

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

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 strategy is focused on offering quality and affordable testing solutions to high volume market segments where reimbursement pressures have caused challenges for our customers within these segments. Our customers need cost of goods savings. To achieve this, we have taken common workflows and applied Enzo's innovative technical expertise to each platform part in order to achieve integrative cost effective solutions.

Our objective is to develop and manufacture high value, affordable and reliable 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 enter and compete in markets that until now have been out of reach due to poor economic standing caused by high costs of reagents and equipment rental arrangements from molecular diagnostic companies coupled with lower reimbursement from governmental payers and commercial healthcare insurers.

Our objective allows clinical laboratories to purchase low cost reagents and kits to be run on open system platforms already in use in their labs, or to use Enzo as a low cost reference laboratory. Enzo's integrated business model not only provides benefits to clinical laboratories, but also to insurance providers who will benefit from more clinical laboratories being 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 utilizing 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, we are positioned 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 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 validation and commercialization.

- The unique ability to deliver high performance, easily adaptable products and services that are also cost effective for independent labs as well as Enzo's own clinical lab in a steadily declining reimbursement environment
- 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 marketplace, as well as in the important segments of Anatomical Pathology, Cytology and Immunohistochemistry.

Our development activities are directed to each step of the clinical testing process, from sample collection and processing through analysis. Our goal is to manufacture the components required for each step in the diagnostic process for integration into an open platform. Enzo's system solutions will enable clinical laboratories to more effectively participate in the diagnostics market where declining reimbursements and rigid costs from suppliers currently prevail.

Current technology platforms under development include:

- AMPIPROBE® Genetic Amplification Platform – easily adaptable, affordable, real time DNA amplification and detection
- FLOWSCRIPT® Gene Expression Platform – enhanced flow cytometry for single cell analysis
- POLYVIEW PLUS® Enhanced Immunohistochemistry – optimized reagents for clear, consistent immunohistochemistry and in situ hybridization results moving Pathology to the next generation
- Enhanced Immunoassays – pushing sensitivity to expand immunoassay applications

Enzo's proprietary platforms and the related assays developed can provide more sensitive diagnostic information at lower costs than many other currently marketed tests. The Company designs its products to be able to work with lower specimen volume which not only allows the laboratories to run more tests from 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 solutions under development by Enzo to address the critical needs of clinical laboratories that are often locked into closed-system contracts with molecular diagnostics suppliers which, with ever-declining reimbursements, reduce or even eliminate operating margins.

New Molecular Diagnostic platform

Enzo has developed and validated a new molecular diagnostics platform, GENFLEX[®] Molecular System, which, unlike current closed system platforms, has an open access feature, flexibility and compatibility with a full clinical workflow. It is believed to be uniquely characterized as an automated, clinically compatible, open platform that operates with multiple reagents and sample types allowing for cost savings and Laboratory Developed Tests (LDTs), while remaining comparable with FDA-approved products. It has been optimized to fully address existing clinical work flows while also providing the flexibility to develop and incorporate new work flows. The clinical diagnostic industry is challenged by declining reimbursements and high reagent costs associated with “closed systems” diagnostic platforms that prohibit the use of third-party reagents. The new Enzo “open system” molecular diagnostic platform is compatible with existing sample collection devices. It runs on a standardized, simplified sample processing (fluid handling and nucleic acid isolation) and amplification/detection workflow, and was designed to provide high performance and adaptable solutions to existing lab workflow, while addressing the critical need for lower cost solutions. The platform is compatible with a sample input capacity up to 1 ml of whole blood, serum, plasma, urine, gynecological and non-gynecological specimens, and offers high throughput, 96-well plate molecular testing in less than four hours run time. At full capacity, the platform can process as many as three 96-well plates (268 samples total) in about eight hours for most of the company’s tests. Using our proven AMPIPROBE[®] technology, Enzo has developed multi-target viral load assays and multi-target DNA-based women’s health assays optimized for the new automated, open system platform, and is currently in the process of developing a screening assay for oncogenic forms of HPV. The platform has current compatibility with more than sixteen (16) Enzo-developed clinical tests in the areas of sexual health (STIs), women’s health, virology, upper respiratory infections, plus others, with a built-in capacity to run new or esoteric laboratory developed tests.

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 solution is the AMPIPROBE[®] platform, which is our 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 the GENFLEX[®] platform it may be possible to increase the number of analytes that can be assayed 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, the GENFLEX[®] platform 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. With several GENFLEX[®] assays already developed and validated, we continue to invest in the development of a consistent pipeline of additional assays.

The FLOWSCRIPT[®] Gene Expression platform is another unique technology translation offering additional alternatives to common molecular assays. We have already introduced the first product using our FLOWSCRIPT[®] platform technology for the identification of gene expression in clinical samples specifically 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 that 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 using a homogeneous system that eliminates washing steps that can reduce fluctuation of results. Additionally, the assay’s use of an 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 using this platform for a multitude of applications such as study of other cancers and the evaluation of an individual’s 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 utilizing our proprietary technology and bringing 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 our strategy of utilizing our integrated structure to produce products that are relevant to today's evolving healthcare marketplace.

Expand platform development to other important, but financially stressed, diagnostic areas

Enzo's POLYVIEW PLUS[®] Enhanced Immunohistochemistry platform offers solutions within the area of Anatomical Pathology through optimized assays for clear, consistent immunohistochemistry and in situ hybridization results moving Pathology to the next generation. This platform has been used in conjunction with validated biomarkers for detecting cancers and their progression especially in the areas of women's health.

Maximize our resources by collaborating with others in therapeutics 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.

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. Products 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.

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 maintains relationships with academic and commercial groups worldwide in sourcing and commercializing high value reagents developed by leading researchers. We have also developed a sales and marketing infrastructure to directly service our 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 is integrated and consolidated as 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, Biomarker Detection, 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 broadly 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 2021, we were issued 20 patents and expanded our patent estate in the area of nucleotides, amplification, labeling 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 Sciences-Clinical Labs structure continues to be instrumental in its ability to seamlessly develop and advance products from innovation and manufacturing in our life sciences group to validation and commercialization through our clinical laboratory.

With the coronavirus pandemic affecting people on a regional and global basis, the Company launched a rapid response to market demand for COVID-19 testing products and services. Enzo is delivering testing and lab services to schools, institutions, urgent care facilities, and core multi-state network of medical practices. Furthermore, the Company's GENFLEX[®] platform received Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) in July 2020 for its proprietary product for the detection of SARS-CoV-2. FDA EUA demonstrates the Company's unique integrated in-house capability in developing low cost, high throughput sensitive detection platforms for COVID-19 as well as other diseases. The Authorization was for a comprehensive platform enabling rapid scalability of testing, including internal use within Enzo's Clinical Lab as well as for the sale of instrumentation, consumables, and reagents to other diagnostic testing customers. The Authorization includes three diverse platforms: Enzo's proprietary GENFLEX[®] automated high-throughput platform, a medium-throughput industry standard platform, and Enzo's manual workflow. Launching a COVID-19 test on its proprietary GENFLEX[™] molecular diagnostics platform serves as representative of the Company's capabilities as it develops other tests on the platform including an upper respiratory panel, STDs and expanded women's health panels. The Company is well positioned to replicate this success in response to new emerging health issues and needs, including, but not limited to, upper respiratory, sexually transmitted diseases, viral load, and women's health.

The Company's development pipeline includes an extensive line of assays for detection of numerous women's health infectious agents, particularly sexual health infections (STIs) 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 products and services are targeted at a market currently estimated to be in excess of \$7 billion annually.

Since 2015 we have had 10 submissions and approvals on lab developed tests (LDTs) from the New York State Department of Health for clinical analysis based on Enzo's proprietary technology platforms, and four Emergency Use Authorizations (EUAs) or EUA expansions by the FDA. The comprehensive program includes 16 analytes and multiple specimen source and collection devices.

We have received approval of AMPIPROBE[®] HCV Assay for the quantitative detection of Hepatitis C and AMPIPROBE[®] HBV Assay for the quantitative detection of Hepatitis B. These assays are based on the proprietary nucleic acid amplification and detection technology platform which 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. We were granted final 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. We were granted final approval for three additional women's health related molecular diagnostic tests for use with the Company's versatile and economic AMPIPROBE[®] platform. Approval was given for a real-time PCR-based method for qualitative detection of *Neisseria gonorrhoea*, *Chlamydia trachomatis* and *Trichomonas vaginalis* in vaginal swab specimens. The Company's AMPIPROBE[®]-based pipeline includes an extensive line of assays for identification of additional women's health infectious diseases as well as for the quantification of viral load in serum or plasma specimens. This proprietary technology platform is the foundation of our ever-increasing line of medically relevant, cost-effective and easily adaptable solutions for clinical laboratories. We were granted conditional approval of another women's health infectious disease diagnostic panel, which when combined with the Company's previously approved panels, makes for one of the most comprehensive, efficient and affordable diagnostic products and services on the market today. A variety of infections, including sexually transmitted ones, are detected from a single vaginal swab collection via the Company's proprietary, versatile and cost-effective AMPIPROBE[®] platform. In July 2019, we announced the New York State Health Department approval for Ampiprobe *Neisseria gonorrhoea* (NG) and *Chlamydia trachomatis* (CT) DNA tests with oral (pharyngeal) and rectal specimens. This expands the Company's menu allowing Enzo to provide one of the most comprehensive panels for STI testing for not only women but also men, who represent a rapidly growing segment for such testing. 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.

On July 20, 2021, we received an expansion of our FDA EUA for the rapid extraction method on our proprietary test system for the detection of coronavirus SARS-CoV-2 including the genetic variants that are now proliferating globally. The EUA enables laboratories to immediately use our faster extraction process to reduce the time by over one hour, or more than 25%, enabling more test runs on a single instrument. The rapid extraction method can be used on platforms including our proprietary GENFLEX[®] automated high-throughput platform, Qiagen's QIASymphony[®] SP lower-throughput platform and our manual workflow. The AMPIPROBE[®] SARS-Cov-2 Test System includes three components: sample collection, AMPIEXTRACT[™] SARS-CoV-2 Extraction Kit for sample processing, and AMPIPROBE[®] SARS-CoV-2 Assay Kit for detection and analysis.

In April 2021, the FDA cleared our AMPICOLLECT[™] Sample Collection kit (manufactured under GMP) for distribution under EUA. The AMPICOLLECT[™] Sample Collection kit is now available for sample collection for COVID-19 testing protocols in the United States. Our sample collection kit has been shown to meet the FDA's policy standard as outlined in "Enforcement Policy for Viral Transport Media during the Coronavirus Disease 2019 (COVID-19) Public Health Emergency." The AMPICOLLECT[™] kit is not only authorized for use with our proprietary GENFLEX[®] molecular diagnostic platform, but can also be used for sample collection with other PCR-based molecular diagnostic platforms or antigen-based testing platforms that require the collection of upper respiratory specimens.

In January 2021, we received an expansion of our EUA from the FDA authorizing the use of pooled samples containing up to five individual swab specimens with our AMPIPROBE® SARS-Cov-2 Test System utilizing tests on three different platforms including our proprietary GENFLEX® automated high-throughput platform.

In November 2020, we began the commercial launch of a small portable microplate reader for use with the company's immunoassays and, ultimately, molecular diagnostics, providing new opportunities in point-of-care medicine. This affordable device enables us to offer a complete solution to academic, CRO, and industrial customers.

In October 2020, we launched GoTestMeNow™, an online platform that enables consumers to directly order physician-authorized laboratory testing. GoTestMeNow™ can be used to access necessary medical tests without the need for a doctor's office visit. Specimen collection and testing is accomplished through a network of patient service centers in the New York/New Jersey metro area. Consumers can obtain results through a secure online portal. The GoTestMeNow™ direct-to-consumer laboratory testing capability will initially support access to COVID-19 molecular and antibody testing, and the platform will be expanded to offer access to a broad range of additional tests in the near future.

In July 2020, we received Emergency Use Authorization (EUA) from the FDA for our proprietary product for the detection of Coronavirus SARS-CoV-2. The EUA enables other laboratories to use this product with three diverse platforms without requiring further validation. These platforms include our proprietary GENFLEX® automated high-throughput platform, Qiagen's QIASymphony® SP lower-throughput platform and Enzo's manual workflow. The AMPIPROBE® SARS-Cov-2 Test System includes three components: sample collection, AMPIXTRACT™ SARS-CoV-2 Extraction Kit for sample processing, and the AMPIPROBE® SARS-CoV-2 Assay Kit for detection and analysis.

In February 2020, we received New York State approval for our CT/NG/TV tests using liquid-based cytology sample collection on our proprietary GENFLEX® platform. GENFLEX® is a commercially available sample-to-result molecular diagnostic platform that includes sample collection, sample processing, amplification and detection. The GENFLEX® open system delivers high-throughput, high capacity, workflow efficiency and flexibility at a much greater level of affordability than existing systems. The platform will provide a cost-effective, comprehensive menu of molecular diagnostic products and services and highlights our continued ability to deliver high performance, open, flexible, adaptable and cost-effective products, devices and services. Compared favorably to all other proprietary platforms dominating the diagnostic testing market, our GENFLEX® platform offers 30-50% cost-savings over current closed systems and addresses the \$450 million annualized global CT/NG/TV diagnostic market as well as the \$1.3 billion Women's health market. Extensions of the GENFLEX® platform, which we are currently developing, could eventually address the entire \$7 billion molecular diagnostic market.

In January 2018, we validated p16, a marker used extensively as a key diagnostic and prognostic biomarker of several cancers. Enzo's validated p16 provides clear detection of tissue abnormalities in the field of cancer diagnostics, including cervical cancer's progression. Additional compounds validated include in-situ HPV probes and antibody markers such as CD138, Ki-67, p53, Vimentin, and prostate cancer markers. P16 complements our POLYVIEW® immunochemistry detection. With current mounting cost and reimbursement pressures, Enzo's new p16 test provides a highly cost-effective alternative. Other p16 tests on the market have of late become unaffordable as a result of increasing reagent costs outweighing average reimbursements. When p16 is used in combination with Enzo's POLYVIEW® detection system's reduction of false-positives, the economics are substantially enhanced. This and other similar compounds comprise a \$200 million market.

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.

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:

| Product/Technology | Expected Availability (1) | Platform |
|--|---------------------------|--|
| HPV high risk AMPIPROBE® REAL-TIME AMPLIFICATION AND DETECTION | Q1 2022 | GENFLEX® Molecular System |
| AMPIVIEW SARS-CoV-2 RNA Probes | Q1 2022 | <i>IN SITU</i> HYBRIDIZATION RNA DETECTION |
| AMPIVIEW HPV High Risk RNA Probes/RNA ISH | Q3 2022 | <i>IN SITU</i> HYBRIDIZATION RNA DETECTION |
| AMPIVIEW HPV 6/11 RNA Probes/RNA ISH | Q3 2022 | <i>IN SITU</i> HYBRIDIZATION RNA DETECTION |
| FLU AB-RSV Resp Panel 1 AMPIPROBE REALTIME AMPLIFICATION AND DETECTION | Q4 2022 | GENFLEX® Molecular System |
| HSV 1&2/VZV AMPIPROBE® REAL-TIME AMPLIFICATION AND DETECTION | Q1 2023 | GENFLEX® Molecular System |
| Group Strep B AMPIPROBE® REAL-TIME AMPLIFICATION AND DETECTION | Q1 2023 | GENFLEX® Molecular System |

(1) Represents the calendar period. There can be no assurances these products can be successfully developed within these timeframes or available on these dates, if at all.

Core Technologies

We have developed a portfolio of proprietary technologies with a variety of research, diagnostic and therapeutic applications.

Gene analysis technology

All gene-based testing is premised on the knowledge that DNA forms a double helix comprised of two complementary strands that match and bind to each other. If a complementary piece of DNA (a probe) is introduced into a sample containing its matching DNA, it will bind to, or hybridize, to form a double helix with that DNA. Gene-based testing is carried out by:

- amplification of the target DNA sequence (a process that is essential for the detection of very small amounts of nucleic acid);
- labeling the probe with a marker that generates a detectable signal upon hybridization;
- addition of the probe to the sample containing the DNA; and
- binding or hybridization of the probe to the target DNA sequence, if present, to generate a detectable signal.

We have developed AMPIPROBE[®] as a broad technology base for the labeling, detection, amplification and analysis of nucleic acids which is supported by our significant proprietary position in these fields. This and other proprietary technologies are the building blocks of our GENFLEX[®] Molecular System and other molecular diagnostics 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 acids, 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 diagnostics that can impart higher sensitivity at a 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 analyze 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 disorder patient monitoring, and other cancers.

Non-Radioactive Labeling and Detection

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

Formats

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

Therapeutic Platform Development

Cell Signaling Pathway

The sphingosine pathway is a cell signaling pathway that has been implicated in tumor cell growth and pathological inflammation. The enzyme Sphingosine kinase 1 is a critical enzyme in this pathway that acts by phosphorylating the cellular lipid Sphingosine to Sphingosine 1-Phosphate (S1P), an important biological mediator of tumor cell proliferation and drug resistance in various cancers, and of immune function. The compound SK1-I is Enzo's proprietary small molecule inhibitor of Sphingosine kinase 1, which the Company is currently developing for the treatment of hepatocellular carcinoma (HCC), the most common form of liver cancer. SK1-I has shown activity against HCC in both *in vitro* cell culture experiments and in an *in vivo* xenotransplantation animal model of human HCC.

The compound SK1-I and related compounds, as well as their use in oncology and other therapeutic areas, are covered by a family of issued U.S. patents co-owned by Enzo and Virginia Commonwealth University (VCU) and exclusively licensed by VCU to Enzo. Foreign patent family members have also issued or been allowed.

Wnt Cell Signaling Pathway

One area of Enzo's therapeutic platform development is related to the development of pharmaceutical agents that affect protein-protein interactions. Over the past several years, our scientists and collaborators have unlocked the secrets of a major cell signaling pathway, thus producing a means to modify biological 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 and 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 synthesized proprietary molecules capable of producing biological effects in cell-based systems and animal models of disease.

Through this work, we have identified both small molecules and peptides capable of reversing sclerostin-mediated inhibition of Wnt signaling. Preclinical animal studies with several of the candidate small molecules 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

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 Crohn's disease.

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 New York, New Jersey and Connecticut medical communities. As part of our ongoing strategic growth plan we have recently expanded service to Connecticut and other New England states. 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. Anatomical 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 esoteric, and molecular diagnostic 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 to 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 services 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 two fully equipped STAT laboratories in New York City and Connecticut. 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 accordingly notified by our customer service personnel.

For fiscal years ended July 31, 2021, 2020 and 2019, respectively, approximately 74%, 65% and 63% of the Company's revenues were derived from the Clinical Laboratory Services segment. Revenues, net of contractual adjustment, from direct billings under the Federal Medicare program during the years ended July 31, 2021, 2020 and 2019 were approximately 15%, 23% and 21%, respectively, of the clinical laboratory services 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 22%, 24% and 36%, respectively, of the Clinical Laboratory Services segment's net revenue for the fiscal year ended July 31, 2021, 2020 and 2019. Revenues from Blue Cross Blue Shield represented approximately 13% of the Clinical Laboratory Services segment's net revenue for the fiscal year ended July 31, 2021.

At July 31, 2021 and 2020, approximately 59% and 68%, respectively, 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 and expanding institutional relationships with direct billing. 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;
- disparity in coverage and information requirements among various payers; and
- differences in medical policies established by various payers.

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 changes to 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 establishes procedures and continuously evaluates and implements changes in the reimbursement process.

Diagnostic Products

We are 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 nearly 45 years of experience, Enzo continues to provide integrated solutions for drug development, pipeline basic research, drug discovery, quality control in drug development and diagnostics. 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 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 assays for our own use and to sell to independent labs. With direct sales operations in the US, Switzerland, Germany, UK, France, and Benelux, Enzo Life Sciences also supports its products through a global network of dedicated distributors.

With a passion for genomics, Enzo was the first to develop products for 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 we produce and supply include small molecules, proteins, antibodies, peptides, probes, immunoassays, biochemical assays 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:

- Bioprocess
- Cancer
- Cell Death/Autophagy
- Cell cycle
- Drug discovery
- Epigenetics
- FISH
- Genomics
- HPV
- ImmunoHistochemistry
- Viral signaling and detection
- Immunology/Inflammation/Innate Immunity
- Metabolism
- Pathology
- *In situ* Hybridization
- Microarray Labeling
- Neuroscience
- Oxidative Stress
- Proteostasis
- Signal Transduction
- Stem Cell
- Stress Proteins
- Toxicology

We maintain the technology and products from 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 histories. 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 100,000 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 sciences field as a result of over 40 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, 2021, 2020 and 2019, the Company incurred costs of approximately \$3.3 million, \$4.4 million and \$3.2 million, respectively, for research and development activities. Starting in fiscal 2018, the Company's research and development program was refocused to areas that had greater opportunity in molecular diagnostics and immunology chemistry 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, immunology, flow cytometry 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 is to sell our life sciences 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 Clinical Laboratory Services, we focus our sales efforts on obtaining and retaining profitable accounts. We market these services to a broad range of ordering physicians in the metro New York, New Jersey and Connecticut regions through our direct sales force who are supported by client 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 technologies, 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.

Recently issued patents

In February 2021, we were issued U.S. Patent No. 10,899,827 entitled “Antibodies Specific for Sulfation Sites of Sclerostin.” The new patent is a member of a broader U.S. and international patent family that also includes issued patents and pending patent applications for therapies including monoclonal antibodies and small synthetic peptides used to inhibit sclerostin in the treatment of bone disorders such as osteoporosis. This patent focuses on polyclonal antibodies that bind a specific region of human sclerostin, a protein that is a negative regulator of bone growth. Sclerostin is produced in osteocytes, a type of bone cell, and is known to inhibit bone formation. The maintenance of bone over time requires a balance between the formation of new bone tissue and the breakdown and removal (resorption) of old bone tissue.

In June 2020, we announced the issuance of a patent entitled Sphingosine Pathway Modulating Compounds for the Treatment of Cancers. This patent is directed to methods for treating hepatocellular carcinoma (HCC), the most common human liver cancer, using our proprietary compound SK1-I.

In May 2020, we announced the issuance of a U.S. Patent entitled Sulfonated Sclerostin, Antibodies, Epitopes and Methods for Identification and Use Therefor. The patent is directed to methods for producing monoclonal antibodies against specific regions of human Sclerostin, a protein that is a negative regulator of bone growth. Inhibition of Sclerostin using monoclonal antibodies can be used to promote bone growth for the treatment of osteoporosis. This patent is a member of a broader U.S. and international patent family that includes issued patents and pending patent applications directed to antibodies and their use in inhibiting Sclerostin as well as small synthetic peptides and their use in inhibiting Sclerostin in the treatment of bone disorders such as osteoporosis. In April 2020, we announced the issuance of a U.S. patent entitled Sphingosine Kinase Type 1 Inhibitors and Uses Thereof. This patent is directed to methods for inhibiting the enzyme Sphingosine kinase 1 in patients using the company's proprietary compound SK1-I and related Sphingosine kinase 1 inhibitors. Based on the results obtained in the lupus model and prior work demonstrating the anti-inflammatory activity of SK1-I in animal models of other immune disorders and on isolated human blood cells, the company is exploring avenues for the development of SK1-I as a potential treatment for COVID-19.

In August 2019, we announced the issuance of a U.S. patent entitled Nucleic Acid Probes for In Situ Hybridization. This patent is related to a new probe technology developed by Enzo and transformative methods of testing using the probes, which allow for significantly more cost effective, simple and scalable processes. These new probes can be used to detect clinically relevant genomic targets with high-sensitivity in cell samples and biopsy tissue obtained from patients.

At the end of fiscal 2021, we owned or licensed 472 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 Services

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, and/or decrease the amount of reimbursement. Our clinical laboratory and where applicable patient service centers (PSCs) are licensed and accredited as required by law.

CLIA (the Clinical Laboratory Improvement Amendments of 1988 and its implementing regulations) regulates virtually all clinical laboratories in the United States. Among other things, CLIA requires non-exempt clinical 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 pre-empt state laws that are more stringent than federal laws. As such, certain clinical laboratories must also meet state specific standards, including inspection, proficiency testing, and personnel requirements. Clinical laboratory certificates, permits, or licenses are also required by various state and local laws, including certain jurisdictions that require an out-of-state clinical laboratory to obtain a license/permit if they accept specimens from the state. Enzo has obtained licenses or permits in the states of New York, New Jersey, California, Pennsylvania, Maryland, and Rhode Island. Enzo also operates a clinical laboratory in the state of Connecticut.

CLIA assigns testing services 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 tests performed. A laboratory that performs high complexity testing must meet more stringent requirements than a laboratory that performs only moderate complexity testing, while those that perform only waived testing may apply for a certificate of waiver that if granted, would exempt the laboratory from most CLIA requirements. Our laboratory in Farmingdale, NY is certified to perform high complexity testing. In general, regulations promulgated by the United States Department of Health and Human Services (“HHS”) require clinical laboratories that perform high or moderate complexity testing 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 an exemption from CLIA. Therefore, as long as New York maintains a licensure program that is CLIA-exempt, laboratories in New York may comply with CLIA requirements by establishing that they meet requirements for clinical laboratories under New York law. Enzo’s two New York laboratories are licensed in New York State and have ongoing programs that ensure that their operations are in compliance with all applicable regulatory requirements, including the requirement to obtain approval to perform certain analyte-specific testing or other methodologies which are not reviewed by FDA as laboratory-developed tests (LDTs).

Sanctions for non-compliance with applicable regulations may include, but are not limited to, suspension, revocation, or limitation of a laboratory’s CLIA certificate and/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 are 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 insurers 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 so 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. In general, 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 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 services 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 are paid based upon the volume-weighted median of private payer rates as reported by certain clinical laboratories across the US, replacing the previous system which was based upon fee schedules derived from historical charges for tests from the mid 1980's.

Since Enzo's clinical laboratory receives more than 50% of its total Medicare revenue from the Part B Clinical Laboratory Fee Schedule (CLFS) and the Physician Fee Schedule and receives more than \$12,500 in Medicare CLFS revenues per year, we are considered an "applicable laboratory", and as such, are required to report private payer rate information to CMS. Enzo initially reported data from the first two quarters of Calendar Year (CY) 2016 during Q1 2017, and this information was used (along with data from other relevant laboratories) to calculate Medicare reimbursement rates for CY 2018-2022. The current reporting cycle requires us to report private payer rates for fee reimbursements for the period January 1, 2019 to June 30, 2019 to CMS during Q1 2022. This combined data (and data from other laboratories) will be aggregated and utilized again as the basis for the 2023-2025 Medicare CLFS that is expected to be finalized in November 2022.

