ENZO BIOCHEM INC
Form 10-K
October 14, 2008

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549
FORM 10-K

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

For the fiscal year ended July 31, 2008

or

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

For the transition period from _____ to _____
Commission File Number 001-09974

ENZO BIOCHEM, INC.

(Exact name of registrant as specified in its charter)

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

(212) 583-0100

(Registrant s telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.
Yes o No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes x No o
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

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

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

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

The aggregate market value of the registrant s voting stock held by non-affiliates of the registrant was approximately $303,311,000 as of January 31, 2008.

The number of shares of the Company s common stock, $.01 par value, outstanding at October 6, 2008 was approximately 37,382,300.

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 22, 2009 are incorporated by reference into Part III of this annual report.

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PART I

Item 1. Business

Overview

Enzo Biochem, Inc. (the Company we , our or Enzo) is a life sciences and biotechnology company focused on harnessing genetic processes to develop research tools, diagnostics and therapeutics and on serving as a provider of diagnostic services to the medical community. Since our founding in 1976, our strategic focus has been on the development of enabling technologies in the life sciences field. Our pioneering work in genomic analysis coupled with its extensive patent estate and enabling platforms have strategically positioned the Company to play an important role in the rapidly growing life sciences and molecular medicine marketplaces.

In the course of our research and development activities, we have built a substantial portfolio of intellectual property assets, with 236 issued patents worldwide, and 213 pending patent applications, along with extensive enabling technologies and platforms.

Recent Developments

On May 8, 2008, Enzo Life Sciences, Inc. acquired substantially all of the U.S. based assets and certain liabilities of Biomol International, LP through a newly formed US subsidiary Biomol International, Inc. and all of the stock of Biomol s wholly-owned United Kingdom subsidiary, Affinity Limited. by Axxora UK, a wholly-owned subsidiary of Enzo Life Sciences, referred to as Biomol for approximately $18.1 million in cash and stock, subject to adjustment, exclusive of acquisition costs of approximately $800,000 and contingent payments of $2.5 million on each of the next two anniversary dates. Effective May 8, 2008, Biomol became a wholly-owned subsidiary of Enzo Life Sciences. The acquisition was financed with the Company s cash and cash equivalents and Enzo common stock. (See Item 7, Recent Developments and Note 2 in the notes to consolidated financial statements).

Operating Segments

We are comprised of three operating segments, of which the Therapeutics and Life Sciences segments have evolved out of our core competencies: the use of nucleic acids as informational molecules and the use of compounds for immune modulation. Information concerning sales by geographic area and business segments for the years ended July 31, 2008, 2007 and 2006 is located in Note 17 in the notes to consolidated financial statements.

Below are brief descriptions of each of our operating segments:

Enzo Life Sciences is a company that manufactures, develops and markets biomedical research products and tools to research and pharmaceutical customers world-wide and has amassed a large patent and technology portfolio. The pioneering platforms developed by Enzo Life Sciences enable the development of a wide range of products in the research products marketplace. We are internationally recognized and acknowledged as a leader in manufacturing, in-licensing, and commercialization of over 8,000 innovative high quality research reagents in key research areas. The division is an established source for a comprehensive panel of products to scientific experts in the fields of gene expression, non-radioactive labeling and detection, adipokines & obesity, apoptosis, bioactive lipids, cell cycle, cytoskeletal research, DNA damage & repair, epigenetics, immunology & cancer research, inflammation, neurobiology, nitric oxide & oxidative stress, and signal transduction.

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

Enzo Clinical Labs is a regional clinical laboratory to the New York Metropolitan and New Jersey areas. The Company believes this allows us to capitalize firsthand on our extensive advanced molecular and cytogenetic capabilities and the broader trends in predictive diagnostics. Enzo Clinical Labs offers a menu of routine and esoteric clinical laboratory tests or procedures used in general patient care by physicians to establish or support a diagnosis, monitor treatment or medication, and search for an otherwise undiagnosed condition.

We operate a full-service clinical laboratory in Farmingdale, New York, a network of 23 patient service centers, a stand alone stat or rapid response laboratory in New York City, and a full-service phlebotomy department.