Future changes in federal, state and local regulations (or in the interpretation of current regulations) affecting governmental reimbursement for clinical laboratory testing may 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, (1) reimbursement denials by third party payers, commercial insurers and health maintenance organizations, (2) reductions or delays in the establishment of reimbursement rates, (3) carrier limitations on the insurance coverage of the Company's services and (4) the use of the Company as a service provider may have a negative effect on the Company's future revenues. During our fiscal 2016 and 2017, Medicare reimbursement rates remained constant with 2015 levels. However, PAMA-based cuts in Medicare reimbursement for certain services impacted fiscal 2018 results beginning in January 2018. PAMA cuts were implemented in calendar year 2019 for certain services, which also impacted our financial results for our fiscal 2020 and 2019. Additional cuts were mandated in calendar year 2020 and negatively impacted our fiscal 2021 results. The impact of subsequent adjustments to Medicare rates are unclear at this time.

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 federal "Anti-Kickback Statute," contains broad prohibitions against knowingly and willfully offering, paying, soliciting (i.e., asking for) or receiving remuneration (i.e., anything of value) in any form (e.g., cash, gifts, certain discounts, cross-referrals between parties, etc.), either directly or indirectly, to induce or in return for the referral of an individual for the furnishing of or arranging for the furnishing of any item or service for which payment may be made in whole or in part by a federal health care program. or the purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering of any good, facility, item or service for which payment may be made in whole or in part by a federal health care program.

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.

Federal substance abuse legislation enacted in October 2018 (Eliminating Kickbacks in Recovery Act of 2018 or EKRA) contains an all-payer anti-kickback provision that is, by its terms, applicable to laboratories. We are attempting to clarify the application of that legislation.

The federal 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 federal 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 federal False Claims Act violation. These private parties (known as “qui tam relators”) may share in a percentage of the proceeds that result from a federal False Claims Act action or settlement. A person or entity found to have violated the federal False Claims Act may be held liable for a per claim civil penalty. For penalties assessed after June 19, 2020, whose associated violations occurred after November 2, 2015, the penalties range from \$11,665 to \$23,331 for each false claim, plus three times the amount of damages sustained by the government. The minimum and maximum per claim penalty amounts are subject to annual increases for inflation. A person violating the federal 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 federal False Claims Act or similar state laws. For example, 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 (or whose immediate family member has) a financial relationship with an entity that furnishes Medicare-covered “designated health services,” which includes clinical laboratory services (including anatomic pathology and clinical chemistry services), from referring Medicare beneficiaries to that entity for “designated health services” unless a specific exception applies.

In addition, laboratories may not bill federal health care programs, or any other payer, 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. The Stark law also prohibits state receipt of federal Medicaid matching funds for services furnished pursuant to a prohibited referral. This provision of the Stark law has not been implemented by regulations, but some courts have held that the submission of claims to Medicaid that would be prohibited as self-referrals under the Stark law for Medicare could implicate the federal False Claims Act. Many states, including New York have adopted laws that are similar to the federal Stark law, which contain similar prohibitions and penalties and apply regardless of payer.

Various federal and state laws, including the Stark law and New York State laws, may also apply in ways that impose restrictions on the supplies and other items that laboratories may provide to their clients without charge. For example, in the case of the Stark law, laboratories may provide clients with items, devices or supplies that are used solely to collect, transport or store specimens for the laboratory or to communicate results or tests without implicating the law, but not surgical items, devices or supplies.. The Company has implemented procedures to ensure compliance with these laws and restrictions.

In 1997, the Department of Health and Human Services, Office of the Inspector General (OIG) released a model compliance plan for the clinical laboratory industry and in 1998 released a voluntary compliance program guidance for laboratories. One key aspect of the OIG guidance was an emphasis on the responsibility of laboratories to notify physicians that Medicare covers only medically necessary services. The OIG guidance on notices 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, the notice could potentially affect physicians’ test ordering habits more broadly. The Company is unable to predict whether, or to what extent, notices 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.

Standards for Electronic Healthcare Transactions and Privacy, Security and Breach Notification Requirements

The Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH Act") (together, "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. HIPAA's implementing regulations set forth standards for conducting certain electronic transactions, as well as privacy, security and breach notification requirements applicable to certain health information. As part of its standards for electronic transactions, HIPAA requires the use of 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 that engage in certain standard electronic transactions, which may include physicians and clinical. Such health care providers, together with health plans and health care clearinghouses are subject to HIPAA as "Covered Entities". HIPAA also applies to the "Business Associates" of Covered Entities, which are generally individuals or entities that create, receive, maintain, transmit, use, or disclose protected health information in performing certain functions or services for or on behalf of 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 requirements 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. However, to the extent the Company engages in electronic standards that do not comply with applicable standards under HIPAA, payments to the Company may be delayed or denied.

Adhering to the privacy, security and breach notification requirements under HIPAA requires an extensive compliance infrastructure. We are required to maintain numerous policies and procedures in order to comply with these requirements. Furthermore, we need to continuously ensure that there are mechanisms 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. In addition, to comply with the HIPAA security regulations in particular, we must ensure the confidentiality, integrity and availability of all electronic PHI ("E PHI") that we create, receive, maintain, or transmit. We have some flexibility to fashion our own security measures to accomplish these goals. The security regulations strongly emphasize that we must periodically conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity and availability of our E PHI and then document our response to the various security regulations on the basis of that assessment.

The privacy, security and breach notification regulations under HIPAA were last modified in 2013 as a result of final regulations published pursuant to the HITECH Act (“Omnibus Rule”). The HITECH Act requires, among other things, that Covered Entity health care providers, which may include laboratories, notify patients of breaches of unsecured PHI, enter into business associate agreements with their business associates that meet certain requirements, and take other steps to comply with the privacy, security, and breach notification requirements of the HITECH Act, which include making necessary revisions to many of their existing privacy policies and procedures. In addition, the HITECH Act makes Business Associates directly liable to the Federal government for compliance with certain aspects of the privacy, security and breach notification regulations. In addition, as implemented in the Omnibus Rule, 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.

Covered Entities and Business Associates are subject to potentially significant civil and criminal penalties for violating HIPAA. Under the Omnibus Rule, health care providers, such as laboratories, that are subject to HIPAA as a Covered Entity are also 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.

We may also be subject to state laws that are not pre-empted by HIPAA to the extent the state law is more stringent than HIPAA, provides individuals with greater rights with respect to their protected health information, or are broader in scope than HIPAA. Every U.S. state has also enacted its own breach notification law that requires regulated entities to report certain data breaches to affected individuals, state regulators, and other parties. Failure to comply with applicable state privacy, security or breach notification laws may result in civil or criminal liability, private causes of action by individuals, administrative actions brought by state regulators, or other consequences that may adversely impact our business or reputation.

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

In February 2020, the HHS Secretary determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. On the basis of this determination, the Secretary then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19.

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 undergo premarket review (and receive “510(k) clearance”, *de novo* 510(k) authorization, or pre-market approval (“PMA”) from the FDA, as may be applicable) before they can be marketed in the United States. The FDA’s premarket review processes may be costly and time consuming, but the process of obtaining PMA approval is typically the most costly, lengthy and uncertain, followed by the *de novo* 510(k) process, and then the 510(k) process. Regardless of the premarket review pathway that applies to a particular product, we cannot be sure that we will successfully complete the FDA premarket review process for any product we propose to market.

The FDA decides the premarket review process that applies to a particular device 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 a “pre-amendment” class III device (i.e., one that was legally in commercial distribution before May 1976) for which the FDA has not yet called for submission of a PMA application, or a device which has been reclassified from Class III to Class II or I, a device which has been found substantially equivalent through the 510(k) process, or a device that was granted marketing authorization via the *de novo* classification process that is not exempt from premarket notification requirement.

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 *de novo* 510(k) authorization or PMA approval (as applicable). The FDA requires each manufacturer to make the determination regarding whether a modification triggers the requirement for a new submission in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer’s decision not to seek premarket review for the modified device, the agency may retroactively require the manufacturer to do so. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until the premarket review process has been successfully completed.

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 many 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 by design or intention introduce energy into the subject, and is not used as a diagnostic procedure without confirmation by another medically established test or procedure.

Notwithstanding the above, certain IVD products can be marketed without going through the premarket review process if they are intended 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 that would otherwise apply to medical devices, it is important that they are not distributed for clinical diagnostic 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 without FDA clearance, authorization or approval in a 2013 final guidance document.

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, our failure 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. In recent years, however, the FDA has indicated that it intends to end enforcement discretion and regulate certain LDTs as medical devices. In October 2014, the FDA officially a draft guidance document that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. The FDA has indicated that it does not intend to modify its policy of enforcement discretion until the draft guidance documents are finalized. Subsequently, in January 2017, the FDA published a “discussion paper” in which the agency outlined a substantially revised “possible approach” to the oversight of LDTs. The discussion paper explicitly states that it is not a final version of the 2014 draft guidance and that it does not represent the agency’s “formal position;” rather, the discussion paper describes the evolution of the agency’s thinking on LDTs, which the agency posted to “spur further dialogue.” Notably, in the discussion paper, the agency expressed its willingness to consider “grandfathering” currently marketed LDTs from most or all FDA regulatory requirements. It is unclear at this time when, or if, the FDA will finalize its plans to end enforcement discretion, and even then, the new regulatory requirements are expected to be phased-in over time. Nevertheless, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time.

Legislative proposals addressing the FDA’s oversight of LDTs have been introduced in previous Congresses, and we expect that new legislative proposals will be introduced from time to time. The likelihood that Congress will pass such legislation and the extent to which such legislation may affect the FDA’s plans to regulate certain LDTs as medical devices is difficult to predict at this time.

In so far as the products that we manufacture or distribute are subject to regulation as medical devices, a host of additional regulatory requirements may apply beyond premarket review requirements, including establishment registration, device 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 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, authorizations, and approvals, as well as 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 therapeutic 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) would file an 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), typically 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. 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. 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.

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, unless shown to be clinically superior. Certain expedited pathways may be available and would 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.

After completion of clinical trials of an investigational 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 10 months and 6 months for priority review. 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, recordkeeping 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.

Manufacturing and Research Facilities

Our integrated laboratory and scientific efforts for our three segments currently take place primarily at three adjacent facilities in Farmingdale, New York. A major part of one facility is utilized by Life Science products 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 centered its US logistics, reagent and kit manufacturing at its facility in Ann Arbor, Michigan, and has European logistics operations in Lausen, Switzerland. We began renovation of an acquired facility in Farmingdale, NY which is adjacent to the other two starting in July 2020. This facility is being used for manufacturing operations and some administrative functions. Effective September 30, 2021 we exited the Ann Arbor, Michigan facility and brought its manufacturing operations to Farmingdale, NY in order to consolidate our United States operations into one geographic location. 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, 2021, we employed 451 full-time and 63 part-time employees. Of the full-time employees, 132 were engaged in research, development, manufacturing, and marketing of research products, 270 in performing testing, marketing and billing our clinical laboratories services and 49 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 services 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 Pathologists (“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 CAP accredited.

FORWARD - LOOKING AND CAUTIONARY STATEMENTS

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

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

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

Enzo Biochem, Inc.
527 Madison Ave.
New York, New York 10022
Tel: (212) 583-0100
Attn: Investor Relations

Item 1A. Risk Factors

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:

- The continued impact on our operations from the COVID-19 pandemic depending on its severity and duration, competition from larger commercial clinical laboratories, hospital affiliated laboratories, and physician office laboratories;
- health care reform regulations affecting providers and plan sponsors, including those stemming from the Affordable Care Act of 2010 (ACA) or its repeal, amendment or replacement;
- changes in reimbursement policies by third party and government payers, especially those stemming from The Protecting Access to Medicare Act of 2014 (“PAMA”);
- customer demand for our products due to changes in purchasing requirements and research needs;
- the introduction of new products by us or our competitors;
- the timing of our research and development, sales and marketing expenses;
- general worldwide economic conditions affecting funding of research;
- seasonal fluctuations in revenues due to the impact of weather and holiday periods
- expenses associated with defending our intellectual property portfolio
- foreign currency exchange rate fluctuations;
- changes in tax laws, the results of tax audits or the measurement of tax uncertainties; and
- the success of identifying, acquiring and integrating businesses that complement our product offerings, add new technology or add presence in a market;

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

The COVID-19 pandemic significantly and adversely affected our consolidated results of operations, financial position and cash flows during fiscal 2020. Though our operations recovered in fiscal 2021, the pandemic may adversely affect future operations depending on the severity and duration of the pandemic, its impact on the U.S. healthcare system and the timing, scope and effectiveness of federal, state and local governmental responses to the pandemic.

The novel strain of coronavirus (“COVID-19”) and its variants continue to spread and impact the economy of the United States and other countries around the world. The Company has made substantial investments to expand the amount of COVID-19 testing available and is currently offering direct testing at its drive-through testing facilities as well as accepting tests for processing at its clinical laboratory. The Company and its employees are committed to being a part of the coordinated public and private sector response to this unprecedented challenge. The Company also put preparedness plans in place at its facilities to maintain continuity of operations, while also taking steps to keep colleagues and customers healthy and safe.

While the rate of transmission of COVID-19 fluctuates in the US and Europe, it continues to spread in other parts of the world and negatively impact the world economy. Federal, state and local governmental policies and initiatives designed to reduce the transmission of COVID-19 have resulted in, among other things, a significant reduction in physician office visits, the cancellation of elective medical procedures, customers of our products remaining closed or continuing to severely curtail their operations (voluntarily or in response to government orders), and the continuation of work-from-home or shelter-in-place policies. The COVID-19 impact on the Company's operations is consistent with the overall industry and publicly issued statements from competitors, partners, and vendors.

During the fiscal years ended July 31, 2021 and 2020, COVID-19 testing revenues represented 48% and 8%, respectively of Clinical Services revenues. Enzo applied its technical expertise in molecular diagnostics to develop next generation COVID-19 diagnostic and antibody testing options which were approved under the FDA Emergency Use Authorization (EUA). This testing had a positive impact on revenue, profitability and cash flow throughout fiscal 2021. However, it is too early to determine the long term significance of any positive impact from increased COVID-19 testing and our proprietary COVID-19 product offerings on our businesses.

The extent to which our businesses may continue to be affected by the COVID-19 pandemic will largely depend on both current and future developments, including its duration, the emergence and spread of variants, its treatment with authorized vaccines and vaccines in various stages of development and federal approval, work and travel advisories and restrictions, and the timing of their easing, all of which are highly uncertain and cannot be reasonably predicted at this time. Global supply chain issues due to the pandemic continue to hamper both the manufacturing of products within the life science segment as well as testing capabilities in the clinical laboratory.

The extent to which the COVID-19 pandemic impacts the Company's business and consolidated results of operations, financial position and cash flows will depend on numerous evolving factors including, but not limited to: the magnitude and duration of the COVID-19 pandemic, the extent to which it will impact worldwide macroeconomic conditions including, but not limited to, employment rates and health insurance coverage, the speed of the anticipated recovery, and governmental and business reactions to the pandemic. These factors are beyond the Company's knowledge and control, and as a result, at this time the Company cannot reasonably estimate the adverse impact the COVID-19 pandemic will have on its businesses but the adverse impact could be material. The Company assessed certain accounting matters that generally require consideration of forecasted financial information in context with the information reasonably available to the Company and the unknown future impacts of COVID-19 as of July 31, 2021 and through the date of this report. The accounting matters assessed included, but were not limited to, the Company's patient self-pay revenue concessions and credit losses in the Clinical Services segment, accounts receivable, inventories and the carrying value of goodwill and other long-lived assets. The Company's future assessment of the magnitude and duration of COVID-19, as well as other factors, could result in additional material impacts to the Company's consolidated financial statements in future reporting periods. We expect COVID-19 volume to decline in the quarters ahead as the percentage of Americans who are vaccinated increases. However, the emergence and spread of variants may cause our COVID-19 testing volume to increase again.

Even after the COVID-19 pandemic has moderated and the business and social distancing restrictions have eased, we may continue to experience similar adverse effects to our businesses, consolidated results of operations, financial position and cash flows resulting from a recessionary economic environment that may persist. The impact that the COVID-19 pandemic will have on our businesses, consolidated results of operations, financial position and cash flows could exacerbate the additional risks identified below.

A significant proportion of our Products revenues are from 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 Products revenues are from 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 product 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 services 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.

We manufacture and distribute 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.

We rely on network and information systems and other technology whose failure or misuse could cause a disruption of services or loss or improper disclosure of personal data, business information, including intellectual property, or other confidential information, resulting in increased costs, loss of revenue or other harm to our business.

Network and information systems and other technologies, including those related to the Company's network management, are important to its business activities. The Company also relies on third party providers for certain technology and "cloud-based" systems and services that support a variety of business operations. Network and information systems-related events affecting the Company's systems, or those of third parties upon which the Company's business relies, such as computer compromises, cyber threats and attacks, computer viruses, worms or other destructive or disruptive software, process breakdowns, denial of service attacks, malicious social engineering or other malicious activities, or any combination of the foregoing, as well as power outages, equipment failure, natural disasters (including extreme weather), terrorist activities, war, human or technological error or malfeasance that may affect such systems, could result in disruption of the Company's business and/or loss, corruption or improper disclosure of personal data, business information, including intellectual property, or other confidential information. In addition, any design or manufacturing defects in, or the improper implementation of, hardware or software applications the Company develops or procures from third parties could unexpectedly compromise information security. In recent years, there has been a rise in the number of cyber-attacks on companies' network and information systems, and such attacks have become more sophisticated, targeted and difficult to detect and prevent against. As a result, the risks associated with such an event continue to increase, particularly as the Company's digital businesses expand. While the Company has developed and implemented security measures and internal controls that are designed to protect personal data, business information, including intellectual property, and other confidential information, to prevent data loss, and to prevent or detect security breaches, such security measures cannot provide absolute security and may not be successful in preventing these events from occurring, particularly given that techniques used to access, disable or degrade service, or sabotage systems change frequently, and any network and information systems-related events could require the Company to expend significant resources to remedy such event. Moreover, the development and maintenance of these measures is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become more sophisticated. While the Company maintains cyber risk insurance, this insurance may not be sufficient to cover all losses from any future breaches of our systems.

A significant failure, compromise, breach or interruption of the Company's systems, or those of third parties upon which its business relies, could result in a disruption of its operations, customer, audience or advertiser dissatisfaction, damage to its reputation or brands, regulatory investigations and enforcement actions, lawsuits, remediation costs, a loss of customers, advertisers or revenues and other financial losses. If any such failure, interruption or similar event results in the improper disclosure of information maintained in the Company's information systems and networks or those of its vendors, including financial, personal, credit card, confidential and proprietary information relating to personnel, customers, vendors and the Company's business, including its intellectual property, the Company could also be subject to liability under relevant contractual obligations and laws and regulations protecting personal data and privacy. In addition, media or other reports of perceived security vulnerabilities to our systems or those of third parties upon which the Company's business relies, even if nothing has actually been attempted or occurred, could also adversely impact our brand and reputation and materially affect 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. Changes in the way the FDA regulates the reagents, and other consumables we use when developing, validating, and performing our tests could result in delay or additional expense in bringing our tests to market or performing such tests for our customers. 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. The FDA has regulatory responsibility over, among other areas, instruments, software, test kits, reagents and other devices used by clinical laboratories to perform diagnostic testing in the U.S. The tests we develop internally are offered as lab developed tests or LDTs. The FDA has claimed regulatory authority over all LDTs, but has stated that it exercised enforcement discretion with regard to most LDTs performed by high complexity CLIA-certified laboratories. As the FDA moves to regulate more clinical laboratory testing, its approach to regulation is impacting industry practices and participants, new competitors may enter the industry, and competition may come in new forms. In late 2018, legislation was introduced in Congress that would enable the FDA to regulate LDTs, in vitro diagnostics, software and other items used in the diagnosis of disease. If this legislation were to become law, the FDA could regulate diagnostic tests and components and platforms used as part of these tests. If such legislation were to become law, it could have a significant impact on the clinical laboratory testing industry, including regulating LDTs in new ways and creating avenues of opportunity and competition regarding clinical laboratory testing. New competitors may enter the industry, and competition may come in new forms. Pursuant to the 21st Century Cures Act, the FDA issued guidance regarding its position on the regulation of clinical decision software, which may be used in, or in connection with, LDTs. The guidance attempts to clarify whether FDA approval of certain software is required. In January 2019 the FDA issued draft guidance on a pre-certification pilot program to help software developers have a speedier and less restrictive path to clearance or approval of their software.

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 fiscal years 2021 and 2019, 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 years 2021 and 2019, when we reported net income of \$7.9 million and \$2.5 million, respectively, we incurred net losses of \$28.5 million, \$11.4 million, and \$2.5 million for the fiscal years ended July 31, 2020, 2018 and 2017 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 our products business with higher margin products and increase our market share and continue to grow the Laboratory Services business with new tests with higher reimbursements and increase our service volume which may require significant additional capital that may not be available to us. We may need additional financing due to future developments, changes in our business plan or failure of our current business plan to succeed, which could result from increased marketing, distribution or research and development costs. Our actual funding requirements could vary materially from our current estimates. If additional financing is needed, we may not be able to raise sufficient funds on favorable terms or at all. If we issue common stock or securities convertible into common stock in the future, such issuance will result in the then-existing stockholders sustaining dilution to their relative proportion of our outstanding equity. If we fail to obtain any necessary financing on a timely basis, then our ability to execute our current business plan may be limited, and our business, liquidity and financial condition could be harmed.

Our outstanding debt may impair our financial and operating flexibility and a failure to satisfy the covenants under agreements governing our outstanding debt could limit the availability of borrowings or result in an event of default under such agreements.

The Company had \$13.5 million in cash, cash equivalents and restricted cash and \$30.0 million in short term investments in bond funds on its balance sheet as of July 31, 2021. Also as of that date, we had approximately \$3.4 million of short term debt and \$18.9 million in long term debt. The short term debt is primarily related to operating leases. The long term debt is primarily related to operating leases and a ten-year mortgage obligation of approximately \$4.1 million with Citibank, N.A., which bears a fixed interest rate of 5.09% per annum and contains various restrictive covenants. These restrictions could limit our ability to use operating cash flow in other areas of our business because we must use a portion of these funds to make principal and interest payments on our debt. Our ability to comply with the restrictive financial ratio and liquidity covenants in the mortgage debt agreement will depend upon our future performance and various other factors, including but not limited to the impact on our business, consolidated results of operations, financial condition and cash flows associated with the COVID-19 pandemic, any prolonged recessionary economic environment that may develop and competitive and regulatory factors, many of which are beyond our control. We may not be able to maintain compliance with all of the covenants. In that event, we may not be able to find and access any other borrowing availability and we may need to seek waivers to the covenants or amendments to the mortgage agreement or would need to refinance the mortgage. There can be no assurance that we can obtain additional waivers of our mortgage agreement covenants, or be able to refinance it, and, even if we were able to obtain a waiver or additional amendment in the future, such relief may only last for a limited period. Any noncompliance by us with the covenants under our mortgage agreement could result in an event of default under the agreement, which may allow the lender to accelerate payment of the mortgage. In the event our creditor accelerates the repayment of our mortgage, we cannot assure that we would have sufficient assets to make such repayment.

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. Intangible assets with finite lives are assessed for impairment when, and if, an indicator of potential impairment is identified.

As of July 31, 2021 and 2020, goodwill and finite lived intangible assets represented approximately 7% 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 Laboratory Services segment

The clinical testing business is highly competitive, and if we fail to provide an appropriately priced level of service or otherwise fail to compete effectively it could have a material adverse effect on our revenues and profitability.

The clinical testing business is a fragmented and highly competitive industry. We primarily compete with three types of clinical testing providers: other commercial clinical laboratories, hospital-affiliated laboratories and physician-office laboratories. We also compete with other providers, including anatomic pathology practices and large physician group practices. Hospitals generally maintain on-site laboratories to perform testing on their patients (inpatient or outpatient). In addition, many hospitals compete with commercial clinical laboratories for outreach (non-hospital patients) testing. Hospitals may seek to leverage their relationships with community clinicians and encourage the clinicians to send their outreach testing to the hospital's laboratory. As a result of this affiliation between hospitals and community clinicians, we compete against hospital-affiliated laboratories primarily based on quality and scope of service as well as pricing. In addition, hospitals that own physician practices may require the practices to refer testing to the hospital's laboratory. In recent years, there has been a trend of hospitals acquiring physician practices, increasing the percentage of physician practices owned by hospitals. Increased hospital ownership of physician practices may enhance clinician ties to hospital-affiliated laboratories and may strengthen their competitive position. The diagnostic information services industry also is faced with changing technology and new product introductions. Competitors may compete using advanced technology, including technology that enables more convenient or cost-effective testing. Competitors also may compete on the basis of new service offerings. Competitors also may offer testing to be performed outside of a commercial clinical laboratory, such as (1) point-of-care testing that can be performed by physicians in their offices; (2) advanced testing that can be performed by hospitals in their own laboratories; and (3) home testing that can be carried out without requiring the services of outside providers.

Our clinical laboratory services 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.

Reimbursements from third-party payers including managed care organizations and Medicare, upon which our clinical laboratory business is dependent, are subject to varying rates and coverage and legislative reform that are beyond our control. Any reforms that decrease coverage and rates could reduce our earnings and harm our business.

Our clinical laboratory services 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 the areas of clinical and 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.

Government payers, such as Medicare and Medicaid, have taken steps to reduce the utilization and reimbursement of healthcare services, including clinical testing services. U.S. healthcare reform legislation may result in significant change and our business could be adversely impacted if we fail to adapt.

We face efforts by government payers to reduce utilization of and reimbursement for diagnostic information services. We expect efforts to reduce reimbursements, to impose more stringent cost controls and to reduce utilization of clinical test services will continue. Pursuant to The Protecting Access to Medicare Act of 2014 (PAMA), which was implemented in 2018, the Centers for Medicare and Medicaid Services (CMS) promulgated revised reimbursement rate schedules for the years 2018 through 2020 for clinical laboratory testing services provided under Medicare. Reimbursement rates for clinical laboratory testing were reduced in 2018 and 2019 and were reduced again by approximately 10% in 2020. PAMA calls for further revision of the Medicare Clinical Laboratory Fee Schedule (CLFS) for years after 2021, based on future surveys of private payer market rates; reimbursement rate reduction from 2021-23 is capped by PAMA at 15% annually. The CARES Act provided a one year delay of a reimbursement rate reduction of 15% for clinical laboratory services provided under Medicare that was scheduled to start January 1, 2021.

Private health plans and other third parties have taken steps to reduce the utilization and reimbursement of health services, including clinical testing services.

We face efforts by non-governmental third-party payers, including health plans, to reduce utilization of and reimbursement for clinical testing services. Examples include increased use of prior authorization requirements and increased denial of coverage for services. Since the passage of ACA, there is increased market activity regarding alternative payment models, including bundled payment models. We expect continuing efforts by third-party payers, including in their rules, practices and policies, to reduce reimbursements, to impose more stringent cost controls and to reduce utilization of clinical testing services. The healthcare industry has experienced a trend of consolidation among health insurance plans, resulting in fewer but larger insurance plans with significant bargaining power to negotiate fee arrangements with healthcare providers, including clinical testing providers. These health plans, and independent physician associations, may demand that clinical testing providers accept discounted fee structures or assume all or a portion of the financial risk associated with providing testing services to their members through capitated payment arrangements. Some health plans also are reviewing test coding, evaluating coverage decisions and requiring preauthorization of certain testing. There are also an increasing number of patients enrolling in consumer driven products and high deductible plans that involve greater patient cost-sharing. The increased consolidation among health plans also has increased pricing transparency and bargaining power and the potential adverse impact of ceasing to be a contracted provider with any such insurer.

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 visits to our customer physician locations and the complexity and expense of the billing process in our clinical laboratory services 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 operating results 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 CLIA amendments 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.

Our business operations and reputation may be materially impaired if we do not comply with privacy laws or information security policies.

In our business, we collect, generate, process or maintain sensitive information, such as patient data and other personal information. If we do use or not adequately safeguard that information in compliance with applicable requirements under federal, state and international laws, or if it were disclosed to persons or entities that should not have access to it, our business could be materially impaired, our reputation could suffer and we could be subject to fines, penalties and litigation. In the event of a data security breach, we may be subject to notification obligations, litigation and governmental investigation or sanctions, and may suffer reputational damage, which could have an adverse impact on our business. We are subject to laws and regulations regarding protecting the security and privacy of certain healthcare and personal information, including: (a) the federal Health Insurance Portability and Accountability Act (HIPPA) and the regulations thereunder, which establish (i) a complex regulatory framework including requirements for safeguarding protected health information and (ii) comprehensive federal standards regarding the uses and disclosures of protected health information; (b) state laws; and (c) the European Union's General Data Protection Regulation.

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, among other areas, instruments, test kits, reagents and other devices used by clinical laboratories to perform diagnostic testing in the U.S. A number of tests we develop internally are offered as lab developed tests (LDTs). The FDA has claimed regulatory authority over all LDTs, but has stated that it exercised enforcement discretion with regard to most LDTs performed by high complexity CLIA-certified laboratories. The FDA has published a "Discussion Document" that provides the FDA's views on legislation to govern LDTs. New legislation could significantly impact the clinical laboratory testing business, including by increasing or modifying the regulation of LDTs, hindering our ability to develop and market new services, causing an increase in the cost of our services, delaying our ability to introduce new tests or hindering our ability to perform testing.

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:

- federal anti-kickback laws, which constrain 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;
- 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 manufacturing, inventory, distribution and website and the clinical laboratory services 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 laboratory 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 we will be able to continue to obtain adequate coverage, we cannot assure that we will be able to do so at acceptable costs.

Risks relating to our international operations

Foreign currency exchange rate fluctuations may adversely affect our business.

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

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

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

We operate internationally primarily through wholly-owned subsidiaries located in North America and Europe. Revenues outside the United States were approximately 16% of total revenues in fiscal 2020. Our sales and earnings could be adversely affected by a variety of factors resulting from our international operations, including

- future fluctuations in foreign currency 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, including the potential impact Brexit will have on our UK operations;
- 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.

With our commercialization activities outside of the United States, we are subject to the 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.

Our failure to establish and maintain effective internal controls over financial reporting and information technology access could result in material misstatements in our consolidated financial statements, our failure to meet our reporting obligations and cause investors to lose confidence in our reported financial information, which in turn could cause the trading price of our common stock to decline.

Under Section 404 of the Sarbanes-Oxley Act of 2002 and rules promulgated by the SEC, companies are required to conduct a comprehensive evaluation of their internal control over financial reporting. As part of this process, we are required to document and test our internal control over financial reporting; management is required to assess and issue a report concerning our internal control over financial reporting; and our independent registered public accounting firm may be required to attest to the effectiveness of our internal control over financial reporting. Our internal control over financial reporting may not prevent or detect misstatements because of its inherent limitations, including the possibility of human error, the circumvention or overriding of controls, or fraud.

Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be prevented or detected timely. Even effective internal controls over financial reporting can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements.

The existence of a material weakness could result in errors in our financial statements that could result in a restatement of financial statements, which could cause us to fail to meet our reporting obligations, lead to a loss of investor confidence and have a negative impact on the trading price of our common stock.

Item 1B. Unresolved Staff Comments

None

Item 2. Properties

The following are the principal facilities of the Company:

| Location | Primary use | Segments | Leased / owned | Square footage |
|---------------------------------|--|---|---------------------------|---------------------------|
| Farmingdale, NY (Note 1) | Clinical laboratory and research | Clinical Laboratory Services | Leased | 43,000 |
| Farmingdale, NY | Manufacturing, research, sales and administrative office | Life Sciences Products, Therapeutics | Owned | 22,000 |
| Farmingdale, NY (Note 2) | Manufacturing and administrative office | Clinical Laboratory Services and Life Sciences Products | Owned | 36,000 |
| Farmingdale, NY (Note 3) | Administrative office | Clinical Laboratory Services, Life Sciences Products, and Other | Leased | 12,000 |
| New York, NY (Note 4) | Corporate headquarters | Other | Leased | 11,300 |
| Lausen, Switzerland (Note 5) | Operational headquarters in Europe, including sales and distribution | Life Sciences Products | Leased | 9,626 |
| Ann Arbor, Michigan (Note 6) | Manufacturing, research, and distribution | Life Sciences Products | Leased | 26,820 |

| | |
|--------|---|
| Note 1 | On October 9, 2015, this lease was amended and extended through March 31, 2027. |
| Note 2 | On November 27, 2018 we closed on the \$6 million purchase of this facility, which was subleased through June 30, 2020. |
| Note 3 | This lease commenced June 15, 2021 and expires on June 15, 2024. |
| Note 4 | In June 2017, the lease, which includes 4,100 square feet under a sublease rental agreement through December 31, 2019, was extended through June 2028. We are currently evaluating this lease and considering all alternatives including, but not limited to, a sublease and/or buyout of the term. |
| Note 5 | In June 2019, the lease was amended and extended through July 2020 and automatically renews for one year on each anniversary. |
| Note 6 | This lease expired in May 2021 and subsequently ran on a month to month basis. Operations at this facility ceased on September 30, 2021 and were moved to Farmingdale, NY. |

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

Item 3. Legal Proceedings

The Company has brought cases in the United States District Court for the District of Delaware ("the Court"), alleging patent infringement against various companies. In 2017, the Court ruled that the asserted claims of the '180 and '405 Patents are invalid for nonenablement in cases involving Abbott, Becton Dickinson, Gen-Probe, Hologic, and Roche. That ruling was affirmed by the United States Court of Appeals for the Federal Circuit ("Federal Circuit") in June 2019. Enzo subsequently filed a petition for certiorari regarding the invalidity ruling for the '180 and '405 Patents in February 2020; the Supreme Court denied Enzo's petition on March 30, 2020. There are currently two cases that were originally brought by the Company in the Court. In those two cases, Enzo alleges patent infringement against Becton Dickinson Defendants and Roche Defendants, respectively. The claims in those cases involve the '197 Patent. Both cases are stayed.

In separate inter partes review proceedings before the U.S. Patent and Trademark Office ("PTO") involving, among others, Becton Dickinson, certain claims of the '197 Patent were found unpatentable as anticipated or obvious and cancelled by the Patent Trial and Appeals Board ("Board"). Enzo appealed that decision to the Federal Circuit. On August 16, 2019, the Federal Circuit affirmed the Board's decision, finding that each of the challenged claims is unpatentable. The Company filed a petition for rehearing and rehearing en banc on October 30, 2019, which the Federal Circuit denied on December 4, 2019. The Company filed a petition for certiorari with the Supreme Court on March 3, 2020, which was denied.

In April 2019, the Company entered into an agreement with Hologic and Grifols, resolving litigation resulting from four cases originally brought by the Company in the Court. As a result, Enzo dismissed (1) a stayed patent litigation regarding the '180 and '197 Patent against Hologic in the Court; (2) the Consolidated Appeals against Gen-Probe and Hologic resulting from two cases filed in the Court, and (3) the Company's appeal in the litigation involving the '581 Patent that involved both Hologic and Grifols. As a result of the agreement with Hologic, Hologic withdrew from Enzo's Federal Circuit appeal of the Board's adverse rulings in the *inter partes* review proceedings regarding the '197 Patent filed by Hologic and joined by Becton Dickinson mentioned above.

On September 2, 2021, the PTO issued a non-final office action in an ex parte reexamination concerning the '197 Patent. In the office action, the PTO rejected certain claims of the '197 Patent under 35 U.S.C. § 102 and for nonstatutory double-patenting. Enzo's response to the office action is forthcoming.

On February 5, 2020, Harbert Discovery Fund, LP and Harbert Discovery Co-Investment Fund I, LP (“Plaintiffs”) brought an action in the United States District Court for the Southern District of New York against the Company and five of its present or former Directors, Dr. Elazar Rabbani, Barry W. Weiner, Dr. Bruce A. Hanna, Dov Perlysky and Rebecca Fischer. On March 26, 2020, Plaintiffs filed an amended complaint against the same defendants. Count I asserted the Company violated Section 14(a) of the Securities and Exchange Act of 1934 and Rule 14a-9 thereunder by disseminating proxy materials that made two purportedly false statements: (a) a “January 28, 2020 Enzo press release [that purportedly] falsely stated that the Annual Meeting would be ‘delayed’ by action of the Board to February 25, 2020 when, in fact, the Annual Meeting would convene as planned on January 31, 2020”, and (b) a “January 31 Enzo Proxy [that purportedly] falsely stated that the Proposed By-Law Amendment [to Article II, Section 9] would be approved if it received... a majority of the votes....rather than the required Supermajority Vote as provided for in the Charter. “Count II asserted a claim against the individual defendants under Section 20(a) of the Exchange Act premised on Enzo’s purported violation of Section 14(a) and Rule 14a-9. Count III asserted the individual defendants breached their fiduciary duty, based on the same conduct and by seeking to entrench themselves. Finally, Count IV purported to assert a derivative claim for a declaration that any amendment to Article II, Section 2 requires the approval of 80% of Enzo’s shareholders. On July 16, 2020, the day before the defendants’ motion to dismiss was due, plaintiffs asked the Court to dismiss their claims without prejudice. Defendants asked plaintiffs to dismiss the claims with prejudice, but they refused. On July 17, 2020, the Court dismissed the claims without prejudice. If plaintiffs reassert the claims, defendants intend to vigorously defend against them.

On November 27, 2020, the Company brought an action in the United States District Court for the Southern District of New York against Harbert Discovery Fund, LP, Harbert Discovery Co-Investment Fund I, LP, Harbert Fund Advisors, Inc., Harbert Management Corp. and Kenan Lucas. The Company alleges the defendants made false and misleading representations, or omitted to state material facts necessary to make their statements not misleading, in proxy materials they disseminated seeking the election to the Company’s Board of Directors at its 2019 Annual Meeting of two candidates they nominated, in violation of Section 14(a) of the 1934 Exchange Act and Rule 14a-9 thereunder. The Company seeks damages and injunctive relief. On February 15, 2021, Defendants filed a motion to dismiss. On March 8, 2021, the Company filed its opposition to that motion. On March 18, 2021 defendants filed their reply in further support of the motion. On September 28, 2021, the Court denied the motion with respect to the Company’s misrepresentation claims and granted it with respect to its omissions claim. The Company intends to vigorously pursue its misrepresentation claim.

There can be no assurance that the Company will be successful in any of 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.

As described in Note 3 to the consolidated financial statements, third-party payers, including government programs, may decide to deny payment or recoup payments for testing that they contend was improperly billed or not medically necessary, against their coverage determinations, or for which they believe they have otherwise overpaid (including as a result of their own error), and we may be required to refund payments already received. During the third fiscal quarter of 2019, a significant third-party payer informed us outside of their typical business practice that they believe it overpaid the Company during certain periods of fiscal 2018. The Company disputed these claims and formally sent legal appeal letters to the payer. During the fiscal 2020 period, we recorded \$0.8 million in legal and related expenses as a result of reduced reimbursements this payer made to us. In April 2020, we and the payer entered into a settlement agreement and release whereby the parties agreed that the \$0.8 million previously withheld by the payer shall fully and completely satisfy the dispute.

The following legal settlements are included in the statement of operations under Legal settlements, net within the Life Science segment for the 2019 period:

The Company, along with its subsidiaries Enzo Life Sciences, Inc. entered into a Settlement Agreement as of February 5, 2019 (the “Agreement”) with Roche Diagnostics GmbH and Roche Molecular Systems, Inc. (together, “Roche”) with respect to an action between the Company and Roche before the U.S. District Court, Southern District of New York, Case No 04-CV4046. Roche agreed to pay the Company \$21 million in settlement pursuant to the Agreement. The Company received \$19.4 million net of attorney contingency payments. This settlement does not affect the Company’s civil action for patent infringement against Roche in the U.S. District Court for the District of Delaware, Enzo Life Sciences Inc. v. Roche Molecular Systems Inc., et al., civil action No. 12 cv-00106, which remains stayed.

The Company, along with its subsidiaries Enzo Life Sciences, Inc. entered into a settlement and license agreement as of April 16, 2019 (the “Agreement”) with Hologic, Inc. (“Hologic”), Grifols, S.A., and Grifols Diagnostic Solutions Inc. (together, “Grifols”) to settle all outstanding patent disputes among the parties. The terms of the agreement include one-time payments totaling \$14 million to the Company in exchange for fully paid-up, worldwide licenses to Hologic and Grifols. The Company received \$9.5 million net of attorney contingency payments.

Item 4. Mine Safety Disclosures

Not applicable.

Part II

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

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

2021 Fiscal Year (August 1, 2020 to July 31, 2021):

| | <u>High</u> | <u>Low</u> |
|-------------|-------------|------------|
| 1st Quarter | \$ 2.61 | \$ 1.82 |
| 2nd Quarter | \$ 3.20 | \$ 1.89 |
| 3rd Quarter | \$ 4.08 | \$ 2.75 |
| 4th Quarter | \$ 3.40 | \$ 2.86 |

2020 Fiscal Year (August 1, 2019 to July 31, 2020):

| | <u>High</u> | <u>Low</u> |
|-------------|-------------|------------|
| 1st Quarter | \$ 3.79 | \$ 3.01 |
| 2nd Quarter | \$ 3.21 | \$ 2.42 |
| 3rd Quarter | \$ 3.87 | \$ 1.82 |
| 4th Quarter | \$ 3.14 | \$ 2.15 |

As of September 30, 2021, the Company had approximately 850 stockholders of record of its common stock.

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

Item 6. Selected Financial Data

Not applicable, reserved.

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

See in this Form 10-K for the fiscal year ended July 31, 2021 Part 1. Item 1. *Business*, for Forward Looking Cautionary Statements.

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

Impact of COVID-19 pandemic

COVID-19 has severely impacted the economy of the United States and other countries around the world. Federal, state and local governmental policies and initiatives designed to reduce the transmission of COVID-19 have resulted in, among other things, a significant reduction in physician office visits, the cancellation of elective medical procedures, customers of our products closing or severely curtailing their operations (voluntarily or in response to government orders), and the adoption of work-from-home or shelter-in-place policies. The COVID-19 impact on the Company's operations is consistent with the overall industry and publicly issued statements from competitors, partners, and vendors.

Enzo was granted FDA Emergency Use Authorizations (EUAs) and EUA extensions for our molecular diagnostic and serological testing for COVID-19 and related antibody testing options, for our sample collection kit, an innovative virus-inactivating specimen collection media that lessens transmission risks for healthcare providers and clinical laboratory personnel, for our use of pooled samples, and for our rapid extraction method. Other innovations include the development of more relevant positive controls for the tests, and improved sensitivity. During fiscal 2021, we experienced growing demand for COVID-19 testing and we made significant investments to expand our capacity throughout the period in order to satisfy the demand, which substantially increased our testing volumes.

The extent to which our businesses may continue to be affected by the COVID-19 pandemic will largely depend on both current and future developments, including its duration, spread and emergence of variants, its treatment with approved and authorized vaccines, mask and vaccine mandates, work and travel advisories and restrictions, and the timing of their easing, all of which are highly uncertain and cannot be reasonably predicted at this time. We expect COVID-19 volume to decline in the quarters ahead as the percentage of Americans who are vaccinated increases, although the emergence and spread of variants may cause our COVID-19 testing volume to increase again. Global supply chain issues due to the pandemic continue to hamper both the manufacturing of products within the life science segment as well as testing capabilities in the clinical laboratory.

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act)

In March 2020, in response to the COVID-19 pandemic, the CARES Act was signed into law. The CARES Act provides numerous tax provisions and other stimulus measures. The CARES Act also includes a number of benefits that are applicable to us and other healthcare providers including, but not limited to:

- Providing clinical laboratories a one-year reprieve from the Centers for Medicare and Medicaid Services (CMS) private payer prices reporting requirements under the Protecting Access to Medicare Act ("PAMA") as well as a one-year delay of a reimbursement rate reduction of 15% for clinical laboratory services provided under Medicare that was scheduled to take place starting January 1, 2021. Further revisions of the Medicare Clinical Laboratory Fee Schedule (CLFS) for calendar years after 2021 will be based on future surveys of private payer market rates. Medicare and Medicaid reimbursement reduction for calendar years 2022-2024 is capped by PAMA at 15% annually, which we estimate could then negatively impact our annualized Medicare and Medicaid revenues by approximately \$2.9 million. In this regard, the American Clinical Laboratory Association (ACLA) has filed a federal civil action challenging the legal basis for the private payer data collection methodology CMS used to derive the data from which median prices were calculated. ACLA continues to work with Congress on potential legislative reform of PAMA, which if adopted could reduce the negative impact of PAMA as currently implemented by CMS. The long-term effect of these efforts on Medicare CLFS rates is not determinable
- Appropriating \$100 billion to health care providers for related expenses or lost revenues that are attributable to the COVID-19 pandemic. In April 2020, we received from Medicare a CARES Act Relief Payment grant of approximately \$750 from the initial tranche and in July 2020 we received a second grant of approximately \$750.
- Allocated \$349 billion to small businesses as Payment Protection Program (PPP) loans through the Small Business Administration (SBA). In April 2020, we received approximately \$7.0 million from the initial tranche of this program. In June 2021 the SBA fully forgave our PPP loan.
- Providing an advance on testing services payments which can be either paid back at any time or earned back starting one year from receipt. In April 2020 we applied for and received a Medicare advance payment of \$2.5 million, which is being paid back.
- Suspended Medicare sequestration from May 2020 to December 2020. The Consolidated Appropriations Act of 2021 extended the suspension period to March 31, 2021. An Act to Prevent Across-the-Board Direct Spending Cuts, and for Other Purposes, signed into law on April 14, 2021, extended the suspension period to December 31, 2021. We estimate that the suspension of Medicare sequestration resulted in a small benefit to us in the form of higher reimbursement rates for diagnostic testing services performed on behalf of Medicare beneficiaries.

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

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

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

Enzo Life Sciences Products manufactures, develops and markets products and tools to life sciences, drug development and clinical research customers world-wide and has amassed a large patent and technology portfolio. Enzo Life Sciences, Inc. is a recognized leader in labeling and detection technologies across research and diagnostic markets. Our strong portfolio of proteins, antibodies, peptides, small molecules, labeling probes, dyes and kits provides life science researchers tools for target identification/validation, high content analysis, gene expression analysis, nucleic acid detection, protein biochemistry and detection, and cellular analysis. We are globally recognized and acknowledged as a leader in manufacturing, in-licensing, and commercialization of over 40,000 products. Our strategic focus is directed to innovative high quality research reagents and kits in the primary key research areas of genomics, immunohistochemistry, immunoassays, cellular analysis, and small molecule chemistry. The segment is an established source for a comprehensive panel of products to scientific experts in the fields of cancer, cardiovascular disease, neurological disorders, diabetes and obesity, endocrine disorders, infectious and autoimmune disease, hepatotoxicity and renal injury.

Enzo Therapeutics is a biopharmaceutical venture that has developed multiple novel approaches in the areas of gastrointestinal, infectious, ophthalmic and metabolic diseases, many of which are derived from the pioneering work of Enzo Life Sciences. The Company has focused its efforts on developing treatment regimens for diseases and conditions in which current treatment options are ineffective, costly, and/or cause unwanted side effects. This focus has generated a clinical and preclinical pipeline, as well as more than 100 patents and patent applications.

The following table summarizes the sources of revenues for the fiscal years ended July 31, 2021, 2020 and 2019 (in \$000's and percentages):

| | 2021 | | 2020 | | 2019 | |
|------------------------------|------------|------|-----------|------|-----------|------|
| Clinical laboratory services | \$ 86,984 | 74% | \$ 47,964 | 63% | \$ 51,115 | 63% |
| Product revenues | 30,747 | 26 | 26,561 | 35 | 30,055 | 37 |
| Grant income | — | — | 1,496 | 2 | — | — |
| Total | \$ 117,731 | 100% | \$ 76,021 | 100% | \$ 81,170 | 100% |

Results of Operations
Fiscal year ending July 31, 2021 compared to July 31, 2020
(in 000s)

Comparative Financial Data for the Fiscal Years Ended July 31,

| | <u>2021</u> | <u>2020</u> | <u>Favorable (Unfavorable)</u> | <u>% Change</u> |
|--------------------------------------|-----------------|--------------------|------------------------------------|-----------------|
| Revenues | \$ 117,731 | \$ 76,021 | \$ 41,710 | 55 |
| Operating costs and expenses: | | | | |
| Cost of revenues | 64,154 | 52,251 | (11,903) | (23) |
| Research and development | 3,252 | 4,448 | 1,196 | 27 |
| Selling, general and administrative | 44,905 | 42,960 | (1,945) | (5) |
| Legal and related expenses | 4,728 | 6,729 | 2,001 | 30 |
| Total operating costs and expenses | <u>117,039</u> | <u>106,388</u> | <u>(10,651)</u> | (10) |
| Operating income (loss) | 692 | (30,367) | 31,059 | ** |
| Other income (expense): | | | | |
| Interest | 8 | 454 | (446) | (98) |
| Other | 6,905 | 488 | 6,417 | ** |
| Foreign currency gain | 270 | 905 | (635) | (70) |
| Income (loss) before income taxes | <u>\$ 7,875</u> | <u>\$ (28,520)</u> | <u>\$ 36,395</u> | ** |

** not meaningful

Consolidated Results:

The “2021 period” and the “2020 period” refer to the fiscal year ended July 31, 2021 and 2020, respectively.

Impacts of COVID-19

In July 2020, Enzo was granted FDA Emergency Use Authorization (EUA) for its molecular diagnostic and serological testing for COVID-19 and related antibody testing options. In January 2021, Enzo received an expansion of its Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) authorizing the use of pooled samples containing up to five individual swab specimens with the Company’s AMPIPROBE[®] SARS-Cov-2 Test System utilizing tests on three different platforms including Enzo’s proprietary GENFLEX[®] automated high-throughput platform. In July 2021, Enzo received an expansion of its FDA Emergency Use Authorization (EUA) for the Company’s rapid extraction method on its proprietary test system.

Due to the effects of the pandemic and COVID-19 testing, accession volume in the 2021 period exceeded accession volume in the 2020 period by 65%, offsetting reductions in non-COVID-19 accessions due to the continuing restrictive effects of COVID-19. At this time, it is too early to determine the long term significance of the positive impact from COVID-19 testing and the Company’s proprietary product offerings on revenue, profitability and cash flow. We experienced a decline in COVID-19 accession volume in the fourth quarter of the 2021 period and fully expect COVID-19 volume to decline in the quarters ahead as the percentage of Americans who are vaccinated increases. However, the emergence and spread of variants have caused our COVID-19 testing volume to increase again subsequent to the end of the fiscal year period. We expect continued COVID-19 testing opportunities based on testing for entertainment and travel as well as for school and workplace reopenings.

Clinical services revenues for the 2021 period were \$87.0 million compared to \$49.5 million in the 2020 period, an increase of \$37.5 million or 76%. Revenues from COVID-19 testing represented 48% and 8% of Clinical revenues in the 2021 and 2020 periods, respectively. Revenues for the 2020 period include two CARES Act Relief Payment grants totaling \$1.5 million; there were no grants in the 2021 period. Diagnostic testing volume measured by the total number of accessions for all our testing services increased approximately 65% period over period due to the positive impact from COVID-19 testing, resulting in the 2021 period's revenue increase. COVID-19 testing services have higher reimbursement rates than our core and specialty testing resulting in an improvement in our overall liquidation rate for collections and revenue per accession. Excluding the impact of COVID-19 testing and the CARES Act grant, revenues for the 2021 period were \$1.1 million higher than the 2020 period, and non COVID-19 testing volume was 1% higher.

Estimated collection amounts are subject to the complexities and ambiguities of third party payer billing, reimbursement regulations and claims processing, as well as issues unique to Medicare and Medicaid programs, and require us to consider the potential for adjustments when estimating variable consideration in the recognition of revenue in the period that the related services are rendered. The effect of PAMA directly negatively impacted reimbursements from Medicare and Medicaid in the 2021 and 2020 periods by approximately \$1.4 million and \$1.2 million, respectively.