The Company s primary sources of revenue have historically been from product revenues and royalty and licensing of Life Sciences products utilized in life science research and from the clinical laboratory services provided to the healthcare community. The following table summarizes the sources of revenues for the fiscal years ended July 31, 2008, 2007 and 2006, (in $000 s and percentages):

Fiscal year ended July 31,	2008		2007		2006	
Product revenues	$ 28,087	36%	$ 6,658	13%	$ 4,750	12%
Royalty and license fees	7,630	10	5,820	11	3,150	8
Clinical laboratory services	42,078	54	40,430	76	31,926	80
Total	$ 77,795	100%	$ 52,908	100%	$ 39,826	100%

Markets

Background

Deoxyribonucleic Acid (DNA) is the source of biological information that governs the molecular mechanisms underlying life. This information is stored in the linear sequences of nucleotides that comprise DNA. The sequence of the human genome, comprising well over 30,000 genes, has been identified by genome research, including the Human Genome Project. The ongoing challenge of the scientific research community is to determine the function and relevance of each gene. This information will facilitate the understanding of biological mechanisms and how variations and mutations in such mechanisms may result in disease, enabling more rapid and accurate detection of specific diseases and the development of new therapeutics to treat them.

Tools for biomedical and pharmaceutical research

There is an increasing demand by biomedical and pharmaceutical researchers for diagnostics tools that both facilitate and accelerate the generation of biological information. This demand can be met by gene-based diagnostics for which a variety of formats, or tools, have been developed that enable researchers to study biological pathways and to identify mutations in gene sequences and variations in gene expression levels that can lead to disease. These tools include DNA sequencing instruments and systems, microarrays, biochips, microspheres, and microfluidic chips. Common among these formats is the need for reagents that allow the identification, quantification and characterization of specific genes or nucleic acid sequences.

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

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

Clinical diagnostics

The clinical diagnostics market has been reported by industry sources to be greater than $22 billion annually. It is comprised of a broad range of tests based on clinical chemistry, microbiology, immunoassay, blood banking and cancer screening assays. Many of these tests employ traditional technologies, such as immunoassays and cell culture technologies, for the detection of diseases. Immunoassays are based on the use of antibodies directed against a specific target, or antigen, to detect that antigen in a patient sample. Cell culturing techniques involve the growth, isolation and visual detection of the presence of a microorganism.

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

Gene-based diagnostics has many advantages over the traditional technologies. Since gene-based diagnostics focuses on the identification of diseases at the gene level, it 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 $4 billion per year, and is acknowledged as one of the fastest growing segments in the in-vitro diagnostic industry. Contributing to this growth are, among other factors:

the increasing number of diagnostic tests being developed from discoveries in genome research;

advances in formats and other technologies that automate and accelerate gene-based diagnostic testing:

growing emphasis by the health care industry on early diagnosis and treatment of disease; and

application of gene-based diagnostics as tools to match therapies to specific patient genetics commonly referred to as pharmacogenomics.

Therapeutics

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

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

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

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

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

Synthetic gene medicine involves the administration of synthetic nucleic acid sequences called oligos that are designed to bind to, and thus deactivate, ribonucleic acid (RNA) produced by a specific gene. To date, this approach has demonstrated limited success. Since a single cell may contain thousands of strands of RNA, large amounts of oligos are necessary to shut down the production of unwanted proteins. Also, they are quickly metabolized or eliminated by the body. Consequently, large quantities of oligos must be delivered in multiple treatments, which can be both toxic to the body as well as costly.

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

A major challenge in designing gene therapy medicines has been to enable the efficient and safe delivery of the gene to the appropriate target cell. Gene delivery is often accomplished using a delivery vehicle known as a vector. A critical quality of the vector is its ability to bind to the target cell and effectively deliver, or transduce, the gene into the cell. It is also critical that the nucleic acid of the vector not produce proteins or antigens that can trigger an adverse immune response.

Strategy

Our objective is to be a leading developer and provider of the tools and diagnostic technologies used to study and detect disease at the molecular level and to be a provider of therapeutic approaches to manage specific diseases. There can be no assurance that our objective will be met. Key elements of our strategy involving three separate platforms include our ability to:

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

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

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

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

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

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

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

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

Apply our biomedical research technology to the clinical diagnostics market

We intend to develop our proprietary research technology for use in the clinical diagnostics market. We currently offer over 25 gene-based tests for the research market, for the identification of such viruses as human papillomavirus, *cytomegalovirus*, and Epstein-Barr virus. We also have an extensive library of probes for the detection of various diseases. We have developed a standardized testing format that can permit multiple diagnoses to be performed on the same specimen.