Product revenues were \$30.7 million in the 2021 period and \$26.6 million in the 2020 period, an increase of \$4.2 million or 16%. During the 2020 period, the negative effect of COVID-19 related government policies intended to reduce the spread of the pandemic impacted our Products revenues in the U.S. markets more than in markets in the rest of the world. A greater portion of the 2021 period increase came from markets outside the U.S., though the U.S. market also increased, especially in the fourth quarter of the 2021 period. The worldwide growth is due to the improvement in infection rates and a rebound in demand as academia returned from complete shutdown, though some industrial customers still have not returned to full operations.

The cost of Clinical Services was \$48.2 million in the 2021 period and \$38.9 million in the 2020 period, an increase of \$9.3 million from increased COVID-19 testing volume. Utilizing our internal manufacturing capabilities we reduced some of our reliance on reagents sourced from third parties. The gross profit margin on Clinical Services revenues in the 2021 period was approximately 45% versus 19% in the 2020 period, excluding the 2020 period grants. In the 2021 period, the high margin on COVID-19 testing and liquidation rate improvements offset the effect of reduced volumes of certain specialty testing services, such as genetics testing.

The cost of Product revenues was \$16.0 million in the 2021 period and \$13.4 million in the 2020 period, an increase of \$2.6 million or 19%. The gross profit margin on Products was 48.0% in the 2021 period and 49.6% in the 2020 period, negatively impacted by an increase in headcount, overhead and the cost of production materials.

Research and development expenses were \$3.3 million in the 2021 period and \$4.4 million in the 2020 period, a decrease of \$1.2 million or 27%. The decrease is attributable to the Clinical Services segment, where with the increased commercialization of COVID-19 testing, certain research and development resources transitioned to testing services in the current period. During the 2020 period, the segment's efforts were directed toward lab developed tests (LDTs) for the detection of COVID-19 and antibodies. Research and development expenses also declined for the Therapeutics segment, due to the timing of activities.

Selling, general and administrative expenses were \$44.9 million during the 2021 period versus \$43.0 million during the 2020 period, an increase of \$1.9 million or 5%. The Clinical Services expense increased \$2.5 million primarily due to higher sales commissions and support services compensation resulting from higher revenues and activity from COVID-19, partially offset by the impact of cost savings initiatives undertaken throughout our fiscal year that ended July 31, 2020. The Life Sciences Products expense increased \$0.5 million due to higher information technologies expenses and accrual of plant closure costs. The Other segment decreased \$1.1 million primarily due to lower self-insured healthcare benefit costs.

Legal and related expenses were \$4.7 million during the 2021 period compared to \$6.7 million in the 2020 period, a decrease of \$2.0 million or 30%. There were contested proxy activities in both periods, but we incurred legal expenses relating to the contested proxy through more of the 2020 period compared to the 2021 period.

Interest income, net was zero in the 2021 period versus interest income, net of \$0.5 million in the 2020 period, an unfavorable variance of \$0.5 million, and in both periods represents interest on cash and cash equivalents and marketable securities net of interest expense, primarily on a mortgage. During the latter half of the 2021 period, we invested in and began to earn interest on marketable securities in bond funds since no interest was being earned on cash in money market funds because the Federal Reserve cut its target interest rates to near zero in response to COVID-19. During most of the 2020 period, we earned interest in money market funds, which earned a significant yield prior to the Federal Reserve's interest rate cuts as it targeted near zero interest rates.

Other income in the 2021 and 2020 period was \$7.0 million and \$0.5 million respectively, an increase of \$6.4 million. In June 2021, our \$7.0 million PPP loan was fully forgiven by the Small Business Administration and the loan liability was reversed into income.

The foreign currency revaluation gain recognized by the Life Sciences Products segment during the 2021 period was \$0.3 million compared to a revaluation gain of \$0.9 million in the 2020 period, an unfavorable variance of \$0.6 million. The 2021 period revaluation gain was due to significant appreciation of the British pound versus the U.S. dollar as of the end of the period compared to its start. The revaluation gain in the 2020 period was larger due to significant appreciation of the British pound, Swiss franc and Euro versus the U.S. dollar as of the end of that period compared to its start.

Results of Operations
Fiscal year ending July 31, 2020 compared to July 31, 2019
(in 000s)

Comparative Financial Data for the Fiscal Years Ended July 31,

| | <u>2020</u> | <u>2019</u> | <u>Favorable (Unfavorable)</u> | <u>% Change</u> |
|--|--------------------|-----------------|------------------------------------|-----------------|
| Revenues | \$ 76,021 | \$ 81,170 | \$ (5,149) | (6) |
| Operating costs and expenses: | | | | |
| Cost of revenues | 52,251 | 57,922 | 5,671 | 10 |
| Research and development | 4,448 | 3,175 | (1,273) | (40) |
| Selling, general and administrative | 42,960 | 44,265 | 1,305 | 3 |
| Legal and related expenses | 6,729 | 3,000 | (3,729) | (124) |
| Legal settlements, net | — | (28,925) | (28,925) | (100) |
| Total operating costs, expenses and legal settlements, net | <u>106,388</u> | <u>79,437</u> | <u>(26,951)</u> | <u>(34)</u> |
| Operating (loss) income | (30,367) | 1,733 | (32,100) | ** |
| Other income (expense): | | | | |
| Interest | 454 | 1,056 | (602) | (57) |
| Other | 488 | 382 | 106 | 28 |
| Foreign currency gain (loss) | 905 | (682) | 1,587 | ** |
| (Loss) income before income taxes | <u>\$ (28,520)</u> | <u>\$ 2,489</u> | <u>\$ (31,009)</u> | <u>**</u> |

** not meaningful

Consolidated Results:

The “2020 period” and the “2019 period” refer to the fiscal year ended July 31, 2020 and 2019, respectively.

Clinical services revenues for the 2020 period were \$49.5 million compared to \$51.1 million in the 2019 period, a decrease of \$1.6 million or 3%. Revenues for the 2020 period include two CARES Act Relief Payment grants totaling \$1.5 million. Due to COVID-19, diagnostic testing volume measured by the total number of accessions for all our testing services decreased 7% period over period, resulting in the 2020 period’s revenue decrease. COVID-19 testing services provided in the four months of the 2020 period partially offset the impact of the decline in total testing volume and also contributed to liquidation rate improvement. In the latter part of our third quarter, while accessions had not returned to prior year levels, we started to see accession volume rebound. Due to the addition of COVID-19 testing, accession volume in the month of July 2020 exceeded July 2019 volume. In the normal course of business, estimated collection amounts are subject to the complexities and ambiguities of third party payer billing, reimbursement regulations and claims processing, as well as issues unique to Medicare and Medicaid programs, and require us to consider the potential for adjustments when estimating variable consideration in the recognition of revenue in the period that the related services are rendered. The impact from the Protecting Access to Medicare Act (“PAMA”) continues to negatively impact reimbursements from Medicare and third party payers.

Product revenues for the 2020 and 2019 periods were \$26.6 million and \$30.1 million, respectively. The decrease of \$3.5 million or 12% is the result of the policies and initiatives ordered by national and local governments designed to reduce the transmission of COVID-19. The negative effect of these government policies on our products revenues was greater in the U.S. market than markets in the rest of the world, and began in the latter half of the third quarter of the 2020 period.

The cost of Clinical Services was \$38.9 million in the 2020 period and \$44.2 million in the 2019 period, a decrease of \$5.3 million, attributable to the overall decline in testing volume, resulting in reduction in reagent usage and outside reference testing expense. The gross profit margin on Clinical Services revenues, excluding the grants in the 2020 period, was 19.0% in the 2020 period and 13.4% in the 2019 period. In the 2020 period, liquidation rate improvements and the higher margin on COVID-19 testing helped to offset the effect of reduced volumes of our genetics and core testing services.

The cost of product revenues was \$13.4 million in the 2020 period and \$13.7 million in the 2019 period, a decrease of \$0.3 million or 2% due to the decrease in revenues. The gross profit margin on products was 49.6% in the 2020 period and 54.4% in the 2019 period, negatively impacted by the decline of higher margin sales in the U.S. market from COVID-19.

Research and development expenses were \$4.4 million in the 2020 period and \$3.2 million in the 2019 period, an increase of \$1.2 million or 38%. The increase is entirely attributed to the Clinical Services segment for lab developed tests (LDTs) including those based on our proprietary GENFLEX[®] platform. During the 2020 period, our research was focused on lab developed tests for the detection of COVID-19 and for the detection of COVID-19 antibodies. Our lab developed test for the detection of COVID-19 was approved under the FDA's Emergency Use Authorization (EUA) authority. Other tests based on GENFLEX[®] were approved by The New York State Department of Health.

Selling, general and administrative expenses were \$43.0 million during the 2020 period versus \$44.3 million during the 2019 period, a decrease of \$1.3 million or 3%. The Clinical Services expense decreased \$0.7 million due to cost savings initiatives and lower commissions. The Life Sciences Products expense decreased \$1.4 million due to reductions in sales, marketing and administrative salaries and related costs, travel expenses, and intangibles amortization. The other segment increased \$0.8 million primarily for higher self-insured healthcare benefit costs and occupancy costs.

Legal and related expenses were \$6.7 million during the 2020 period compared to \$3.0 million in the 2019 period, an increase of \$3.7 million. During the 2020 period, we incurred \$4.1 million for contested proxy costs relating to our February 2020 annual shareholders meeting. Third-party payers, including government programs, may decide to deny payment or recoup payments for testing that they contend was improperly billed or not medically necessary, against their coverage determinations, or for which they believe they have otherwise overpaid (including as a result of their own error), and we may be required to refund payments already received. During the third fiscal quarter of 2019, a significant third-party payer informed us outside of their typical business practice that they believed it overpaid us during certain periods of fiscal 2018. We disputed these claims and sent legal appeal letters to the payer. In the 2020 period, we recorded \$0.8 million in legal and related expenses as a result of reduced reimbursements this payer made to us. In the third quarter of the 2020 period, we and the payer entered into a settlement agreement and release whereby the parties agree that the \$0.8 million previously withheld by the payer fully and completely satisfied the dispute. Legal expense associated with other legal activity including costs associated with on-going litigation and contract disputes decreased \$1.2 million due to the timing of activities.

Legal settlements, net were \$28.9 million in the 2019 period versus none in the 2020 period. During the 2019 period the Company as plaintiff finalized and executed settlement agreements with Roche (\$19.4 million, net), and Hologic Inc. (\$9.5 million, net).

Interest income, net was \$0.5 million in the 2020 period and \$1.1 million in the 2019 period and represents interest on cash and cash equivalents net of interest expense. During the 2020 period, the amount of investable cash was lower as were interest rates earned on deposits. Due to the actions by the Federal Reserve to cut its target interest rates near zero in response to COVID-19, we expect there will be substantially no interest earned on our cash and cash equivalents for the foreseeable future.

The foreign currency revaluation gain recognized by the Life Sciences Products segment during the 2020 period was \$0.9 million compared to a loss of \$0.7 million in the 2019 period, a favorable variance of \$1.6 million. The gain was due to year over year appreciation of the British pound and Swiss franc versus the U.S. dollar as of the end of the 2020 period, compared to their year over year depreciation as of the end of the 2019 period.

Liquidity and Capital Resources

At July 31, 2021, the Company had cash and cash equivalents and marketable securities totaling \$43.5 million of which \$0.9 million was in foreign accounts, as compared to cash and cash equivalents of \$47.9 million, of which \$0.9 million was in foreign accounts at July 31, 2020. It is the Company's current intent to permanently reinvest these foreign funds outside of the United States, and its current plans do not demonstrate a need to repatriate them to fund its United States operations. The Company had working capital of \$44.5 million at July 31, 2021, compared to \$36.0 million at July 31, 2020, an increase of \$8.5 million. The increase in working capital was primarily due to a decrease in current liabilities, particularly the Paycheck Protection Program (PPP) loan of \$7.0 million, which was forgiven during the fourth quarter of the year ended July 31, 2021.

Net cash provided by operating activities during the fiscal 2021 period was approximately \$0.4 million, compared to cash used in operations of \$17.2 million during the fiscal 2020 period, an improvement of approximately \$17.6 million. The net cash provided in the 2021 period was due primarily to net income of \$7.9 million which was offset by net non-cash adjustments of \$2.7 million and by a net increase of \$4.8 million in operating assets and liabilities including, but not limited to inventories and other assets. Net cash used in operating activities in fiscal 2020 was approximately \$17.2 million as compared to net cash provided by operating activities of \$4.8 million in fiscal 2019, an increase in net cash used in operations of approximately \$22.0 million. This increase in net cash used in operating activities in the 2020 period versus 2019 was due to the year over year increase of \$31.0 million in net loss, partially offset by a positive net change in adjustments and operating assets and liabilities of \$9.0 million.

Net cash used in investing activities during the fiscal 2021 period was approximately \$34.5 million as compared to \$2.2 million in the 2020 period, an increase of \$32.3 million. During the 2021 period, we purchased marketable securities totaling \$30.1 million. Capital expenditures during the 2021 period increased \$2.2 million compared to the 2020 period to support and grow our existing operations, related to investments in information technology, laboratory equipment and the buildout of our Farmingdale campus. Net cash used in investing activities in fiscal 2020 was approximately \$2.2 million as compared to \$8.1 million in the 2019 period, a decrease of \$5.9 million. The decrease in the 2020 period is primarily due to the purchase of a facility in the 2019 period.

Cash used in financing activities in fiscal 2021 was \$0.2 million for payments related to a mortgage and finance leases. Cash provided by financing activities in fiscal 2020 was \$7.0 million net, due to the PPP and Corona Krise loans of \$7.0 million and \$0.4 million, respectively. During fiscal 2021 we applied for and received loan forgiveness for the full amount of the PPP loan, which is included in Other Income. The Corona Krise loan is still outstanding as of July 31, 2021 and has a remaining term of four years.

As of July 31, 2021 we have a mortgage principal balance of \$4.1 million entered into for the purchase of a building facility, which bears a fixed interest rate of 5.09% per annum. It requires monthly mortgage payments of \$30. Our obligations under the mortgage agreement are secured by the facility and by a \$750 cash collateral deposit with the mortgagee as additional security, which is included in other assets as of July 31, 2021. Effective October 19, 2020, the Company and the mortgagee agreed to a covenant restructure whereby the mortgagee waived the Company's financial ratio covenant for the fiscal period ended July 31, 2020 and modified the mortgage to replace that covenant with a liquidity covenant. The liquidity covenant required that we own and maintain at all times, and throughout the remaining term of the loan, at least \$25 million of liquid assets, defined as time deposits, money market accounts and commercial paper, and obligations issued by the U.S. government or any of its agencies. The cash collateral agreement was also modified to require compliance with the liquidity covenant for two consecutive fiscal years before the collateral is released back to us. As of July 31, 2021, the Company was in compliance with the financial and liquidity covenants related to this mortgage.

Effective September 29, 2021 the Company and the mortgagee agreed to further covenant restructuring whereby (a) the liquidity covenant was reduced to 150% of the loan principal (or approximately \$6 million at July 31, 2021) from \$25 million previously, and (b) the collateral requirement was increased from \$0.75 million to \$1.0 million.

Effect of New Accounting Pronouncements

Recently Adopted Accounting Pronouncements

On August 1, 2019, the Company adopted a new accounting standard issued by the Financial Accounting Standards Board (“FASB”) on accounting for leases using the modified retrospective method. This new accounting standard requires a lessee to recognize an asset and liability for most leases on its balance sheet. The Company elected the optional transition method that allowed for a cumulative-effect adjustment to the opening balance of retained earnings recorded on August 1, 2019 and did not restate previously reported results in the comparative periods. The Company also elected the package of practical expedients, which among other things, allowed it to carry forward its historical lease classification.

As a result of adoption of the new standard, the Company recorded right-of-use assets and operating lease liabilities of approximately \$24.4 million and \$25.1 million, respectively as of August 1, 2019. The operating lease liability was determined based on the present value of the remaining minimum rental payments and the right-of-use asset was determined based on the value of the lease liability, adjusted for deferred rent balances of approximately \$0.7 million, which were previously included in accrued expenses. There was no cumulative effect adjustment to the opening balance of accumulated deficit. Accounting for the Company’s finance leases remains substantially unchanged. The adoption of the new standard did not materially impact the Company’s consolidated results of operations or cash flows. The adoption of this new accounting standard resulted in increased qualitative and quantitative disclosures regarding the amount, timing, and uncertainty of cash flows arising from leases.

The Company elected the package of three practical expedients. As such, the Company did not reassess whether expired or existing contracts are or contain a lease and did not need to reassess the lease classifications or reassess the initial direct costs associated with expired or existing leases. The Company did not elect the hindsight practical expedient. Further, the land easement practical expedient was not elected as the practical expedient is not applicable to the Company. The Company elected to take the practical expedient to not separate lease and non-lease components of all asset classes entered into or modified after the effective date. For further details, see Note 9.

Pronouncements Issued but Not Yet Adopted

In June 2016, FASB issued ASU No. 2016-13 Financial Instruments – Credit Losses (Topic 326). This standard changes the impairment model for most financial instruments, including trade receivables, from an incurred loss method to a new forward-looking approach, based on expected losses.

The estimate of expected credit losses will require entities to incorporate considerations of historical information, current information and reasonable and supportable forecasts. Adoption of this standard is required for our annual and interim periods beginning August 1, 2023, provided we qualify as a smaller reporting company at the end of fiscal 2022 and must be adopted using a modified retrospective transition approach. We are currently assessing the impact of the adoption of this standard on our results of operations, financial position and cash flows.

In December 2019, the FASB issued ASU No. 2019-12 *Income Taxes (Topic 740) Simplifying the Accounting for Income Taxes*. The amendments in the ASU simplify the accounting for income taxes by removing certain exceptions to the general principles of Topic 740. The amendments also improve consistent application of and simplify U.S. GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The amendments in this ASU are required for our annual and interim periods beginning August 1, 2021. The adoption of the amendments in this ASU is not expected to have a material impact on our consolidated results of operations, financial position or cash flows.

We reviewed all other recently issued accounting pronouncements and have concluded they are not applicable or not expected to be significant to the accounting for our operations.

Contractual Obligations

The Company has entered into various real estate and equipment operating leases, reagent rental agreements, and employment agreements with certain executive officers. The real estate lease for the Company's Farmingdale Clinical Lab and Research facility is with a related party. See Item 2, Properties, and Note 9 and Note 15 in the Notes to the Consolidated Financial Statements for a further description of these leases and obligations.

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

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Estimates

General

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

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

Contingencies

Contingencies are evaluated and a liability is recorded when the matter is both probable and reasonably estimable. Gain contingencies are evaluated and not recognized until the gain is realizable or realized.

Product revenues

Products revenues consist of the sale of single-use products used in the identification of genomic information and are recognized at a point in time following the transfer of control of such products to the customer, which generally occurs upon shipment. Payment terms for shipments to end-user and distributor customers may range from 30 to 90 days. Any claims for credit or return of goods may be made generally within 30 days of receipt. Revenues are reduced to reflect estimated credits and returns, although historically these adjustments have not been material. Taxes collected from customers relating to product sales and remitted to governmental authorities are excluded from revenue. Amounts billed to customers for shipping and handling are included in revenue, while the related shipping and handling costs are reflected in cost of products.

Revenues - Clinical laboratory services

Net revenues in the Company's clinical services business are primarily comprised of a high volume of relatively low-dollar transactions. The services business, which provides clinical testing services, satisfies its performance obligation and recognizes revenues upon completion of the testing process for a specific patient and reporting to the ordering physician. The Company may also perform clinical testing services for other laboratories and will recognize revenue from those services when reported to the ordering laboratory. The Company estimates the amount of consideration it expects to receive from customer groups using the portfolio approach. These estimates of the expected consideration include the impact of contractual allowances and price concessions on our customer group portfolios consisting of healthcare insurers, government payers, client payers and patients. Contracts with customers in our laboratory services business do not contain a financing component, based on the typically limited period of time between performance of services and collection of consideration. The transaction price includes variable consideration in the form of the contractual allowance and price concessions as well as the collectability of the transaction based on patient intent and ability to pay. The Company uses the expected value method in estimating the amount of the variability included in the transaction price.

Contractual Adjustment

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

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

During the years ended July 31, 2021, 2020 and 2019, the contractual adjustment percentages, determined using current and historical reimbursement statistics, were approximately 83%, 88% and 88%, respectively, of gross billings. The Company believes a decline in reimbursement rates or a shift to managed care, or similar arrangements may be offset by the positive impact of an increase in the number of tests we perform. However, there can be no assurance that we can increase the number of tests we perform or that if we do increase the number of tests we perform, that we can maintain that higher number of tests performed, or that an increase in the number of tests we perform would result in increased revenue.

The Company estimates (by using a sensitivity analysis) that each 1% point change in the contractual adjustment percentage could result in a change in clinical laboratory services revenues of approximately \$5.1 million, \$3.9 million and \$4.4 million for the years ended July 31, 2021, 2020, and 2019, respectively, and a change in the net accounts receivable of approximately \$0.6 million and \$0.5 million as of July 31, 2021 and 2020, respectively.

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

- an analysis of industry reimbursement trends;
- an evaluation of third-party reimbursement rates changes and changes in reimbursement arrangements with third-party payers;
- a rolling monthly analysis of current and historical claim settlement and reimbursement experience statistics with payers;
- an analysis of current gross billings and receivables by payer.

Accounts Receivable

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

The following is a table of the Company's net accounts receivable by segment. The Clinical Laboratory Services segment's net receivables are detailed by billing category and as a percent to its total net receivables. As of July 31, 2021 and 2020, approximately 56% and 68% respectively, of the Company's net accounts receivable relates to its Clinical Laboratory Services business, which operates in the New York, New Jersey and Connecticut medical communities. The Life Sciences products segment's accounts receivable includes approximately \$1.4 million or 33% and \$1.0 million or 34% of foreign receivables as of July 31, 2021 and 2020, respectively.

Net accounts receivable (in thousands)

| Clinical Labs (by billing category) | July 31, 2021 | | July 31, 2020 | |
|--|-------------------------|-------------|-------------------------|-------------|
| | Total Amount | % | Total Amount | % |
| Third party payers | \$ 2,195 | 36 | \$ 2,455 | 40 |
| Patient self-pay | 2,007 | 33 | 2,044 | 33 |
| Medicare | 1,122 | 19 | 884 | 14 |
| HMO's | 692 | 12 | 797 | 13 |
| Total Clinical Labs | 6,016 | 100% | 6,180 | 100% |
| Total Life Sciences | 4,182 | | 2,961 | |
| Total accounts receivable – net | \$ 10,198 | | \$ 9,141 | |

The Company's ability to collect outstanding receivables from third party payers is critical to its operating performance and cash flows. The primary collection risk lies with uninsured patients or patients for whom primary insurance has paid but a patient portion remains outstanding. The Company assesses the current state of its billing functions in order to identify any known collection or reimbursement issues. The Company assesses the impact, if any, on the allowance estimates, which involves Company's management judgment. It is important to note that the collection of these receivables is not guaranteed from Third Party Payers. The Company believes that the collectability of its receivables is directly linked to the quality of its billing processes, most notably, those related to obtaining the accurate patient information to effectively bill for the services provided. Should circumstances change (e.g. shift in payer mix, decline in economic conditions or deterioration in aging of receivables), our estimates of net realizable value of receivables could be reduced by a material amount. As of July 31, 2021, approximately 27% of Clinical Labs receivables are from two payers other than Medicare.

Billing for laboratory services is complicated due to several factors, including, but not limited to, the differences between our standard gross fee schedule for all payers and the reimbursement rates of the various payers we deal with, disparity of coverage and information requirements among the various payers, and disputes with payers as to which party is responsible for reimbursement.

Income Taxes

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

Inventory

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

Goodwill and Intangible Assets

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

The Company tests goodwill annually as of the first day of the fourth quarter, or more frequently if indicators of potential impairment exist. In assessing goodwill for impairment, the Company has the option to first perform a qualitative assessment to determine whether the existence of events or circumstances leads to a determination that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If the Company determines that it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, the Company is not required to perform any additional tests in assessing goodwill for impairment. However, if the Company concludes otherwise or elects not to perform the qualitative assessment, then it identifies the reporting units and compares the fair value of each of these reporting units to their respective carrying amount. If the carrying amount of the reporting unit is less than its fair value, no impairment exists. If the carrying amount of the reporting unit is higher than its fair value, the impairment charge is the amount by which the carrying amount exceeds its fair value, not to exceed the total amount of goodwill allocated to the reporting unit.

The Company reviews the recoverability of the carrying value of long-lived assets (including intangible assets with finite lives) of an asset or asset group for impairment annually as of the end of the fiscal year, or more frequently if indicators of potential impairment exist. Should indicators of impairment exist, the carrying values of the assets are evaluated in relation to the operating performance and future undiscounted cash flows of an asset or asset group. The net book value of the long lived asset is adjusted to fair value if its expected future undiscounted cash flow is less than its book value.

During fiscal years 2021, 2020 and 2019, there was no impairment of goodwill or long-lived assets.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

Foreign Currency Exchange Rate Risk

The financial reporting of our non-U.S. subsidiaries is denominated in currencies other than the U.S. dollar. Since the functional currency of our non-U.S. subsidiaries is the local currency, foreign currency translation adjustments are accumulated as a component of accumulated other comprehensive income in stockholders' equity. Assuming a hypothetical decline of 10% in the exchange rates of foreign currencies against the U.S. dollar at July 31, 2021, our assets and liabilities would decrease by \$0.4 million and \$0.1 million, respectively, and our net sales and net earnings (loss) would decrease by \$1.0 million and \$0.1 million, respectively, on an annual basis.

We also maintain intercompany balances and loans receivable with subsidiaries with different local currencies. These amounts are at risk of foreign exchange losses if exchange rates fluctuate. Assuming a hypothetical increase of 10% in the exchange rates of foreign currencies against the U.S. dollar at July 31, 2020, our pre-tax earnings (loss) would be unfavorably impacted by approximately \$1.8 million on an annual basis.

Interest Rate Risk

As of July 31, 2021, we have fixed interest rate financing on mortgage debt and equipment finance leases.

Item 8. Financial Statements and Supplementary Data

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

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

None.

Item 9A. Controls and Procedures

1. Disclosure Controls and Procedures

We maintain disclosure controls and procedures (Disclosure Controls) within the meaning of Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our Disclosure Controls are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act, such as this Annual Report on Form 10-K, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Our Disclosure Controls are also designed to ensure 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. In designing and evaluating our Disclosure Controls, 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, and management necessarily applied its judgment in evaluating and implementing possible controls and procedures.

As of the end of the period covered by this Annual Report on Form 10-K, we evaluated the effectiveness of the design and operation of our Disclosure Controls, which was done under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer. Based on the evaluation of our Disclosure Controls, our Chief Executive Officer and Chief Financial Officer have concluded that, as of July 31, 2021, our Disclosure Controls were effective to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and 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.

2. Change in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the year ended July 31, 2021, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

3. Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, a company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect of our consolidated financial statements.

There are inherent limitations on the effectiveness of any system of internal controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures may deteriorate. Accordingly, even effective internal controls and procedures can only provide reasonable assurance of achieving their control objectives.

Management assessed the effectiveness of our internal control over financial reporting as of July 31, 2021. In making this assessment, management used the criteria established in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on this assessment, management has concluded that, as of July 31, 2021, our internal control over financial reporting was effective.

Item 9B. Other Information

None

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required under this item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission on or before November 24, 2021 and is incorporated herein by reference.

Item 11. Executive Compensation

The information required under this item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission on or before November 24, 2021 and is incorporated herein by reference.

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

The information required under this item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission on or before November 24, 2021 and is incorporated herein by reference.

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

The information required under this item will be set forth in the Company's proxy statement to be filed with the Securities and Exchange Commission on or before November 24, 2021 and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required under this item will be set forth in the Company's proxy statement expected to be filed with the Securities and Exchange Commission on or before November 24, 2021 and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

- (a) (1) [Consolidated Financial Statements](#)
 - [Consolidated Balance Sheets - July 31, 2021 and 2020](#)
 - [Consolidated Statements of Operations - Years ended July 31, 2021, 2020 and 2019](#)
 - [Consolidated Statements of Comprehensive Income \(Loss\) - Years ended July 31, 2021, 2020 and 2019](#)
 - [Consolidated Statements of Stockholders' Equity - Years ended July 31, 2021, 2020 and 2019](#)
 - [Consolidated Statements of Cash Flows - Years ended July 31, 2021, 2020 and 2019](#)
 - [Notes to Consolidated Financial Statements](#)
- (2) Financial Statement Schedule

Schedule II - Valuation and Qualifying Accounts

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

(3) Exhibits

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

| Exhibit No. | Description |
|--------------------|---|
| 3(a) | Certificate of Incorporation (1) |
| 3(b) | Certificate of Incorporation, as amended on March 17, 1980. (1) |
| 3(c) | Certificate of Amendment of the Certificate of Incorporation as amended on June 16, 1981. (2) |
| 3(d) | Certificate of Amendment to the Certificate of Incorporation as of July 22, 1988. (3) |
| 3(e) | Amended and restated Bylaws (4) |
| 3(f) | Amended and restated Bylaws (29) |
| 3(g) | Amended and restated Bylaws (31) |
| 10(a) | 1994 Stock Option Plan (5) |
| 10 (b) | 1999 Stock Option Plan (6) |
| 10 (c) | 2005 Equity Compensation Incentive Plan (7) |
| 10 (d) | 2011 Incentive Plan (8) |
| 10 (e) | Lease agreement with Pari Management (9) |
| 10 (f) | Settlement and Release Agreement between the Company and Sigma Aldrich (10) |

| | |
|----------|--|
| 10 (g) | <u>Stock Purchase Agreement By and Among Enzo Life Sciences, Inc., Axxora Life Sciences Inc., and the Stock holders, Option holders and Warrant holders (12)</u> |
| 10 (h) | <u>Stock Asset Purchase Agreement By and Among Buyer Parties and Seller Parties with respect to the Biomol International and affiliate acquisition (13)</u> |
| 10 (i) | <u>Asset Purchase Agreement By and Among Enzo Life Sciences, Acquisition, Inc. and Assay Designs, Inc.(14)</u> |
| 10 (j) | <u>Amendment No. 1 to Amended and Restated Employment Agreement with Elazar Rabbani (15)</u> |
| 10 (k) | <u>Amendment No. 1 to Amended and Restated Employment Agreement with Barry Weiner (15)</u> |
| 10 (l) | <u>Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co, as sales agent (16)</u> |
| 10 (m) | <u>Revolving Loan and Security Agreement among the Enzo Biochem, Inc., Enzo Clinical Labs, Inc., Enzo Life Sciences, Inc., Axxora, LLC and Enzo Realty, LLC as borrowers, and Enzo Therapeutics, Inc. as a guarantor, and Healthcare Finance Group, LLC as Lender (17)</u> |
| 10 (n) | <u>Settlement and Release Agreement between the Company and Affymetrix (18)</u> |
| 10 (o) | <u>Settlement and Release Agreement between the Company and PerkinElmer (19)</u> |
| 10 (p) | <u>Settlement and Release Agreement between the Company and U.S. Department of Justice (20)</u> |
| 10 (q) | <u>Settlement and Release Agreement between the Company and Luminex Corporation (21)</u> |
| 10 (r) | <u>Settlement and Release Agreement between the Company and Siemens Healthcare Diagnostics Inc. (22)</u> |
| 10 (s) | <u>Amendment of Lease with Pari Management (23)</u> |
| 10 (t) | <u>Settlement and Release Agreement between the Company and Affymetrix (24)</u> |
| 10 (u) | <u>Settlement and Release Agreement between the Company and Illumina, Inc. (25)</u> |
| 10 (v) | <u>Purchase and Sale Agreement by and between Building Blocks Realty Co. LLC (seller) and Enzo Realty LLC (Purchaser) (26)</u> |
| 10 (w) | <u>Settlement Release Agreement between the Company and Roche Diagnostics GmbH and Roche Molecular Systems Inc. (27)</u> |
| 10 (y) | <u>Settlement Release Agreement between the Company and Hologic, Inc., Grifolds, S.A. and Grifolds Diagnostic Solutions Inc. (28)</u> |
| 10 (z) | <u>Fee and Leasehold Mortgage and Security Agreement from the Town of Babylon Industrial Development Agency and Enzo Realty II, LLC, to Citibank, N.A. (30)</u> |
| 10 (aa) | <u>Paycheck Protection Program Loan Note (32)</u> |
| 10 (ab)* | <u>Amended and Restated 2011 Incentive Plan</u> |
| 14 (a) | <u>Code of Ethics (11)</u> |
| 21* | <u>List of subsidiaries of the Company</u> |
| 23.1* | <u>Consent of Independent Registered Public Accounting Firm</u> |

| | |
|----------|--|
| 31 (a)* | Certification of CEO Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 31 (b)* | Certification of CFO Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 32 (a)* | Certification of CEO Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 32 (b)* | Certification of CFO Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 101.INS* | Inline XBRL Instance Document |
| 101.SCH* | Inline XBRL Taxonomy Extension Schema Document. |
| 101.CAL* | Inline XBRL Taxonomy Extension Calculation Linkbase Document. |
| 101.DEF* | Inline XBRL Taxonomy Extension Definition Linkbase Document. |
| 101.LAB* | Inline XBRL Taxonomy Extension Label Linkbase Document. |
| 101.PRE* | Inline XBRL Taxonomy Extension Presentation Linkbase Document. |
| 104* | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101). |

Notes to exhibits

* Filed herewith

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

- (1) The exhibits were filed as exhibits to the Company's Registration Statement on Form S-18 (File No. 2-67359) and are incorporated herein by reference.
- (2) This exhibit was filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended July 31, 1981 and is incorporated herein by reference.
- (3) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 1989 and is incorporated herein by reference.
- (4) This exhibit was filed with the Company's Current Report on Form 8-K dated January 22, 2013 and is incorporated herein by reference.
- (5) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 1995 and is incorporated herein by reference.
- (6) This exhibit was filed with the Company's Registration Statement on Form S-8 (333-87153) and is incorporated herein by reference.
- (7) This exhibit was filed with the Company's Proxy Statement on Schedule 14A filed on November 26, 2004 and is incorporated herein by reference.
- (8) This exhibit was filed as appendix B to the Company's Definitive Proxy Statement on Schedule 14A, which was filed on November 16, 2010 and is incorporated herein by reference.
- (9) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 2005 and is incorporated herein by reference.
- (10) This exhibit was filed with the Company's Current Report on Form 8-K on September 21, 2006 and is incorporated herein by reference.

- (11) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 2003 and is incorporated here by reference.
- (12) This exhibit was filed with the Company's Current Report on Form 8-K on May 30, 2007 and is incorporated herein by reference.
- (13) This exhibit was filed with the Company's Current Report on Form 8-K on May 8, 2008 and is incorporated herein by reference.
- (14) This exhibit was filed with the Company's Current Report on Form 8-K on March 13, 2009 and is incorporated herein by reference.
- (15) This exhibit was filed with the Company's Current Report on Form 8-K on January 10, 2017 and is incorporated herein by reference.
- (16) This exhibit was filed with the Company's Current Report on Form 8-K on March 28, 2013 and incorporated herein by reference.
- (17) This exhibit was filed with the Company's Current Report on Form 10-K for the year ended July 31, 2013 and incorporated herein by reference.
- (18) This exhibit was filed with the Company's Current Report on Form 8-K on April 24, 2014 and incorporated herein by reference.
- (19) This exhibit was filed with the Company's Current Report on Form 8-K on June 23, 2014 and incorporated herein by reference.
- (20) This exhibit was filed with the Company's Current Report on Form 10-K for the year ended July 31, 2014 and is incorporated herein by reference.
- (21) This exhibit was filed with the Company's Current Report on Form 8-K on July 7, 2015 and incorporated herein by reference.
- (22) This exhibit was filed with the Company's Current Report on Form 8-K on July 22, 2015 and incorporated herein by reference.
- (23) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 2015 and is incorporated herein by reference.
- (24) This exhibit was filed with the Company's Current Report on Form 8-K on October 13, 2015 and incorporated herein by reference.
- (25) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 2016.
- (26) This exhibit was filed with the Company's Annual Report on Form 10-K for the year ended July 31, 2018 and is incorporated herein by reference.
- (27) This exhibit was filed with the Company's Current Report on Form 8-K on February 11, 2019 and is incorporated herein by reference.
- (28) This exhibit was filed with the Company's Current Report on Form 8-K on April 22, 2019 and is incorporated herein by reference.
- (29) This exhibit was filed with the Company's Current Report on Form 8-K on December 3, 2018 and is incorporated herein by reference.
- (30) This exhibit was filed with the Company's Current Report on Form 8-K on November 21, 2018 and is incorporated herein by reference.
- (31) This exhibit was filed with the Company's Current Report on Form 8-K on March 2, 2020 and is incorporated herein by reference.
- (32) This exhibit was filed with the Company's Current Report on Form 8-K on April 24, 2020 and is incorporated herein by reference.

SIGNATURES

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

ENZO BIOCHEM, INC.

Date: October 12, 2021

By: /s/ Elazar Rabbani Ph.D.
Elazar Rabbani Ph.D.
Chairman of the Board, Chief Executive Officer

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

By: /s/ Elazar Rabbani October 12, 2021
Elazar Rabbani, Ph.D.,
Chairman of Board of Directors and Secretary
(Principal Executive Officer)

By: /s/ Barry W. Weiner October 12, 2021
Barry W. Weiner,
President and Treasurer

By: /s/ David Bench October 12, 2021
David Bench,
Chief Financial Officer,
Principal Accounting Officer

By: /s/ Dov Perlysky October 12, 2021
Dov Perlysky, Director

By: /s/ Mary Tagliaferri October 12, 2021
Mary Tagliaferri, M.D., Director

By: /s/ Rebecca J. Fischer October 12, 2021
Rebecca J. Fischer, Director

By: /s/ Ian B. Walters October 12, 2021
Ian B. Walters, M.D., Director

ENZO BIOCHEM, INC.

**LIST OF CONSOLIDATED FINANCIAL STATEMENTS AND
FINANCIAL STATEMENT SCHEDULE**

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

| | |
|--|-----|
| List of Consolidated Financial Statements and Financial Statements Schedule | F-1 |
| Report of Independent Registered Public Accounting Firm | F-2 |
| Consolidated Balance Sheets - July 31, 2021 and 2020 | F-3 |
| Consolidated Statements of Operations - Years ended July 31, 2021, 2020 and 2019 | F-4 |
| Consolidated Statements of Comprehensive Income (Loss) - Years ended July 31, 2021, 2020 and 2019 | F-5 |
| Consolidated Statements of Stockholders' Equity - Years ended July 31, 2021, 2020 and 2019 | F-6 |
| Consolidated Statements of Cash Flows - Years ended July 31, 2021, 2020 and 2019 | F-7 |
| Notes to Consolidated Financial Statements | F-8 |
| Schedule II - Valuation and Qualifying Accounts - As of and for the Years ended July 31, 2021, 2020 and 2019 | S-1 |

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Enzo Biochem, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Enzo Biochem, Inc. and subsidiaries (the “Company”) as of July 31, 2021 and 2020, and the related consolidated statements of operations, comprehensive income (loss), stockholders’ equity, and cash flows for each of the years in the three-year period ended July 31, 2021, and the related notes and the financial statement schedule identified in Item 15 (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of July 31, 2021 and 2020, and the consolidated results of their operations and their cash flows for each of the years in the three-year period ended July 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Valuation Clinical Labs – Contractual Adjustment

As described in Notes 1 and 3 to the consolidated financial statements, the Company’s Clinical Labs net revenues and accounts receivables are recorded among four payer categories, which include third-party payers, Medicare, Health Maintenance Organizations (HMO’s), and patient self-pay. The Clinical Labs net accounts receivables were \$6 million as of July 31, 2021, and the Clinical Labs revenues were \$87 million for the year ended July 31, 2021. Management’s process to determine the amount of consideration it expects to receive from its payer categories is based on the amounts billed, net of a contractual adjustment for differences between the amounts billed and the estimated consideration Clinical Labs expects to receive from such payers, which considers historical collection experience, payer denials, terms of contractual arrangements, and other external factors that could affect the collectability of its receivables.

We identified the valuation of the contractual adjustment for Clinical Labs revenues and related accounts receivables as a critical audit matter due to the significant judgment and estimation by management to determine the contractual adjustment. This in turn led to a high degree of auditor judgment and subjectivity, and significant audit effort was required in performing procedures to evaluate the valuation of the contractual adjustment for Clinical Labs revenues and related accounts receivables.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements.

We obtained an understanding of and evaluated the design of controls relating to the valuation of the contractual adjustment for Clinical Labs revenues and related accounts receivables. Our procedures included, among others, testing management’s process for developing the estimate for the contractual adjustments, including evaluating the appropriateness of the methodology, testing the accuracy of the billing and collection data, which is used as an input in management’s analysis, and performing a retrospective analysis of actual cash collected to the prior year estimate of net accounts receivables.

/s/ EisnerAmper LLP

We have served as the Company’s auditor since 2013.

EISNERAMPER LLP
New York, New York
October 12, 2021

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

| | <u>July 31,</u> <u>2021</u> | <u>July 31,</u> <u>2020</u> |
|---|--------------------------------|--------------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 13,524 | \$ 47,865 |
| Marketable securities | 29,978 | — |
| Accounts receivable, net | 10,198 | 9,141 |
| Inventories | 12,652 | 7,784 |
| Prepaid expenses | 4,230 | 3,975 |
| Total current assets | <u>70,582</u> | <u>68,765</u> |
| Property, plant, and equipment, net | 16,585 | 14,482 |
| Right-of-use assets | 17,020 | 19,916 |
| Goodwill | 7,452 | 7,452 |
| Intangible assets, net | 244 | 538 |
| Other, including restricted cash of \$750 | 1,808 | 1,385 |
| Total assets | <u>\$ 113,691</u> | <u>\$ 112,538</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable - trade | 8,123 | 8,503 |
| Accrued liabilities | 14,301 | 12,833 |
| Current portion of operating lease liabilities | 3,419 | 4,121 |
| Other current liabilities and finance leases short term | 233 | 344 |
| Other short term debt | — | 7,000 |
| Total current liabilities | <u>26,076</u> | <u>32,801</u> |
| Other liabilities and finance leases long term | 115 | 192 |
| Operating lease liabilities, non-current | 14,558 | 16,679 |
| Long term debt - net | 4,356 | 4,485 |
| Total liabilities | <u>\$ 45,105</u> | <u>\$ 54,157</u> |
| Commitments and contingencies – see Notes 15 and 16 | | |
| Stockholders' equity: | | |
| Preferred Stock, \$.01 par value; authorized 25,000,000 shares; no shares issued or outstanding | — | — |
| Common Stock, \$.01 par value; authorized 75,000,000 shares; shares issued and outstanding: 48,471,771 at July 31, 2021 and 47,895,050 at July 31, 2020 | 485 | 479 |
| Additional paid-in capital | 337,126 | 334,473 |
| Accumulated deficit | (270,377) | (278,252) |
| Accumulated other comprehensive income | 1,352 | 1,681 |
| Total stockholders' equity | <u>68,586</u> | <u>58,381</u> |
| Total liabilities and stockholders' equity | <u>\$ 113,691</u> | <u>\$ 112,538</u> |

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

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

| | Years ended July 31, | | |
|---|----------------------|--------------------|-----------------|
| | 2021 | 2020 | 2019 |
| Revenues | \$ 117,731 | \$ 76,021 | \$ 81,170 |
| Operating costs, expenses and legal settlements, net: | | | |
| Cost of revenues | 64,154 | 52,251 | 57,922 |
| Research and development | 3,252 | 4,448 | 3,175 |
| Selling, general, and administrative | 44,905 | 42,960 | 44,265 |
| Legal and related expenses | 4,728 | 6,729 | 3,000 |
| Legal settlements, net | — | — | (28,925) |
| Total costs, expenses and legal settlements, net | <u>117,039</u> | <u>106,388</u> | <u>79,437</u> |
| Operating income (loss) | 692 | (30,367) | 1,733 |
| Other income (expense): | | | |
| Interest | 8 | 454 | 1,056 |
| Other | 6,905 | 488 | 382 |
| Foreign exchange gain (loss) | <u>270</u> | <u>905</u> | <u>(682)</u> |
| Income (loss) before income taxes | 7,875 | (28,520) | 2,489 |
| Income taxes | — | — | — |
| Net income (loss) | <u>\$ 7,875</u> | <u>\$ (28,520)</u> | <u>\$ 2,489</u> |
| Net (loss) income per common share: | | | |
| Basic | <u>\$ 0.16</u> | <u>\$ (0.60)</u> | <u>\$ 0.05</u> |
| Diluted | <u>\$ 0.16</u> | <u>\$ (0.60)</u> | <u>\$ 0.05</u> |
| Weighted average common shares outstanding: | | | |
| Basic | <u>48,191</u> | <u>47,696</u> | <u>47,351</u> |
| Diluted | <u>48,325</u> | <u>47,696</u> | <u>47,476</u> |

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

ENZO BIOCHEM, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(in thousands)

| | Years Ended July 31, | | |
|--|----------------------|-------------|----------|
| | 2021 | 2020 | 2019 |
| Net income (loss) | \$ 7,875 | \$ (28,520) | \$ 2,489 |
| Other comprehensive (loss) income: | | | |
| Foreign currency translation adjustments | (329) | (899) | 480 |
| Comprehensive income (loss) | \$ 7,546 | \$ (29,419) | \$ 2,969 |

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

ENZO BIOCHEM, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
Years ended July 31, 2021, 2020, and 2019
(in thousands, except share data)

| | <i>Common Stock Shares Issued</i> | Common Stock Amount | Additional Paid-in Capital | Accumulated Deficit | Accumulated Other Comprehensive Income | Total Stockholders' Equity |
|--|---|------------------------------------|---|--------------------------------|---|---|
| Balance at July 31, 2018 | 47,182,254 | \$ 472 | \$ 330,770 | \$ (252,221) | \$ 2,100 | \$ 81,121 |
| Net income for the year ended July 31, 2019 | — | — | — | 2,489 | — | 2,489 |
| Vesting of restricted stock | 986 | — | — | — | — | — |
| Share-based compensation charges | — | — | 939 | — | — | 939 |
| Net issuance of common stock for employee 401(k) plan match | 315,472 | 3 | 829 | — | — | 832 |
| Net issuance of common stock for options exercise by Directors | 23,376 | — | — | — | — | — |
| Net exercise of stock options | 34,719 | 1 | 166 | — | — | 167 |
| Foreign currency translation adjustments | — | — | — | — | 480 | 480 |
| Balance at July 31, 2019 | <u>47,556,807</u> | <u>\$ 476</u> | <u>\$ 332,704</u> | <u>\$ (249,732)</u> | <u>\$ 2,580</u> | <u>\$ 86,028</u> |
| Net (loss) for the year ended July 31, 2020 | — | — | — | (28,520) | — | (28,520) |
| Vesting of restricted stock | 811 | — | — | — | — | — |
| Issuance of common stock for share-based compensation | 4,167 | — | 10 | — | — | 10 |
| Share-based compensation charges | — | — | 923 | — | — | 923 |
| Issuance of common stock for employee 401(k) plan match | 333,265 | 3 | 836 | — | — | 839 |
| Foreign currency translation adjustments | — | — | — | — | (899) | (899) |
| Balance at July 31, 2020 | <u>47,895,050</u> | <u>\$ 479</u> | <u>\$ 334,473</u> | <u>\$ (278,252)</u> | <u>\$ 1,681</u> | <u>\$ 58,381</u> |
| | <i>Common Stock Shares Issued</i> | Common Stock Amount | Additional Paid-in Capital | Accumulated Deficit | Accumulated Other Comprehensive Income | Total Stockholders' Equity |
| Net income for the year ended July 31, 2021 | — | — | — | 7,875 | — | 7,875 |
| Vesting of restricted stock | 817 | — | — | — | — | — |
| Exercise of stock options | 34,667 | 1 | 96 | — | — | 97 |
| Issuance of common stock for previously accrued bonuses | 332,700 | 3 | 872 | — | — | 875 |
| Share-based compensation charges | — | — | 907 | — | — | 907 |
| Issuance of common stock for employee 401(k) plan match | 208,537 | 2 | 778 | — | — | 780 |
| Foreign currency translation adjustments | — | — | — | — | (329) | (329) |
| Balance at July 31, 2021 | <u>48,471,771</u> | <u>\$ 485</u> | <u>\$ 337,126</u> | <u>\$ (270,377)</u> | <u>\$ 1,352</u> | <u>\$ 68,586</u> |

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

ENZO BIOCHEM, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

| | Years ended July 31, | | |
|---|----------------------|-------------|-----------|
| | 2021 | 2020 | 2019 |
| Cash flows from operating activities: | | | |
| Net income (loss) | \$ 7,875 | \$ (28,520) | \$ 2,489 |
| Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities: | | | |
| Depreciation and amortization of property, plant and equipment | 2,332 | 2,256 | 2,194 |
| Amortization of intangible assets | 321 | 524 | 842 |
| Share-based compensation charges | 907 | 933 | 939 |
| Share-based 401(k) employer match expense | 731 | 836 | 855 |
| Foreign exchange (gain) loss | (88) | (1,165) | 493 |
| Unrealized loss on marketable securities | 83 | — | — |
| Paycheck Protection Program (PPP) loan forgiveness | (7,000) | — | — |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | (1,110) | 1,617 | 2,404 |
| Inventories | (4,937) | 85 | (572) |
| Prepaid expenses and other assets | (707) | (216) | (182) |
| Accounts payable - trade | (395) | 1,214 | (2,508) |
| Accrued liabilities, other current liabilities and other liabilities | 2,375 | 5,257 | (2,148) |
| Total adjustments | (7,488) | 11,341 | 2,317 |
| Net cash provided by (used in) operating activities | 387 | (17,179) | 4,806 |
| Cash flows from investing activities: | | | |
| Capital expenditures | (4,436) | (2,170) | (8,126) |
| Purchases of marketable securities | (30,061) | — | — |
| Net cash used in investing activities | (34,497) | (2,170) | (8,126) |
| Cash flows from financing activities: | | | |
| Proceeds from borrowings under government programs and mortgage agreement | — | 7,412 | 4,500 |
| Repayments under mortgage agreement and capital leases | (339) | (411) | (404) |
| Cost to obtain loan | — | — | (70) |
| Proceeds from exercise of stock options | 97 | — | 167 |
| Net cash (used in) provided by financing activities | (242) | 7,001 | 4,193 |
| Effect of exchange rate changes on cash and cash equivalents | 11 | 67 | (18) |
| (Decrease) increase in cash and cash equivalents and restricted cash | (34,341) | (12,281) | 855 |
| Cash and cash equivalents and restricted cash - beginning of year | 48,615 | 60,896 | 60,041 |
| Cash and cash equivalents and restricted cash - end of year | \$ 14,274 | \$ 48,615 | \$ 60,896 |
| Composition of cash and cash equivalents and restricted cash is as follows: | | | |
| Cash and cash equivalents | 13,524 | 47,865 | 60,146 |
| Restricted cash | 750 | 750 | 750 |
| Total cash and cash equivalents and restricted cash | \$ 14,274 | \$ 48,615 | \$ 60,896 |

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

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
July 31, 2021
(Dollars in thousands except share data)

Note 1 - Summary of significant accounting policies

Nature of business

Enzo Biochem, Inc. (the “Company”) is an integrated diagnostics, clinical lab, and life sciences company engaged in research, development, manufacturing and marketing of diagnostic and research products based on genetic engineering, biotechnology and molecular biology. These products are designed for the diagnosis of and/or screening for infectious diseases, cancers, genetic defects and other medically pertinent diagnostic information and are distributed in the United States and internationally. The Company is conducting research and development activities in the development of therapeutic products based on the Company’s technology platform of genetic modulation and immune modulation. The Company also operates a clinical laboratory that offers and provides molecular and esoteric diagnostic medical testing services in the New York, New Jersey, and Connecticut medical communities. The Company operates in three segments (see Note 17).

Impact of COVID-19 pandemic

While the rate of transmission of COVID-19 fluctuates in the US and Europe, it continues to spread in other parts of the world and negatively impact the world economy. Federal, state and local governmental policies and initiatives designed to reduce the transmission of COVID-19 have resulted in, among other things, a significant reduction in physician office visits, the cancellation of elective medical procedures, customers of our products remaining closed or continuing to severely curtail their operations (voluntarily or in response to government orders), and the continuation of work-from-home or shelter-in-place policies. The COVID-19 impact on the Company’s operations is consistent with the overall industry and publicly issued statements from competitors, partners, and vendors.

During the fiscal year ended July 31, 2021, the Company generated substantial increases in COVID-19 related products and services. Enzo applied its technical expertise in molecular diagnostics to develop next generation COVID-19 diagnostic and antibody testing options which were approved under the FDA Emergency Use Authorization (EUA). This testing had a positive impact on revenue, profitability and cash flow throughout fiscal 2021. Revenues from COVID-19 testing represented 48% and 8% of Clinical revenues in the 2021 and 2020 periods, respectively. However, it is too early to determine the long term significance of any positive impact from increased COVID-19 testing and our proprietary COVID-19 product offerings on our businesses.

The extent to which our businesses may continue to be affected by the COVID-19 pandemic will largely depend on both current and future developments, including its duration, the emergence and spread of variants, its treatment with authorized vaccines and vaccines in various stages of development and federal approval, work and travel advisories and restrictions, and the timing of their easing, all of which are highly uncertain and cannot be reasonably predicted at this time. Global supply chain issues due to the pandemic continue to hamper both the manufacturing of products within the life science segment as well as testing capabilities in the clinical laboratory.

The extent to which the COVID-19 pandemic impacts the Company’s business and consolidated results of operations, financial position and cash flows will depend on numerous evolving factors including, but not limited to: the magnitude and duration of the COVID-19 pandemic, the extent to which it will impact worldwide macroeconomic conditions including, but not limited to, employment rates and health insurance coverage, the speed of the anticipated recovery, and governmental and business reactions to the pandemic. These factors are beyond the Company’s knowledge and control, and as a result, at this time the Company cannot reasonably estimate the adverse impact the COVID-19 pandemic will have on its businesses but the adverse impact could be material. The Company assessed certain accounting matters that generally require consideration of forecasted financial information in context with the information reasonably available to the Company and the unknown future impacts of COVID-19 as of July 31, 2021 and through the date of this report. The accounting matters assessed included, but were not limited to, the Company’s patient self-pay revenue concessions and credit losses in the Clinical Services segment, accounts receivable, inventories and the carrying value of goodwill and other long-lived assets. The Company’s future assessment of the magnitude and duration of COVID-19, as well as other factors, could result in additional material impacts to the Company’s consolidated financial statements in future reporting periods. We expect COVID-19 volume to decline in the quarters ahead as the percentage of Americans who are vaccinated increases. However, the emergence and spread of variants may cause our COVID-19 testing volume to increase again. Even after the COVID-19 pandemic has moderated and the business and social distancing restrictions have eased, we may continue to experience similar adverse effects to our businesses, consolidated results of operations, financial position and cash flows resulting from a recessionary economic environment that may persist.

The Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”) was passed in March 2020 and addressed the various economic impacts of, and otherwise responds to, the COVID-19 outbreak. Under the CARES Act, we received a loan, an advance payment, and two income grants from Medicare during the latter half of our fiscal year ended July 31, 2020, all of which are further described in Note 3, Note 8 and Note 10.

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Principles of consolidation

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

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates.

Contingencies

Contingencies are evaluated and a liability is recorded when the matter is both probable and reasonably estimable. Gain contingencies are evaluated and not recognized until the gain is realizable or realized.

Foreign Currency Translation/Transactions

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

Fair Value Measurements

The Company determines fair value measurements used in its consolidated financial statements based upon the exit price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants exclusive of any transaction costs, as determined by either the principal market or the most advantageous market. Inputs used in the valuation techniques to derive fair values are classified based on a three-level hierarchy. The basis for fair value measurements for each level within the hierarchy is described below with Level 1 having the highest priority and Level 3 having the lowest.

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs are observable in active markets.

Level 3 Valuations derived from valuation techniques in which one or more significant inputs are unobservable.

Cash and cash equivalents

Cash and cash equivalents consist of demand deposits with banks and highly liquid money market funds. At July 31, 2021 and 2020, the Company had cash and cash equivalents in foreign bank accounts of \$909.

Marketable securities

The Company limits its credit risk associated with investments by investing in a mutual fund and an exchange traded fund (ETF) which hold highly rated corporate bonds, asset backed securities, municipal bonds, mortgage obligations and government obligations. These investments are classified as trading securities and are Level 1 fair value investments. As of July 31, 2021, the fair value of these investments was \$29,978 and the cost basis was \$30,061. We recognized unrealized losses of \$83 for the fiscal year ended July 31, 2021.

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Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of cash and cash equivalents and accounts receivable. The Company believes the fair value of the aforementioned financial instruments approximates the cost due to the immediate or short-term nature of these items.

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

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

Other than the Medicare program, two providers whose programs are included in the "Third party payers" and health maintenance organizations ("HMOs") categories represent 35% of Clinical Services net revenue for the year ended July 31, 2021 and represent 27% of the Clinical Services net accounts receivable as of July 31, 2021. Other than the Medicare program, one provider whose programs are included in the "Third-party payers" and "Health Maintenance Organizations" ("HMO's") categories represents 24% and 36% of Clinical Services net revenue for the years ended July 31, 2020 and 2019 respectively, and represents 16% of the Clinical Services net accounts receivable as of July 31, 2020.

Accrual for Self-Funded Employee Medical Insurance

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

Contractual Adjustment

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

During the years ended July 31, 2021, 2020 and 2019, the contractual adjustment percentages, determined using current and historical reimbursement statistics, were approximately 83%, 88% and 88%, respectively, of gross billings.

Accounts Receivable

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

The Company's ability to collect outstanding receivables from third-party payers is critical to its operating performance and cash flows. The primary collection risk lies with uninsured patients or patients for whom primary insurance has paid but a patient portion remains outstanding. In the case of COVID-19 diagnostic and antibody testing, collection risk for uninsured patients is minimized. Federal Reimbursement for Uninsured Patients Testing is processed by submitting a claim to the Health Resources and Services Administration COVID 19 Uninsured Program. This government program provides reimbursement to the Company for COVID-19 diagnostic and antibody testing provided to uninsured patients and requires specific information along with an attestation of attempts to obtain this information accurately in order to submit claims. The program will perform its own validation process and there is required information about the patient that the Company must provide to be considered for reimbursement.

The Company also assesses the current state of its billing functions in order to identify any known collection issues and to assess the impact, if any, on the allowance estimates which involves judgment. The Company believes that the collectability of its receivables is directly linked to the quality of its billing processes, most notably, those related to obtaining the correct information in order to bill effectively for the services provided. Should circumstances change (e.g. shift in payer mix, decline in economic conditions or deterioration in aging of receivables), our estimates of net realizable value of receivables could be reduced by a material amount.

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The Clinical Laboratory Services segment's net receivables are detailed by billing category and as a percent to its total net receivables. At July 31, 2021 and 2020, approximately 59% and 68% respectively, of the Company's net accounts receivable relates to its Clinical Laboratory Services business, which operates in the New York, New Jersey and Connecticut medical communities.

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

| Net accounts receivable by segment | July 31, 2021 | | July 31, 2020 | |
|---|----------------------|-------------|----------------------|-------------|
| | Amount | % | Amount | % |
| Clinical Labs (by billing category) | | | | |
| Third party payers | \$ 2,195 | 36 | \$ 2,455 | 40 |
| Patient self-pay | 2,007 | 33 | 2,044 | 33 |
| Medicare | 1,122 | 19 | 884 | 14 |
| HMO's | 692 | 12 | 797 | 13 |
| Total Clinical Labs | 6,016 | 100% | 6,180 | 100% |
| Total Life Sciences | 4,182 | | 2,961 | |
| Total accounts receivable – net | \$ 10,198 | | \$ 9,141 | |

Inventories

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

Property, plant and equipment

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

Goodwill and Intangible Assets

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

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

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Impairment testing for Goodwill and Long-Lived Assets

The Company tests goodwill annually as of the first day of the fourth quarter, or more frequently if indicators of potential impairment exist. In assessing goodwill for impairment, the Company has the option to first perform a qualitative assessment to determine whether the existence of events or circumstances leads to a determination that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If the Company determines that it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, the Company is not required to perform any additional tests in assessing goodwill for impairment. However, if the Company concludes otherwise or elects not to perform the qualitative assessment, then it identifies the reporting units and compares the fair value of each of these reporting units to their respective carrying amount. If the carrying amount of the reporting unit is less than its fair value, no impairment exists. If the carrying amount of the reporting unit is higher than its fair value, the impairment charge is the amount by which the carrying amount exceeds its fair value, not to exceed the total amount of goodwill allocated to the reporting unit. The Company performed a quantitative assessment in 2021, 2020 and 2019, and concluded there were no goodwill impairments.

The Company reviews the recoverability of the carrying value of long-lived assets (including its intangible assets, all of which have finite lives) of an asset or asset group for impairment annually as of the end of the fiscal year, or more frequently if indicators of potential impairment exist. Should indicators of impairment exist, the carrying values of the assets are evaluated in relation to the operating performance and future undiscounted cash flows of an asset or asset group. The net book value of the long lived asset is adjusted to fair value if its expected future undiscounted cash flow is less than its book value. There were no long-lived asset impairments in 2021, 2020 or 2019. Should the impact of the COVID-19 pandemic be significantly worse than currently expected, it is possible that we could incur impairment charges on goodwill and other long lived assets in the future.

Comprehensive income (loss)

Comprehensive income (loss) consists of the Company's consolidated net income (loss) and foreign currency translation adjustments. Foreign currency translation adjustments included in comprehensive income (loss) were not tax effected as the Company has a full valuation allowance at July 31, 2021. Accumulated other comprehensive income is a separate component of stockholders' equity and consists of the cumulative foreign currency translation adjustments.

Shipping and Handling Costs

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

Research and Development

Research and development costs are charged to expense as incurred.

Advertising

All costs associated with advertising are expensed as incurred. Advertising expense, included in selling, general and administrative expense, approximated \$400, \$437 and \$374 for the years ended July 31, 2021, 2020 and 2019, respectively.

Income Taxes

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

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

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It is the Company's policy to provide for uncertain tax positions and the related interest and penalties based upon management's assessment of whether a tax benefit is more likely than not to be sustained upon examination by tax authorities. At July 31, 2021, the Company believes it has appropriately accounted for any unrecognized tax benefits. To the extent the Company prevails in matters for which a liability for an unrecognized tax benefit is established or is required to pay amounts in excess of the liability, the Company's effective tax rate in a given financial statement period may be affected.

Segment Reporting

The Company separately reports information about each operating segment that engages in business activities from which the segment may earn revenues and incur expenses, whose separate operating results are regularly reviewed by the chief operating decision maker regarding allocation of resources and performance assessment and which exceed specific quantitative thresholds related to revenue and profit or loss. The Company's operating activities are reported in three segments (see Note 17).

Net income (loss) per share

Basic net income (loss) per share represents net income (loss) divided by the weighted average number of common shares outstanding during the period. The dilutive effect of potential common shares, consisting of outstanding stock options and unvested restricted stock, is determined using the treasury stock method. For fiscal 2021 and 2019, approximately 134,000 and 125,000 respectively, of weighted average stock options were included in the calculation of diluted weighted average shares outstanding. Diluted weighted average shares outstanding for fiscal 2020 does not include the potential common shares from stock options and unvested restricted stock because to do so would have been antidilutive and as such is the same as basic weighted average shares outstanding for 2020. The number of potential common shares ("in the money options") and unvested restricted stock excluded from the calculation of diluted weighted average shares outstanding for the year ended July 31, 2020 was 40,000.

For the years ended July 31, 2021, 2020 and 2019, the effect of approximately 1,465,000, 1,904,000 and 1,324,000 respectively, of outstanding "out of the money" options to purchase common shares were excluded from the calculation of diluted weighted average shares outstanding because their effect would be anti-dilutive. The following table sets forth the computation of basic and diluted net income (loss) per share for the years ended July 31:

| | <u>2021</u> | <u>2020</u> | <u>2019</u> |
|--|---------------|---------------|---------------|
| Net income (loss) | \$ 7,875 | \$ (28,520) | \$ 2,489 |
| Weighted-average common shares outstanding – basic | 48,191 | 47,696 | 47,351 |
| Add: effect of dilutive stock options and restricted stock | 134 | — | 125 |
| Weighted-average common shares outstanding – diluted | <u>48,325</u> | <u>47,696</u> | <u>47,476</u> |
| Net (loss) income per share – basic | \$ 0.16 | \$ (0.60) | \$ 0.05 |
| Net (loss) income per share – diluted | \$ 0.16 | \$ (0.60) | \$ 0.05 |

Share-Based Compensation

The Company records compensation expense associated with stock options and restricted stock based upon the fair value of stock based awards as measured at the grant date. The Company determines the award values of stock options using the Black Scholes option pricing model. The expense is recognized by amortizing the fair values on a straight-line basis over the vesting period, adjusted for forfeitures when they occur.

For the years ended July 31, 2021, 2020 and 2019, share-based compensation expense relating to the fair value of stock options, restricted shares and restricted stock units was approximately \$907, \$923 and \$939, respectively (see Note 12). During the year ended July 31, 2020, the Company issued common stock as employee compensation in the amount of \$10. No excess tax benefits were recognized for the year ended July 31, 2021, 2020 and 2019.

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

| | 2021 | 2020 | 2019 |
|--------------------------------------|---------------|---------------|---------------|
| Cost of clinical laboratory services | \$ 93 | \$ 46 | \$ — |
| Selling, general and administrative | 814 | 887 | 939 |
| | <u>\$ 907</u> | <u>\$ 933</u> | <u>\$ 939</u> |

As of July 31, 2021, there was \$755 of total unrecognized compensation cost related to non-vested share-based payment arrangements granted under the Company's incentive stock plans, which will be recognized over a weighted average remaining life of approximately fifteen months.

Effect of New Accounting Pronouncements

Recently Adopted Accounting Pronouncements

On August 1, 2019, the Company adopted a new accounting standard issued by the Financial Accounting Standards Board ("FASB") on accounting for leases using the modified retrospective method. This new accounting standard requires a lessee to recognize an asset and liability for most leases on its balance sheet. The Company elected the optional transition method that allowed for a cumulative-effect adjustment to the opening balance of retained earnings recorded on August 1, 2019 and did not restate previously reported results in the comparative periods. The Company also elected the package of practical expedients, which among other things, allowed it to carry forward its historical lease classification.

As a result of adoption of the new standard, the Company recorded right-of-use assets and operating lease liabilities of approximately \$24.4 million and \$25.1 million, respectively as of August 1, 2019. The operating lease liability was determined based on the present value of the remaining minimum rental payments and the right-of-use asset was determined based on the value of the lease liability, adjusted for deferred rent balances of approximately \$0.7 million, which were previously included in accrued expenses. There was no cumulative effect adjustment to the opening balance of accumulated deficit. Accounting for the Company's finance leases remains substantially unchanged. The adoption of the new standard did not materially impact the Company's consolidated results of operations or cash flows. The adoption of this new accounting standard resulted in increased qualitative and quantitative disclosures regarding the amount, timing, and uncertainty of cash flows arising from leases.

The Company elected the package of three practical expedients. As such, the Company did not reassess whether expired or existing contracts are or contain a lease and did not need to reassess the lease classifications or reassess the initial direct costs associated with expired or existing leases. The Company did not elect the hindsight practical expedient. Further, the land easement practical expedient was not elected as the practical expedient is not applicable to the Company. The Company elected to take the practical expedient to not separate lease and non-lease components of all asset classes entered into or modified after the effective date. For further details, see Note 9.

Pronouncements Issued but Not Yet Adopted

In June 2016, FASB issued ASU No. 2016-13 Financial Instruments – Credit Losses (Topic 326). This standard changes the impairment model for most financial instruments, including trade receivables, from an incurred loss method to a new forward-looking approach, based on expected losses.

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The estimate of expected credit losses will require entities to incorporate considerations of historical information, current information and reasonable and supportable forecasts. Adoption of this standard is required for our annual and interim periods beginning August 1, 2023, provided we qualify as a smaller reporting company at the end of fiscal 2022 and must be adopted using a modified retrospective transition approach. We are currently assessing the impact of the adoption of this standard on our results of operations, financial position and cash flows.

In December 2019, the FASB issued ASU No. 2019-12 *Income Taxes (Topic 740) Simplifying the Accounting for Income Taxes*. The amendments in the ASU simplify the accounting for income taxes by removing certain exceptions to the general principles of Topic 740. The amendments also improve consistent application of and simplify U.S. GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The amendments in this ASU are required for our annual and interim periods beginning August 1, 2021. The adoption of the amendments in this ASU is not expected to have a material impact on our consolidated results of operations, financial position or cash flows.

We reviewed all other recently issued accounting pronouncements and have concluded they are not applicable or not expected to be significant to the accounting for our operations.

Reclassification

Certain prior period amounts have been reclassified to conform to the current period presentation. These reclassifications had no effect on the reported results of operations.

Note 2 – Goodwill and intangible assets

Goodwill

The Company's net carrying amount of goodwill is in the Clinical Laboratory Services segment and is \$7,452 as of July 31, 2021 and 2020.

Intangible assets

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

| | Gross | Accumulated Amortization | Net |
|------------------------------|------------------|-------------------------------------|---------------|
| July 31, 2019 | \$ 27,238 | \$ (26,206) | \$ 1,032 |
| Amortization expense | — | (524) | (524) |
| Foreign currency translation | 448 | (418) | 30 |
| July 31, 2020 | \$ 27,686 | \$ (27,148) | \$ 538 |
| Amortization expense | — | (296) | (296) |
| Foreign currency translation | 89 | (87) | 2 |
| July 31, 2021 | <u>\$ 27,775</u> | <u>\$ (27,531)</u> | <u>\$ 244</u> |

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

| | July 31, 2021 | | | July 31, 2020 | | |
|-------------------------------|----------------------|-------------------------------------|---------------|----------------------|-------------------------------------|---------------|
| | Gross | Accumulated Amortization | Net | Gross | Accumulated Amortization | Net |
| Patents | \$ 11,027 | (11,027) | \$ — | \$ 11,027 | (11,014) | \$ 13 |
| Customer relationships | 12,059 | (11,815) | 244 | 12,003 | (11,478) | 525 |
| Website and acquired content | 1,025 | (1,025) | — | 1,022 | (1,022) | — |
| Licensed technology and other | 494 | (494) | — | 483 | (483) | — |
| Trademarks | 3,170 | (3,170) | — | 3,151 | (3,151) | — |
| Total | <u>\$ 27,775</u> | <u>(27,531)</u> | <u>\$ 244</u> | <u>\$ 27,686</u> | <u>(27,148)</u> | <u>\$ 538</u> |

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At July 31, 2021, information with respect to acquired intangibles is as follows:

| | Useful life assigned | Weighted average remaining useful life |
|------------------------|---------------------------------|---|
| Customer relationships | 8-15 years | Less than 1 year |

At July 31, 2021, the weighted average remaining useful life of intangible assets was less than one year.

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

| | | |
|------|----|-----|
| 2022 | \$ | 244 |
| 2023 | | — |
| 2024 | | — |
| 2025 | | — |
| 2026 | | — |

Amortization expense for the years ended July 31, 2021, 2020, and 2019 was \$296, \$524 and \$842, respectively.

Note 3 – Revenue Recognition

Clinical Services Revenue

Service revenues in the Company's clinical services business accounted for 74%, 63% and 63% of the Company's total revenues for fiscal years ended July 31, 2021, 2020, and 2019, respectively and are primarily comprised of a high volume of relatively low-dollar transactions. The services business, which provides clinical testing services, satisfies its performance obligation and recognizes revenues upon completion of the testing process for a specific patient and reporting to the ordering physician. The Company may also perform clinical testing services for other laboratories and will recognize revenue from those services when reported to the ordering laboratory. The Company estimates the amount of consideration it expects to receive from customer groups using the portfolio approach. These estimates of the expected consideration include the impact of contractual allowances and price concessions on our customer group portfolios consisting of healthcare insurers, government payers, client payers and patients as described below. Contracts with customers in our laboratory services business do not contain a financing component, based on the typically limited period of time between performance of services and collection of consideration. The transaction price includes variable consideration in the form of the contractual allowance and price concessions as well as the collectability of the transaction based on patient intent and ability to pay. The Company uses the expected value method in estimating the amount of the variability included in the transaction price.

The following are descriptions of our laboratory services business portfolios:

Third party payers and Health Maintenance Organizations (HMO's)

Reimbursements from third party payers, primarily healthcare insurers and HMO's are based on negotiated fee-for-service schedules and on capitated payment rates. Revenues consist of amounts billed net of contractual allowances for differences between amounts billed and the estimated consideration the Company expects to receive from such payers, which considers historical collection and denial experience and the terms of the Company's contractual arrangements. Adjustments to the allowances, based on actual receipts from the third-party payers, are recorded upon settlement.

Collection of the consideration the Company expects to receive is normally a function of providing complete and correct billing information to these third party payers within the various filing deadlines, and typically occurs within 30 to 90 days of billing. Provided the Company has billed healthcare insurers accurately with complete information prior to the established filing deadline, there has historically been little to no collection risk. If there has been a delay in billing, the Company determines if the amounts in question will likely go past the filing deadline, and if so, will reserve accordingly for the billing.

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Third-party payers, including government programs, may decide to deny payment or recoup payments for testing that they contend was improperly billed or not medically necessary, against their coverage determinations, or for which they believe they have otherwise overpaid (including as a result of their own error), and we may be required to refund payments already received. Our revenues may be subject to adjustment as a result of these factors among others, including without limitation, differing interpretations of billing and coding guidance and changes by government agencies and payers in interpretations, requirements, and “conditions of participation” in various programs.

Government Payer - Medicare

Reimbursements from Medicare are based on fee-for-service schedules set by Medicare, which is funded by the government. Revenues consist of amounts billed net of contractual allowances for differences between amounts billed and the estimated consideration the Company expects to receive from Medicare, which considers historical collection and denial experience and other factors. Adjustments to the allowances, based on actual receipts from the government payers, are recorded upon settlement.

Collection of consideration the Company expects to receive is normally a function of providing the complete and correct billing information within the various filing deadlines and typically occurs within 60 days of billing. Provided the Company has billed the government payer accurately with complete information prior to the established filing deadline, there has historically been little to no collection risk. If there has been a delay in billing, the Company determines if the amounts in question will likely go past the filing deadline, and, if so, it will reserve accordingly for the billing.

Patient self pay

Uninsured patients are billed based on established patient fee schedules or fees negotiated with physicians on behalf of their patients. Coinsurance and deductible responsibilities based on fees negotiated with healthcare insurers are also billed to insured patients and included in this portfolio. Collection of billings from patients is subject to credit risk and ability of the patients to pay. Revenues consist of amounts billed net of discounts provided to uninsured patients in accordance with the Company’s policies and implicit price concessions. Implicit price concessions represent differences between amounts billed and the estimated consideration the Company expects to receive from patients, which considers historical collection experience and other factors including current market conditions. Adjustments to the estimated allowances, based on actual receipts from the patients, are recorded upon settlement. Patient responsibility is invoiced and if it reaches 91 days outstanding, the account is sent to a collection agency for further processing. After the account has been with the collection agency for at least 105 days, and is determined to be uncollectable it is written off.

The following table represents clinical services net revenues and percentages by type of customer:

| Revenue category | Year ended July 31, 2021 | | Year ended July 31, 2020 | | Year ended July 31, 2019 | |
|--------------------|--------------------------|------|--------------------------|------|--------------------------|------|
| | Revenue | % | Revenue | % | Revenue | % |
| Third-party payers | \$ 52,564 | 60 | \$ 24,893 | 52 | \$ 26,653 | 52 |
| Medicare | 13,084 | 15 | 10,825 | 23 | 10,898 | 21 |
| HMO’s | 11,878 | 14 | 5,983 | 12 | 6,213 | 12 |
| Patient self-pay | 9,458 | 11 | 6,263 | 13 | 7,351 | 15 |
| Total | \$ 86,984 | 100% | \$ 47,964 | 100% | \$ 51,115 | 100% |

For fiscal years ended July 31, 2021, 2020, and 2019 all of the Company’s clinical services revenues were generated within the United States.

Grant income

Under the CARES Act, we were eligible for and received two income grants in April and June 2020 totaling \$1,496 under the Department of Health and Human Services (HHS) Public Health and Social Services Emergency Fund for provider relief. The purpose of the payments is to reimburse the Company for health care related expenses or lost revenues attributable to COVID-19.

We certified that the grant funds were accepted per the regulations and recognized it as Grant income for the fiscal year ended July 31, 2020 in the Clinical Services segment.

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Products Revenue

Products revenues consist of the sale of single-use products used in the identification of genomic information and are recognized at a point in time following the transfer of control of such products to the customer, which generally occurs upon shipment. Payment terms for shipments to end-user and distributor customers may range from 30 to 90 days. Any claims for credit or return of goods may be made generally within 30 days of receipt. Revenues are reduced to reflect estimated credits and returns, although historically these adjustments have not been material. Taxes collected from customers relating to product sales and remitted to governmental authorities are excluded from revenue. Amounts billed to customers for shipping and handling are included in revenue, while the related shipping and handling costs are reflected in cost of products.

Products revenue by geography is as follows:

| | 2021 | 2020 | 2019 |
|------------------|------------------|------------------|------------------|
| United States | \$ 15,617 | \$ 14,824 | \$ 16,966 |
| Europe | 10,386 | 7,720 | 8,551 |
| Asia Pacific | 4,744 | 4,017 | 4,538 |
| Products revenue | <u>\$ 30,747</u> | <u>\$ 26,561</u> | <u>\$ 30,055</u> |

Note 4 - Supplemental disclosure for statement of cash flows

In the years ended July 31, 2021, 2020, and 2019, interest paid by the Company approximated \$237, \$266 and \$138, respectively.

For the years ended July 31, 2021 and 2020, the net reductions in the measurement of right of use assets and liabilities included in cash flows from operating activities was approximately \$74 and \$884, respectively. The changes are included in changes in accrued liabilities, other current liabilities, and other liabilities in the statement of cash flows.

For the years ended July 31, 2021, 2020 and 2019, tax on capital paid by the Company was \$305, \$90 and \$94, respectively.

During the years ended July 31, 2021, 2020 and 2019, the Company issued common stock in connection with its share-based 401(k) employer match in the amount of \$780, \$839 and \$832, respectively. During the year ended July 31, 2021, the Company issued 332,700 restricted shares of common stock to two senior executives in settlement of their accrued bonuses totaling \$875.

For the year ended July 31, 2020, non-cash activities related to the adoption of the new accounting standard for leases are detailed in Note 1.

During fiscal 2019, the Company entered into finance lease agreements totaling \$381 and none during fiscal years 2021 or 2020.

Note 5 - Inventories

Inventories consisted of the following at July 31:

| | 2021 | 2020 |
|-------------------|------------------|-----------------|
| Raw materials | \$ 1,062 | \$ 1,019 |
| Work in process | 2,534 | 2,587 |
| Finished products | 9,056 | 4,178 |
| | <u>\$ 12,652</u> | <u>\$ 7,784</u> |

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Note 6 - Property, plant, and equipment

At July 31, 2021 and 2020, property, plant, and equipment consist of:

| | 2021 | 2020 |
|---|------------------|------------------|
| Building and building improvements | \$ 10,310 | \$ 10,089 |
| Machinery and equipment (includes assets under finance leases - see Note 9) | 12,721 | 8,548 |
| Office furniture and computer equipment | 15,942 | 16,578 |
| Leasehold improvements | 5,692 | 5,377 |
| | <u>44,665</u> | <u>40,592</u> |
| Accumulated depreciation and amortization | (30,142) | (28,172) |
| | <u>14,523</u> | <u>12,420</u> |
| Land and land improvements | 2,062 | 2,062 |
| | <u>\$ 16,585</u> | <u>\$ 14,482</u> |

At July 31, 2021 building and building improvements include construction in progress of approximately \$100.

Note 7 - Income taxes

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

| | 2021 | 2020 | 2019 |
|--------------------------|-------------|-------------|-------------|
| Federal | \$ — | \$ — | \$ — |
| State and local | — | — | — |
| Foreign | — | — | — |
| Deferred benefit | — | — | — |
| Benefit for income taxes | <u>\$ —</u> | <u>\$ —</u> | <u>\$ —</u> |

During the fiscal year ended July 31, 2019, the Company finalized its computation of the impact of the Tax Cuts and Jobs Act of 2017 with no change to the benefit amount recorded in the prior year.

In January 2018, the FASB released guidance on the accounting for tax on the global intangible low-taxed income (“GILTI”) provisions of the Tax Act. The GILTI provisions impose a tax on foreign income in excess of a deemed return on tangible assets of foreign corporations. The guidance allows companies to make an accounting policy election to either (i) account for GILTI as a component of tax expense in the period in which they are subject to the rules (the period cost method), or (ii) account for GILTI in the Company’s measurement of deferred taxes (the deferred method). After completing the analysis of the GILTI provisions, the Company elected to account for GILTI using the period cost method.

On March 27, 2020, the CARES Act was signed into law. The CARES Act includes provisions relating to refundable payroll tax credits, deferment of the employer portion of certain payroll taxes, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. While the Company continues to evaluate the impact of the CARES Act, it does not currently believe it will have a material impact on the Company’s income taxes or related disclosures.

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

| | <u>2021</u> | <u>2020</u> |
|---|----------------|----------------|
| Deferred tax assets: | | |
| Federal tax carryforward losses | \$ 18,140 | \$ 18,173 |
| Provision for uncollectible accounts receivable | 970 | 1,079 |
| State and local tax carry forward losses | 1,658 | 1,187 |
| Accrued royalties | — | 101 |
| Stock compensation | 1,088 | 898 |
| Depreciation | 850 | 799 |
| Research and development and other tax credit carryforwards | 1,527 | 1,477 |
| Lease liabilities | 5,194 | 5,520 |
| Foreign tax carryforward losses | 2,536 | 3,357 |
| Intangibles and goodwill | 858 | 1,162 |
| Inventory | 1,637 | 1,156 |
| Accrued expenses | 1,341 | 1,176 |
| Other, net | 17 | 37 |
| Deferred tax assets | <u>35,816</u> | <u>36,122</u> |
| Right of use assets | (4,917) | (5,288) |
| Prepaid expenses | (946) | (705) |
| Other, net | (79) | (52) |
| Deferred tax liabilities | <u>(5,942)</u> | <u>(6,045)</u> |
| Net deferred tax assets before valuation allowance | 29,874 | 30,077 |
| Less: valuation allowance | (29,874) | (30,077) |
| Net deferred tax liabilities | <u>\$ —</u> | <u>\$ —</u> |

The Company recorded a valuation allowance during the years ended July 31, 2021 and 2020 equal to domestic and foreign net deferred tax assets. The Company believes that the valuation allowance is necessary as it is not more likely than not that the deferred tax assets will be realized in the foreseeable future based on positive and negative evidence available at this time. This conclusion was reached because of uncertainties relating to future taxable income, in terms of both its timing and its sufficiency, which would enable the Company to realize the deferred tax assets. For fiscal years 2021 and 2020, the change in the valuation allowance was (\$200) and \$6,600, respectively.

As of July 31, 2021, the Company had U.S. federal net operating loss carryforwards of approximately \$85,600 of which \$58,500, if not fully utilized, expire between 2030 and 2038 and which \$27,100 do not expire. Utilization is dependent on generating sufficient taxable income prior to expiration of the tax loss carryforwards. In addition, the Company has research and development tax credit carryforwards of approximately \$1,500 which expire between 2025 and 2041. As of July 31, 2021, the Company has state and local net operating loss carryforwards of approximately \$28,800, which if not fully utilized, expire between 2038 and 2041. As of July 31, 2021, the Company had foreign loss carryforwards of approximately \$10,700 which with few exceptions do not expire.

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

| | 2021 | 2020 | 2019 |
|----------------------------|-----------------|--------------------|-----------------|
| United States operations | \$ 8,832 | \$ (27,690) | \$ 4,618 |
| International operations | (957) | (830) | (2,129) |
| Income (loss) before taxes | <u>\$ 7,875</u> | <u>\$ (28,520)</u> | <u>\$ 2,489</u> |

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

| | 2021 | 2020 | 2019 |
|---|-------------|-------------|-------------|
| Federal statutory rate | (21.0)% | 21.0% | (21.0)% |
| Compensation and other expenses not deductible for income tax return purposes | (3.4) | (1.1) | (15.3) |
| PPP loan forgiveness income not taxable for income tax return purposes | 18.7 | — | — |
| Change in valuation allowance, net | 5.7 | (19.9) | 33.6 |
| Other | — | — | 2.7 |
| | <u>—%</u> | <u>—%</u> | <u>—%</u> |

Because there are no undistributed earnings at the Company's foreign subsidiaries at July 31, 2021, no U.S. federal income taxes have been provided. As of July 31, 2021, the Company has no liabilities for uncertain tax positions. It is the Company's policy to record interest and penalties as a component of tax expense. The Company files income tax returns in the U.S. Federal jurisdiction, various U.S. state jurisdictions and several foreign jurisdictions. With few exceptions, the fiscal years that remain subject to examination are July 31, 2018 through July 31, 2021.

During fiscal 2021, the Swiss Federal Tax Administration completed of an examination for the fiscal years 2015 through 2018, which resulted in the tax returns being accepted as filed. During fiscal 2021, the Company received notification from the German tax authorities of an examination for the fiscal years 2015 through 2019. As of July 31, 2021, we had received no preliminary audit findings and no reserves have been recorded with respect to this audit.

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Note 8 – Long term debt

In connection with the purchase of a building in Farmingdale, NY on November 27, 2018, a wholly-owned subsidiary (the “mortgagor subsidiary”) of the Company entered into a Fee Mortgage and Security Agreement (the “mortgage agreement”) with Citibank, N.A. (the “mortgagee”). The mortgage agreement provides for a loan of \$4,500 for a term of 10 years, bears a fixed interest rate of 5.09% per annum and requires monthly mortgage payments of principal and interest of \$30. Debt issuance costs of \$72 are being amortized over the life of the mortgage agreement. The balance of unamortized debt issuance cost was \$53 at July 31, 2021. At July 31, 2021, the balance owed by the subsidiary under the mortgage agreement was \$4,100. The Company’s obligations under the mortgage agreement are secured by the building and by a \$750 cash collateral deposit with the mortgagee as additional security. This restricted cash is included in other assets as of July 31, 2021. We assumed from the seller an operating lease for a tenant at the facility which expired on June 30, 2020. Rental income from the assumed lease is included in other income.

The mortgage agreement includes affirmative and negative covenants and events of default, as defined. Events of default include non-payment of principal and interest on debt outstanding, non-performance of covenants, material changes in business, breach of representations, bankruptcy or insolvency, and changes in control. The mortgage includes certain financial covenants. As of July 31, 2020, the Company was not in compliance with a financial ratio covenant related to the mortgage. Effective October 19, 2020, the Company and the mortgagee agreed to a covenant restructure whereby the mortgagee waived the Company’s financial ratio covenant for the fiscal period ended July 31, 2020 and modified the mortgage to replace that covenant with a liquidity covenant. The liquidity covenant requires that we own and maintain at all times and throughout the remaining term of the loan at least \$25,000 of liquid assets, defined as time deposits, money market accounts and obligations issued by the U.S. government or any of its agencies. The cash collateral agreement was also modified to require compliance with the liquidity covenant for two consecutive fiscal years before the collateral is released back to us. As of July 31, 2021, the Company was in compliance with all the financial and liquidity covenants related to this mortgage. Effective September 29, 2021 the Company and the mortgagee agreed to further covenant restructuring whereby (a) the liquidity covenant was reduced to 150% of the loan principal (or approximately \$6,000 July 31, 2021) from \$25,000 previously, and (b) the collateral requirement was increased from \$750 to \$1,000.

In April 2020, our subsidiary in Switzerland received a loan of CHF 400 (\$400, based on the foreign exchange rate as of July 31, 2020) from the Swiss government under the “Corona Krise” emergency loan program in response to the pandemic. This loan is uncollateralized, bears 0% interest, is due in 5 years, and may be repaid at any time. This loan is included in long term debt – net as of July 31, 2021.

The CARES Act expanded the U.S. Small Business Administration’s (SBA) business loan program to create the Paycheck Protection Program (PPP), which provided employers with uncollateralized loans whose primary purpose is to retain or maintain workforce and salaries for a twenty-four week period (“covered period”) following receipt of the loan. PPP loans have a 1% fixed interest rate and are due from two to five years. The primary features of the PPP loan program are to provide funding to companies to cover eligible expenses, and the potential for forgiveness of that portion of the loan spent on payroll and other permitted operating expenses during the covered period, subject to reductions if the borrower fails to maintain or restore employee and salary levels. We applied for the PPP loan based on the eligibility and need requirements established when the program was announced and in April 2020 received \$7,000 through Citibank N.A., the Company’s existing lender, pursuant to the PPP (the “PPP Loan”). The SBA has announced its intention to audit loans in excess of \$2,000. To date, the SBA has not informed the Company of its intention to audit the Company’s PPP loan. We accrued no interest on the loan.

In June 2021, the SBA approved in full our request for loan forgiveness. For the year ended July 31, 2021, we recognized the forgiveness of the \$7,000 loan in Other income.

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Minimum future annual principal payments under these agreements as of July 31, 2021 are as follows:

| July 31, | Total |
|--|-----------------|
| 2022 | \$ 152 |
| 2023 | 160 |
| 2024 | 167 |
| 2025 | 606 |
| 2026 | 186 |
| Thereafter | 3,290 |
| Total principal payments | 4,561 |
| Less: current portion, included in other current liabilities and other short term debt | (152) |
| unamortized mortgage cost | (53) |
| Long term debt - net | <u>\$ 4,356</u> |

Note 9 - Leases

The Company adopted ASU No. 2016-02 “Leases (Topic 842)”, which requires leases with durations greater than twelve months to be recognized on the balance sheet, using the modified retrospective approach with an effective date of August 1, 2019. We did not apply the new standard to comparative periods and therefore those amounts are not presented below.

The Company determines if an arrangement is or contains a lease at contract inception. The Company leases buildings, office space, patient service centers, and equipment primarily through operating leases, and equipment through a limited number of finance leases. Generally, a right-of-use asset, representing the right to use the underlying asset during the lease term, and a lease liability, representing the payment obligation arising from the lease, are recognized on the balance sheet at lease commencement based on the present value of the payment obligation. For operating leases, expense is recognized on a straight-line basis over the lease term. For finance leases, interest expense on the lease liability is recognized using the effective interest method and amortization of the right-of-use asset is recognized on a straight-line basis over the shorter of the estimated useful life of the asset or the lease term. Short-term leases with an initial term of 12 months or less are not recorded on the balance sheet; the Company recognizes lease expense for these leases on a straight-line basis over the lease term.

The Company primarily uses its incremental borrowing rate in determining the present value of lease payments as the Company’s leases generally do not provide an implicit rate.

The Company has lease agreements with (i) right-of-use asset payments and (ii) non-lease components (i.e. payments related to maintenance fees, utilities, etc.) which have generally been combined and accounted for as a single lease component.

The Company’s leases have remaining terms of less than 1 year to 8 years, some of which include options to extend the leases for up to 5 years. The Company’s lease terms may include renewal options that are reasonably certain to be exercised and termination options that are reasonably certain not to be exercised.

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Certain of the Company's lease agreements include rental payments adjusted periodically for inflation or a market rate which are included in the lease liabilities.

| Leases | Balance Sheet Classification | July 31, 2021 | July 31, 2020 |
|--------------------------------|--|------------------|------------------|
| Assets | | | |
| Operating | Right-of-use assets | \$ 17,020 | \$ 19,916 |
| Finance | Property, plant and equipment, net (a) | 248 | 385 |
| Total lease assets | | \$ 17,268 | \$ 20,301 |
| Liabilities | | | |
| Current: | | | |
| Operating | Current portion of operating lease liabilities | \$ 3,419 | \$ 4,121 |
| Finance | Finance leases short term | 88 | 201 |
| Non-current: | | | |
| Operating | Operating lease liabilities, non-current | 14,558 | 16,679 |
| Finance | Other liabilities and finance leases long term | 110 | 161 |
| Total lease liabilities | | \$ 18,175 | \$ 21,162 |

(a) Accumulated amortization of finance lease assets was approximately \$1,100 and \$1,000 as of July 31, 2021 and 2020, respectively.

For the years ended July 31, components of lease cost were as follows:

| Lease Cost | 2021 | 2020 |
|-------------------------------|-----------------|-----------------|
| Operating lease cost | \$ 5,474 | \$ 5,813 |
| Finance lease cost: | | |
| Amortization of leased assets | 137 | 251 |
| Interest on lease liabilities | 16 | 35 |
| Total lease cost | \$ 5,627 | \$ 6,099 |

The maturity of the Company's lease liabilities as of July 31, 2021 is as follows:

| Maturity of lease liabilities, years ending July 31, | Operating leases | Finance leases | Total |
|--|---------------------|-------------------|------------------|
| 2022 | \$ 4,326 | \$ 88 | \$ 4,414 |
| 2023 | 3,547 | 88 | 3,635 |
| 2024 | 3,385 | 37 | 3,422 |
| 2025 | 3,158 | — | 3,158 |
| 2026 | 3,150 | — | 3,150 |
| Thereafter | 3,224 | — | 3,224 |
| Total lease payments | 20,790 | 213 | 21,003 |
| Less: Interest (a) | (2,813) | (15) | (2,828) |
| Present value of lease liabilities | \$ 17,977 | \$ 198 | \$ 18,175 |

(a) Primarily calculated using the Company's incremental borrowing rate.

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Lease term and discount rate for the years ended July 31 were as follows:

| Lease term and discount rate | 2021 | 2020 |
|--|-------------|-------------|
| Weighted-average remaining lease term (years): | | |
| Operating leases | 5.6 years | 6.2 years |
| Finance leases | 2.5 years | 2.7 years |
| Weighted-average discount rate: | | |
| Operating leases | 4.9% | 4.9% |
| Finance leases | 7.4% | 8.6% |

See Note 4 for cash flow information on cash paid for amounts included in the measurement of lease liabilities for the years ended July 31, 2021 and 2020.

Note 10 - Accrued Liabilities

At July 31, accrued liabilities consist of:

| | 2021 | 2020 |
|-----------------------------------|------------------|------------------|
| Payroll, benefits and commissions | \$ 5,856 | \$ 5,227 |
| Professional fees | 628 | 710 |
| Legal | 2,554 | 2,647 |
| Deferred revenue | 2,675 | 2,526 |
| Other | 2,588 | 1,723 |
| | <u>\$ 14,301</u> | <u>\$ 12,833</u> |

Deferred revenue

In order to increase cash flow to providers of services and suppliers impacted by the pandemic, the Centers for Medicare and Medicaid Services (CMS) expanded its Accelerated and Advance Payment Program to a broader group of Medicare providers. We applied for and received a \$2,526 payment advance from this program in April 2020. The recoupment by CMS of our advance payment had been scheduled to begin 120 days after the date of receipt, at which time every claim we submit from that point would be automatically offset to repay the advance payment. Any unrecouped advance balance remaining after 90 days of the recoupment process was to be repaid such that 210 days after receiving the advance it would be entirely repaid. In October 2020, the Continuing Appropriations Act, 2021 and Other Extensions Act amended the repayment terms of the Advance Payment Program. The recoupment period was extended and the automatic recoupment began one year after the date the advance payment was received, which in our case meant recoupment started April 2021. Additionally, during the first 11 months after recoupment begins, the rate will be 25% and repayment will occur through an automatic recoupment of our Medicare payments. At the end of the 11 month period, the recoupment rate will increase. If the total amount of the advance payment is not recovered within 29 months from the date the advance was received, a demand letter for the outstanding balance will be issued. Since the Company has the right to repay the advance at any time, the entire balance is considered current. As of July 31, 2021, the deferred revenue related to the CMS payment advance was \$1,847.

Self-Insured Medical Plan

The Company self-funds medical insurance coverage for certain of its U.S. based employees. The risk to the Company is believed to be limited through the use of individual and aggregate stop loss insurance. As of July 31, 2021 and 2020, the Company has established a reserve of \$300, which is included in accrued liabilities for payroll, benefits and commissions, for claims that have been reported but not paid and for claims that have been incurred but not reported. The reserve is based upon the Company's historical payment trends, claim history and current estimates.

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Note 11 - Other current liabilities

At July 31, other current liabilities consist of:

| | 2021 | 2020 |
|--|---------------|---------------|
| Finance lease obligations, current portion | \$ 81 | \$ 255 |
| Current portion of mortgage loan | 152 | 136 |
| | <u>\$ 233</u> | <u>\$ 391</u> |

Note 12 - Stockholders' equity

Controlled Equity Offering

The Company has a Controlled Equity OfferingSM Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as sales agent ("Cantor"). Under the Sales Agreement, the Company may offer and sell, from time to time, through Cantor, shares of the Company's common stock, par value \$0.01 per share (the "Common Stock"). The Company pays Cantor a commission of 3.0% of the aggregate gross proceeds received under the Sales Agreement. The Company is not obligated to make any sales of the Shares under the Sales Agreement. The offering of Shares pursuant to the Sales Agreement will terminate upon the earlier of (a) the sale of all of the Shares subject to the Sales Agreement or (b) the termination of the Sales Agreement by Cantor or the Company, as permitted therein. The initial agreement contemplated the sale of shares of the Company's common stock having an aggregate offering price of up to \$20.0 million. In December 2014, the Sales Agreement was amended in order for the Company to offer and sell additional shares of Common Stock having an aggregate offering price of \$20.0 million.

On September 1, 2017, the Company filed with the SEC a Form S-3 "shelf" registration and sales agreement prospectus covering the offering, issuance and sale of our Common Stock that may be issued and sold under the existing Sales Agreement in an aggregate amount of up to \$19.2 million. A total of \$150 million of securities may be sold under this shelf registration, which was declared effective September 15, 2017. The Form S-3 expired in October 2020 but may be refiled at any time at the discretion of the Company.

For the years ended July 31, 2021, 2020, and 2019 the Company did not sell any shares of common stock under the Sales Agreement.

Common stock

In fiscal 2021, the Company issued 208,537 shares of common stock in settlement of its employees' 401(k) matching contribution obligation of \$780. In January 2021, the Company issued 332,700 shares of common stock in payment of accrued executive bonuses of \$875.

In fiscal 2020, the Company issued 333,265 shares of common stock in settlement of its employees' 401(k) matching contribution obligation of \$839. The Company also issued 4,167 shares of common stock as employee compensation and recorded an expense of \$10.

In fiscal 2019, the Company issued 315,472 shares of common stock in settlement of its employees' 401(k) matching contribution obligation of \$832.

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Incentive stock plans

In January 2011, the Company's stockholders approved the adoption of the 2011 Incentive Plan (the "2011 Plan") for the issuance of equity awards, including, among others, options, restricted stock, restricted stock units and performance stock units for up to 3,000,000 shares of common stock. On January 5, 2018, the Company's stockholders approved the amendment and restatement of the 2011 Plan (the "Amended and Restated 2011 Plan") to increase the number of shares of common stock available for grant under the 2011 Plan by 2,000,000 shares of common stock bringing the total number of shares available for grant to 5,000,000 shares of common stock. On October 7, 2020, the Company's Board of Directors approved the amendment and restatement of the Amended and Restated 2011 Plan, with an effective date of October 7, 2020 and subject to approval by the Company's stockholders at the 2020 annual meeting of stockholders of the Company. The amendment and restatement of the Amended and Restated 2011 Plan was for purposes of, among other things, (i) increasing the shares of common stock available for grant under the Amended and Restated 2011 Plan by an additional 4,000,000 shares of common stock bringing the total number of shares available for grant to 9,000,000 shares of common stock and (ii) extending the term of the Amended and Restated 2011 Plan until October 7, 2030. In January 2021, the Company's stockholders approved the amendment and restatement of the Amended and Restated 2011 Plan.

The exercise price of options granted under the Amended and Restated 2011 Plan, as amended and restated, is equal to or greater than fair market value of the common stock on the date of grant. The Amended and Restated 2011 Plan, as amended and restated, will terminate at the earliest of (a) such time as no shares of common stock remain available for issuance under the plan, (b) termination of the plan by the Company's Board of Directors, or (c) October 7, 2030. Awards outstanding upon expiration of the Amended and Restated 2011 Plan, as amended and restated, will remain in effect until they have been exercised or terminated, or have expired. As of July 31, 2021, there were approximately 5,066,000 shares of common stock available for grant under the Amended and Restated 2011 Plan, as amended and restated.

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

Options granted pursuant to the plans may be either incentive stock options or non-statutory options. The 2011 Plan provides for the issuance of stock options, restricted stock and restricted stock unit awards which generally vest over a two to four year period. A summary of the option activity pursuant to the Company's stock option plans for the years ended July 31, 2021, 2020, and 2019 is as follows:

| | 2021 | | 2020 | | 2019 | |
|--|------------------|--|------------------|--|------------------|--|
| | Options | Weighted - Average Exercise Price | Options | Weighted - Average Exercise Price | Options | Weighted - Average Exercise Price |
| Outstanding at beginning of year | 2,636,496 | \$ 4.05 | 2,351,040 | \$ 4.53 | 1,882,116 | \$ 4.96 |
| New Grants | 543,104 | \$ 2.57 | 773,032 | \$ 2.40 | 715,321 | \$ 2.81 |
| Exercised | (34,667) | \$ 2.80 | — | \$ — | (238,230) | \$ 2.69 |
| Expired or forfeited | (640,370) | \$ 3.52 | (487,576) | \$ 3.71 | (8,167) | \$ 6.55 |
| Outstanding at end of year | <u>2,504,563</u> | \$ 3.74 | <u>2,636,496</u> | \$ 4.05 | <u>2,351,040</u> | \$ 4.53 |
| Exercisable at end of year | <u>1,561,326</u> | \$ 4.37 | <u>1,457,162</u> | \$ 5.10 | <u>1,342,564</u> | \$ 5.16 |
| Weighted average fair value of options granted during year | | <u>\$ 1.27</u> | | <u>\$ 1.01</u> | | <u>\$ 1.07</u> |

The intrinsic value of stock option awards that vested during the fiscal year represents the value of the Company's closing stock price on the last trading day of the fiscal year in excess of the exercise price multiplied by the number of options that vested.

Total intrinsic value of outstanding options that vested and were exercisable during the fiscal years ended July 31, 2021, 2020, and 2019 was \$488, \$0 and \$159, respectively.

The intrinsic value of options outstanding at July 31, 2021, 2020, and 2019 was \$1,323, \$79 and \$955, respectively.

The intrinsic value of the options exercised in fiscal 2021, 2020 and 2019 was \$38, \$0 and \$117, respectively.

During the fiscal year ended July 31, 2019 certain directors and officers of the Company exercised 203,511 stock options in non-cash transactions. The officers and directors received 23,376 net shares of common stock. The Company did not receive any proceeds from this exercise. The net shares issued represent the difference between the fair market value of the options on the date of exercise less the strike price cost to exercise the options.

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Listed below are the assumptions used to determine the fair value of options granted during fiscal years 2021, 2020 and 2019:

| Grant Year | Options Granted | Exercise Price Range | Term (years) | Vesting Period (years) | FMV of options Granted/Per Share | Expected Life (years) | Expected Volatility % | Interest Rate % | Vested Shares at 7/31/2021 |
|------------|-----------------|----------------------|--------------|------------------------|----------------------------------|-----------------------|-----------------------|-----------------|----------------------------|
| 2021 | 543,104 | \$ 2.14 - \$2.63 | 5 | 2 - 3 | \$ 1.04 - \$1.30 | 3.25 - 3.5 | 69.36 - 73.26 | 0.19 - 0.26 | — |
| 2020 | 773,032 | \$ 2.20 - \$3.32 | 5 | 2 - 3 | \$ 0.86 - \$1.34 | 3.25 - 3.5 | 53.77 - 66.24 | 0.27 - 1.2 | 271,066 |
| 2019 | 715,321 | \$ 2.80 - \$3.21 | 5 | 2 - 3 | \$ 1.06 - \$1.23 | 3.25 - 3.5 | 48.06 - 50.56 | 2.47 - 2.96 | 525,547 |

The following table summarizes information for stock options outstanding at July 31, 2021:

| Range of Exercise prices | Shares | Weighted-Average Remaining Contractual Life in Years | Weighted-Average Exercise Price |
|--------------------------|------------------|--|---------------------------------|
| \$ 2.14 - \$3.32 | 1,748,017 | 3.5 | \$ 2.57 |
| \$ 4.35 - \$4.42 | 255,000 | 2.0 | \$ 4.42 |
| \$ 5.52 - \$8.36 | 501,546 | 0.7 | \$ 7.15 |
| | <u>2,504,563</u> | | |

The following table summarizes information for stock options exercisable at July 31, 2021:

| Range of Exercise prices | Shares | Weighted-Average Remaining Contractual Life in Years | Weighted-Average Exercise Price |
|--------------------------|------------------|--|---------------------------------|
| \$ 2.20 - \$3.32 | 819,947 | 2.8 | \$ 2.66 |
| \$ 4.35 - \$4.42 | 238,333 | 2.0 | \$ 4.42 |
| \$ 5.52 - \$8.36 | 503,046 | 0.7 | \$ 7.15 |
| | <u>1,561,326</u> | | |

Performance Stock Units

To better align the long-term interest of executives with growing U.S. practices, beginning in fiscal 2018, the Company granted long-term incentive awards in the form of time based stock options and performance-based restricted stock units (“Performance Stock Units” or “PSUs”). The PSUs earned will be determined over a three-year performance period. The primary performance metrics will be revenue and Adjusted EBITDA growth. Payouts based on revenue and adjusted EBITDA goals will be modified based on Total Shareholder Return (“TSR”) performance relative to Enzo’s peer group.

During the fiscal years ended July 31, 2020, 2019 and 2018, the Company awarded PSUs to its executive officers. These awards provide for the grant of shares of our common stock at the end of a three-year period based on the achievement of average revenue growth and adjusted EBITDA growth over that period.

During the fiscal year 2020, a former executive forfeited 4,000 and 10,500 PSUs from the fiscal 2019 and fiscal 2020 awards, respectively. During fiscal year 2021, a former executive forfeited 2,000 and 4,000 PSUs from the fiscal 2018 and fiscal 2019 awards, respectively. During fiscal year 2021, 26,000 remaining PSU’s awarded in fiscal 2018 to current executives with a grant date of July 31, 2018 expired as the growth goals were not achieved by July 31, 2021. During the fiscal year 2021, the Company accrued compensation expense of \$272 for the outstanding PSUs awarded during fiscal years 2020 and 2019 as the achievement of certain growth goals is deemed probable.

The following table summarizes PSU’s granted and outstanding through July 31, 2021:

| Grant Date | Total Grant | Forfeitures | Outstanding | Fair Market Value At Grant Date (000s) |
|------------|-------------|-------------|-------------|--|
| 1/3/2019 | 80,500 | (14,500) | 66,000 | \$ 222 |
| 2/25/2020 | 98,600 | — | 98,600 | \$ 207 |

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Restricted Stock Awards

The fair value of a restricted stock award is determined based on the closing stock price on the award date. There were no awards made during the fiscal years ended July 31, 2021, 2020 or 2019. During the fiscal year ended July 31, 2021, a total of 817 restricted stock awards vested. The fair value of the awards that vested during the years ended July 31, 2021, 2020 and 2019 was \$2, \$2 and \$4. As of July 31, 2021, there were no shares of unvested restricted stock outstanding.

Note 13 - Employee benefit plans

The Company has a qualified Salary Reduction Profit Sharing Plan (the "Plan") for eligible U.S. employees under Section 401(k) of the Internal Revenue Code. The Plan provides for voluntary employee contributions through salary reduction and voluntary employer contributions at the discretion of the Company. For the years ended July 31, 2021, 2020, and 2019, the Company authorized employer matched contributions of 50% of the employees' contribution up to 10% of the employees' compensation, payable in Enzo Biochem, Inc. common stock. The share-based 401(k) employer matched contribution was approximately \$780, \$839 and \$832 in fiscal years 2021, 2020, and 2019, respectively. As of July 31, 2021, 2020 and 2019 the Company accrued a total of \$433, \$481 and \$475, respectively in 401(k) matching contribution obligations within the Accrued liabilities account.

The Company's Swiss operations provide a pension plan named the Enzo Life Sciences (ELS) AG Vertrag - Nr. 2/401144, (the "Swiss Plan") under the Swiss government's social security system for Swiss employees. The current required minimum saving contribution is 13% for employees over age 25 and minimum annual investment return is 1.00%. Employees are required to contribute based on a formula and the Company's Swiss operations make contributions of at least 40% of the employee contribution. The status of the Swiss Plan, which is substantially funded as of December 31, 2020, the latest plan year end, is as follows:

| As of December 31, | 2020 | 2019 | 2018 |
|--------------------------------|-------------|-------------|-------------|
| Total Assets | \$ 2,721 | \$ 2,181 | \$ 2,064 |
| Accumulated Benefit Obligation | \$ 2,890 | \$ 2,401 | \$ 2,308 |
| Funded status | 94% | 91% | 90% |

| Fiscal Year ended July 31, | 2020 | 2019 | 2018 |
|-----------------------------------|-------------|-------------|-------------|
| Employer contributions | \$ 143 | \$ 165 | \$ 208 |

The contract for the Swiss Plan automatically renews on its annual anniversary unless notice of termination is provided three months prior. The current contract will automatically renew on December 31, 2021. Currently the Company has no plans to change the current funding or plan design. No events have occurred that would impact the Swiss Plan status.

Note 14 - Other income

The CARES Act expanded the U.S. Small Business Administration's (SBA) business loan program to create the Paycheck Protection Program (PPP), which provided employers with uncollateralized loans whose primary purpose is to retain or maintain workforce and salaries. We applied for the PPP loan based on the eligibility and need requirements established when the program was announced and in April 2020 received \$7,000 through Citibank N.A., the Company's existing lender, pursuant to the PPP (the "PPP Loan"). We accrued no interest on the loan.

In June 2021, the SBA approved in full our request for loan forgiveness. For the year ended July 31, 2021, we recognized the forgiveness of the \$7,000 loan in Other income.

Note 15 - Commitments

Leases

An entity owned by certain executive officers/directors of the Company owns the building that the Company leases as its main facility for clinical laboratory operations and certain research operations. In addition to the minimum annual rentals of space, the lease is subject to annual increases, based on the consumer price index. Annual increases are limited to 3% per year. Rent expense for this lease, inclusive of real estate taxes, approximated \$1,815, \$1,833 and \$1,849 during fiscal years 2021, 2020 and 2019, respectively.

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Employment Agreements

The Company has employment agreements with certain officers that are cancellable at any time but provide for severance pay in the event an officer is terminated by the Company without cause, as defined in the agreements. Unless cancelled earlier or with notice as defined, the agreements automatically renew for two years. The current agreements expire January 2023. As of July 31, 2021, aggregate minimum compensation commitments under these agreements, exclusive of termination and change in control provisions, is \$2,306.

Note 16 – Contingencies

The Company has brought cases in the United States District Court for the District of Delaware (“the Court”), alleging patent infringement against various companies. In 2017, the Court ruled that the asserted claims of the ’180 and ’405 Patents are invalid for nonenablement in cases involving Abbott, Becton Dickinson, Gen-Probe, Hologic, and Roche. That ruling was affirmed by the United States Court of Appeals for the Federal Circuit (“Federal Circuit”) in June 2019. Enzo subsequently filed a petition for certiorari regarding the invalidity ruling for the ’180 and ’405 Patents in February 2020; the Supreme Court denied Enzo’s petition on March 30, 2020. There are currently two cases that were originally brought by the Company in the Court. In those two cases, Enzo alleges patent infringement against Becton Dickinson Defendants and Roche Defendants, respectively. The claims in those cases involve the ’197 Patent. Both cases are stayed.

In separate inter partes review proceedings before the U.S. Patent and Trademark Office (PTO) involving, among others, Becton Dickinson, certain claims of the ’197 Patent were found unpatentable as anticipated or obvious and cancelled by the Patent Trial and Appeals Board (“Board”). Enzo appealed that decision to the Federal Circuit. On August 16, 2019, the Federal Circuit affirmed the Board’s decision, finding that each of the challenged claims is unpatentable. The Company filed a petition for rehearing and rehearing en banc on October 30, 2019, which the Federal Circuit denied on December 4, 2019. The Company filed a petition for certiorari with the Supreme Court on March 3, 2020, which was denied.

In April 2019, the Company entered into an agreement with Hologic and Grifols, resolving litigation resulting from four cases originally brought by the Company in the Court. As a result, Enzo dismissed (1) a stayed patent litigation regarding the ’180 and ’197 Patent against Hologic in the Court; (2) the Consolidated Appeals against Gen-Probe and Hologic resulting from two cases filed in the Court, and (3) the Company’s appeal in the litigation involving the ’581 Patent that involved both Hologic and Grifols. As a result of the agreement with Hologic, Hologic withdrew from Enzo’s Federal Circuit appeal of the Board’s adverse rulings in the *inter partes* review proceedings regarding the ’197 Patent filed by Hologic and joined by Becton Dickinson mentioned above.

On September 2, 2021, the PTO issued a non-final office action in an ex parte reexamination concerning the ’197 Patent. In the office action, the PTO rejected certain claims of the ’197 Patent under 35 U.S.C. § 102 and for nonstatutory double-patenting. Enzo’s response to the office action is forthcoming.

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On February 5, 2020, Harbert Discovery Fund, LP and Harbert Discovery Co-Investment Fund I, LP (“Plaintiffs”) brought an action in the United States District Court for the Southern District of New York against the Company and five of its present or former Directors, Dr. Elazar Rabbani, Barry W. Weiner, Dr. Bruce A. Hanna, Dov Perlysky and Rebecca Fischer. On March 26, 2020, Plaintiffs filed an amended complaint against the same defendants. Count I asserted the Company violated Section 14(a) of the Securities and Exchange Act of 1934 and Rule 14a-9 thereunder by disseminating proxy materials that made two purportedly false statements: (a) a “January 28, 2020 Enzo press release [that purportedly] falsely stated that the Annual Meeting would be ‘delayed’ by action of the Board to February 25, 2020 when, in fact, the Annual Meeting would convene as planned on January 31, 2020”, and (b) a “January 31 Enzo Proxy [that purportedly] falsely stated that the Proposed By-Law Amendment [to Article II, Section 9] would be approved if it received...a majority of the votes....rather than the required Supermajority Vote as provided for in the Charter. “Count II asserted a claim against the individual defendants under Section 20(a) of the Exchange Act premised on Enzo’s purported violation of Section 14(a) and Rule 14a-9. Count III asserted the individual defendants breached their fiduciary duty, based on the same conduct and by seeking to entrench themselves. Finally, Count IV purported to assert a derivative claim for a declaration that any amendment to Article II, Section 2 requires the approval of 80% of Enzo’s shareholders. On July 16, 2020, the day before the defendants’ motion to dismiss was due, plaintiffs asked the Court to dismiss their claims without prejudice. Defendants asked plaintiffs to dismiss the claims with prejudice, but they refused. On July 17, 2020, the Court dismissed the claims without prejudice. If plaintiffs reassert the claims, defendants intend to vigorously defend against them.

On November 27, 2020, the Company brought an action in the United States District Court for the Southern District of New York against Harbert Discovery Fund, LP, Harbert Discovery Co-Investment Fund I, LP, Harbert Fund Advisors, Inc., Harbert Management Corp. and Kenan Lucas. The Company alleges the defendants made false and misleading representations, or omitted to state material facts necessary to make their statements not misleading, in proxy materials they disseminated seeking the election to the Company’s Board of Directors at its 2019 Annual Meeting of two candidates they nominated, in violation of Section 14(a) of the 1934 Exchange Act and Rule 14a-9 thereunder. The Company seeks damages and injunctive relief. On February 15, 2021, Defendants filed a motion to dismiss. On March 8, 2021, the Company filed its opposition to that motion. On March 18, 2021 defendants filed their reply in further support of the motion. On September 28, 2021, the Court denied the motion with respect to the Company’s misrepresentation claims and granted it with respect to its omissions claim. The Company intends to vigorously pursue its misrepresentation claim.

There can be no assurance that the Company will be successful in any of 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.

As described in Note 3, third-party payers, including government programs, may decide to deny payment or recoup payments for testing that they contend was improperly billed or not medically necessary, against their coverage determinations, or for which they believe they have otherwise overpaid (including as a result of their own error), and we may be required to refund payments already received. During the third fiscal quarter of 2019, a significant third-party payer informed us outside of their typical business practice that they believe it overpaid the Company during certain periods of fiscal 2018. The Company disputed these claims and formally sent legal appeal letters to the payer. During the fiscal 2020 period, we recorded \$0.8 million in legal and related expenses as a result of reduced reimbursements this payer made to us. In April 2020, we and the payer entered into a settlement agreement and release whereby the parties agreed that the \$0.8 million previously withheld by the payer shall fully and completely satisfy the dispute.

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The following legal settlements are included in the statement of operations under Legal settlements, net within the Life Science segment for the 2019 period:

The Company, along with its subsidiaries Enzo Life Sciences, Inc. entered into a Settlement Agreement as of February 5, 2019 (the “Agreement”) with Roche Diagnostics GmbH and Roche Molecular Systems, Inc. (together, “Roche”) with respect to an action between the Company and Roche before the U.S. District Court, Southern District of New York, Case No 04-CV4046. Roche agreed to pay the Company \$21 million in settlement pursuant to the Agreement. The Company received \$19.4 million net of attorney contingency payments. This settlement does not affect the Company’s civil action for patent infringement against Roche in the U.S. District Court for the District of Delaware, Enzo Life Sciences Inc. v. Roche Molecular Systems Inc., et al., civil action No. 12 cv-00106, which remains stayed.

The Company, along with its subsidiaries Enzo Life Sciences, Inc. entered into a settlement and license agreement as of April 16, 2019 (the “Agreement”) with Hologic, Inc. (“Hologic”), Grifols, S.A., and Grifols Diagnostic Solutions Inc. (together, “Grifols”) to settle all outstanding patent disputes among the parties. The terms of the agreement include one-time payments totaling \$14 million to the Company in exchange for fully paid-up, worldwide licenses to Hologic and Grifols. The Company received \$9.5 million net of attorney contingency payments.

Note 17 - Segment reporting

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

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

Legal settlements, net, represent activities for which royalties would have been received in the Company’s Products segment. Management of the Company assesses assets on a consolidated basis only and therefore, assets by reportable segment have not been included in the reportable segments below. The accounting policies of the reportable segments are the same as those described in the summary of significant accounting policies.

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

Year ended July 31, 2021

| | Clinical Laboratory Services | Life Sciences Products | Therapeutics | Other | Consolidated |
|--|---|---------------------------------------|---------------------|-------------------|---------------------|
| Revenues | \$ 86,984 | \$ 30,747 | \$ — | \$ — | \$ 117,731 |
| Operating costs and expenses: | | | | | |
| Cost of revenues | 48,179 | 15,975 | — | — | 64,154 |
| Research and development | 615 | 2,559 | 78 | — | 3,252 |
| Selling, general and administrative | 26,028 | 11,015 | 62 | 7,800 | 44,905 |
| Legal and related expenses | 264 | 25 | — | 4,439 | 4,728 |
| Total operating costs and expenses | <u>75,086</u> | <u>29,574</u> | <u>140</u> | <u>12,239</u> | <u>117,039</u> |
| Operating income (loss) | 11,898 | 1,173 | (140) | (12,239) | 692 |
| Other income (expense) | | | | | |
| Interest | (17) | 37 | — | (12) | 8 |
| Other | (18) | 7 | — | 6,916 | 6,905 |
| Foreign exchange gain | — | 270 | — | — | 270 |
| Income (loss) before taxes | <u>\$ 11,863</u> | <u>\$ 1,487</u> | <u>\$ (140)</u> | <u>\$ (5,335)</u> | <u>\$ 7,875</u> |
| Depreciation and amortization included above | <u>\$ 1,609</u> | <u>\$ 756</u> | <u>\$ —</u> | <u>\$ 288</u> | <u>\$ 2,653</u> |
| Share-based compensation included in above: | | | | | |
| Selling, general and administrative | 33 | 102 | — | \$ 679 | 814 |
| Cost of sales | 93 | — | — | — | 93 |
| Total | <u>\$ 126</u> | <u>\$ 102</u> | <u>\$ —</u> | <u>\$ 679</u> | <u>\$ 907</u> |
| Capital expenditures | <u>\$ 3,352</u> | <u>\$ 752</u> | <u>\$ —</u> | <u>\$ 332</u> | <u>\$ 4,436</u> |

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Year ended July 31, 2020

| | Clinical Laboratory Services | Life Sciences Products | Therapeutics | Other | Consolidated |
|--|------------------------------------|------------------------------|-----------------|--------------------|--------------------|
| Revenues – Services and Products | \$ 47,964 | \$ 26,561 | — | — | \$ 74,525 |
| Grant income | 1,496 | — | — | — | 1,496 |
| Total | 49,460 | 26,561 | — | — | 76,021 |
| Operating costs and expenses:: | | | | | |
| Cost of revenues | 38,855 | 13,396 | — | — | 52,251 |
| Research and development | 1,509 | 2,190 | \$ 749 | — | 4,448 |
| Selling, general and administrative | 23,533 | 10,485 | — | \$ 8,942 | 42,960 |
| Legal and related expenses | 211 | 2 | — | 6,516 | 6,729 |
| Total operating costs and expenses | 64,108 | 26,073 | 749 | 15,458 | 106,388 |
| Operating (loss) income | (14,648) | 488 | (749) | (15,458) | (30,367) |
| Other income (expense) | | | | | |
| Interest | (36) | 56 | — | 434 | 454 |
| Other | 45 | 13 | — | 430 | 488 |
| Foreign exchange gain | — | 905 | — | — | 905 |
| (Loss) income before taxes | \$ (14,639) | \$ 1,462 | \$ (749) | \$ (14,594) | \$ (28,520) |
| Depreciation and amortization included above | \$ 1,553 | \$ 964 | — | \$ 263 | \$ 2,780 |
| Share-based compensation included above: | | | | | |
| Selling, general and administrative | 57 | 74 | — | 756 | 887 |
| Cost of sales | 46 | — | — | — | 46 |
| Total | \$ 103 | \$ 74 | — | \$ 756 | \$ 933 |
| Capital expenditures | \$ 1,811 | \$ 322 | — | \$ 37 | \$ 2,170 |

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

Year ended July 31, 2019

| | Clinical Laboratory Services | Life Sciences Products | Therapeutics | Other | Consolidated |
|--|---|---------------------------------------|---------------------|-------------------|---------------------|
| Revenues | \$ 51,115 | \$ 30,055 | \$ — | \$ — | \$ 81,170 |
| Operating costs, expenses and legal settlements, net: | | | | | |
| Cost of revenues | 44,226 | 13,696 | — | — | 57,922 |
| Research and development | 31 | 2,257 | 887 | — | 3,175 |
| Selling, general and administrative | 24,230 | 11,860 | — | 8,175 | 44,265 |
| Legal and related expenses | 159 | 27 | — | 2,814 | 3,000 |
| Legal settlements, net | — | (28,925) | — | — | (28,925) |
| Total operating costs, expenses and legal settlements, net | <u>68,646</u> | <u>(1,085)</u> | <u>887</u> | <u>10,989</u> | <u>79,437</u> |
| Operating income (loss) | (17,531) | 31,140 | (887) | (10,989) | 1,733 |
| Other income (expense) | | | | | |
| Interest | (64) | 67 | — | 1,053 | 1,056 |
| Other | 16 | 2 | — | 364 | 382 |
| Foreign exchange loss | — | (682) | — | — | (682) |
| Income (loss) before taxes | <u>\$ (17,579)</u> | <u>\$ 30,527</u> | <u>\$ (887)</u> | <u>\$ (9,572)</u> | <u>\$ 2,489</u> |
| Depreciation and amortization included above | <u>\$ 1,625</u> | <u>\$ 1,221</u> | <u>\$ —</u> | <u>\$ 190</u> | <u>\$ 3,036</u> |
| Share-based compensation included above: | | | | | |
| Selling, general and administrative | 147 | 95 | — | 697 | 939 |
| Total | <u>\$ 147</u> | <u>\$ 95</u> | <u>\$ —</u> | <u>\$ 697</u> | <u>\$ 939</u> |
| Capital expenditures | <u>\$ 1,374</u> | <u>\$ 605</u> | <u>\$ —</u> | <u>\$ 6,147</u> | <u>\$ 8,126</u> |

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Geographic financial information is as follows:

| Net Services, Products and Grant revenues from unaffiliated customers, Year ended July 31,: | 2021 | 2020 | 2019 |
|--|-------------------|------------------|------------------|
| United States | \$ 102,602 | \$ 64,284 | \$ 68,081 |
| Europe | 10,386 | 7,720 | 8,551 |
| Asia Pacific | 4,744 | 4,017 | 4,538 |
| Total | <u>\$ 117,731</u> | <u>\$ 76,021</u> | <u>\$ 81,170</u> |

| Long-lived assets, at July 31, | 2021 | 2020 |
|---------------------------------------|------------------|------------------|
| United States | \$ 41,249 | \$ 41,946 |
| Europe | 52 | 442 |
| Total | <u>\$ 41,301</u> | <u>\$ 42,388</u> |

The Company's reportable segments are determined based on the services they perform and the products they sell, not on the geographic area in which they operate. The Company's Clinical Laboratory Services segment operates 100% in the United States with all revenue derived there. The Life Sciences Products segment earns product revenue both in the United States and foreign countries. The following is a summary of the Life Sciences Products segment product revenues attributable to customers located in the United States and foreign countries for the years ended July 31,:

| | 2021 | 2020 | 2019 |
|-------------------|------------------|------------------|------------------|
| United States | \$ 15,617 | \$ 14,824 | \$ 16,966 |
| Foreign countries | 15,130 | 11,737 | 13,089 |
| | <u>\$ 30,747</u> | <u>\$ 26,561</u> | <u>\$ 30,055</u> |

ENZO BIOCHEM, INC
SCHEDULE II
VALUATION AND QUALIFYING ACCOUNTS
As of and for the Years ended July 31, 2021, 2020 and 2019
(in thousands)

| <u>Year ended July 31,</u> | <u>Description</u> | <u>Balance at Beginning of Year</u> | <u>Charged (credited) to costs and expenses</u> | <u>Charged to other accounts</u> | <u>Deductions</u> | <u>Balance at end of Year</u> |
|--------------------------------|--|---|---|--|-------------------|-----------------------------------|
| 2021 | Allowance for doubtful accounts receivable | 194 | 5 | | \$ 19(1) | 180 |
| 2020 | Allowance for doubtful accounts receivable | \$ 166 | \$ 28 | | — | \$ 194 |
| 2019 | Allowance for doubtful accounts receivable | 145 | 42 | | \$ 21(1) | 166 |
| 2021 | Deferred tax valuation allowance | \$ 30,077 | \$ (203) | | — | \$ 29,874 |
| 2020 | Deferred tax valuation allowance | 23,527 | 6,550 | | — | 30,077 |
| 2019 | Deferred tax valuation allowance | 24,471 | (944) | | — | 23,527 |

(1) Write-off of uncollectible accounts receivable.

List of subsidiaries of the Company.

Enzo Clinical Labs, Inc., a New York Corporation

Enzo Life Sciences, Inc., a New York Corporation

Enzo Life Sciences (ELS) AG, in Lausen, Switzerland, a wholly-owned subsidiary of Enzo Life Sciences, Inc.

Enzo Therapeutics, Inc., a New York Corporation

Enzo Realty LLC, a New York Corporation

Enzo Realty II, LLC, a New York Corporation

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Enzo Biochem, Inc. and Subsidiaries on Form S-3 (No. 333-220312) and Form S-8 (Nos. 333-87153, 033-88826, 333-89308, 333-123712, 333-172127, 333-197028, 333-226799, 333-236958 and 333-252159) of our report dated October 12, 2021, on our audits of the consolidated financial statements and financial statement schedule as of July 31, 2021 and 2020 and for each of the years in the three-year period ended July 31, 2021, which report is included in this Annual Report on Form 10-K to be filed on or about October 12, 2021.

/s/ EisnerAmper LLP

EISNERAMPER LLP
New York, New York
October 12, 2021

CERTIFICATIONS

In connection with the Annual Report on Form 10-K of Enzo Biochem, Inc. (“the Company”) for the fiscal year ended July 31, 2021 as filed with the Securities and Exchange Commission on the date hereof, I, Elazar Rabbani, Ph.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 302 of the Sarbanes-Oxley Act of 2002, that:

1. I have reviewed this Annual Report on Form 10-K of Enzo Biochem, Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;
4. The Company’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the Company’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the Company’s internal control over financial reporting that occurred during the Company’s most recent fiscal quarter (the Company’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Company’s internal control over financial reporting; and
5. The Company’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company’s auditors and the audit committee of the Company’s board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company’s ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company’s internal control over financial reporting.

Date: October 12, 2021

By: /s/ Elazar Rabbani, Ph.D.
Elazar Rabbani, Ph.D.
Chairman of the Board, Chief Executive Officer and Director

CERTIFICATIONS

In connection with the Annual Report on Form 10-K of Enzo Biochem, Inc. (“the Company”) for the fiscal year ended July 31, 2021 as filed with the Securities and Exchange Commission on the date hereof, I, David Bench, Chief Financial Officer and Principal Accounting Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 302 of the Sarbanes-Oxley Act of 2002, that:

1. I have reviewed this Annual Report on Form 10-K of Enzo Biochem, Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;
4. The Company’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a - 15(e) and 15d - 15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the Company’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the Company’s internal control over financial reporting that occurred during the Company’s most recent fiscal quarter (the Company’s fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Company’s internal control over financial reporting; and
5. The Company’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company’s auditors and the audit committee of the Company’s board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company’s ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company’s internal control over financial reporting.

Date: October 12, 2021

By: /s/ David Bench
David Bench
Chief Financial Officer, Principal Accounting Officer

**CERTIFICATE PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Enzo Biochem, Inc., and Subsidiaries (“the Company”) on Form 10-K for the fiscal year ended July 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Elazar Rabbani, Ph.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: October 12, 2021

By: /s/ Elazar Rabbani, Ph.D.
Elazar Rabbani, Ph.D.
Chairman of the Board, Chief Executive Officer and Director

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Act Commission or its staff upon request.

**CERTIFICATE PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Enzo Biochem, Inc., and Subsidiaries (“the Company”) on Form 10-K for the fiscal year ended July 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, David Bench, Chief Financial Officer and Principal Accounting Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: October 12, 2021

By: /s/ David Bench
David Bench
Chief Financial Officer, Principal Accounting Officer

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Act Commission or its staff upon request.