Leverage marketing and distribution infrastructure of leading life sciences companies

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

Expand our collaborations with major life sciences companies

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

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

In fiscal 2005, the Company, as plaintiff, finalized and executed a settlement and license agreement with Digene Corporation to settle a patent litigation lawsuit. Digene Corporation was acquired by QIAGEN. The license agreement with the Company was assigned to QIAGEN Gaithersburg Inc. (Qiagen). Under the terms of the license agreement, the Company would earn quarterly running royalties on the net sales of Qiagen products subject to the license until the expiration of the patent on April 24, 2018. In the license agreement, Qiagen was granted a world-wide, non-exclusive license to the Company U.S. Patent number 6,222,581, which is related to the use of a methodology called hybrid-capture in which certain nucleic acid probes are hybridized to target nucleic acids and then captured indirectly on a solid surface. The resulting nucleic acid hybrids are then detected by antibodies conjugated to signal-generating molecules which produce an amplified signal allowing for more sensitive detection of the resultant hybrids. This platform is one of the most desirable formats for the detection of nucleic acids in a reliable and economic manner, and has formed the basis for one of the most commonly ordered genomic-based assays. See Note 13 to the notes to consolidated financial statements.

Expand and protect our intellectual property estate

Since our inception, we have followed a strategy of creating a broad encompassing patent position in the life sciences and therapeutics areas. We have made obtaining patent protection a central strategic policy, both with respect to our proprietary platform technologies and products, as well as broadly in the areas of our research activities. During Fiscal 2008, we were awarded seven patents and expanded our patent estate in the area of nucleotides, amplification, labeling, detection, among others

Core Technologies

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

Diagnostic Technology Platform

Gene analysis technology

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

amplification of the target DNA sequence (a process that is essential for the detection of very small amounts of nucleic acid);

labeling the probe with a marker that generates a detectable signal upon hybridization;

addition of the probe to the sample containing the DNA; and

binding or hybridization of the probe to the target DNA sequence, if present, to generate a detectable signal.

We have developed a broad technology base for the labeling, detection, amplification and formatting of nucleic acids for gene analysis which is supported by our significant proprietary position in these fields.

Amplification. In the early stages of infection, a pathogen may be present in very small amounts and consequently may be difficult to detect. Using DNA amplification, samples can be treated to cause a pathogen s DNA to be replicated, or amplified, to detectable levels. We have developed a proprietary amplification process for multicopy production of nucleic acid, as well as proprietary techniques for amplifying the signals of our probes to further improve sensitivity. Our amplification technologies are particularly useful for the early detection of very small amounts of target DNA and, unlike PCR (currently the most commonly used method of amplification), we have developed isothermal amplification procedures that can be performed at constant temperatures and thus do not require expensive heating and cooling systems or specialized heat-resistant enzymes.

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

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

Therapeutic Technology Platforms

Cell Signaling Pathway

Our newest therapeutic technology platform involves the development of pharmaceutical agents that affect with protein-protein interactions. Over the past several years, our scientists and collaborators have unlocked the secrets of a major cell signaling pathway thus producing a means to modify biologic activity in a number of physiological systems. Further investigation into the design and control of this system has allowed our scientists and their collaborators to determine the structure of key regulatory proteins and to identify active sites that then become targets for Enzo s proprietary technology generating system. Our technology is capable of generating active compounds that range from orally delivered small molecules to peptides, oligonucleotides or antibodies. We have performed pioneering work on the structure and function of LRP and its ligands, developed a screening technology to identify active compounds, and have synthesized proprietary molecules capable of producing biological effects in cell-based systems and animal models of disease. Specifically, this system allows the Company to successfully:

generate biological, genetic, and structural information concerning LRP;

determine the structure of LRP docking sites of its ligands;

identify the functionally important residues via site-directed mutagenesis;

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

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

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

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

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

significant increases in total and femoral bone density through new bone formation;

significant reduction in alveolar bone loss and;

significant reduction in bone resorption.

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

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

Immune Regulation

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

Gene Regulation

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

vector technology. Our vector technology has the following strengths:

Efficient transduction. A principal problem of many gene therapy programs has been inefficient transduction, or an unacceptably low rate of delivery of operating genes to the target cells. We have achieved transduction rates significantly higher than those reported by other researchers.

Immunologically Quiet. Transduced or engineered cells (cells containing the gene that was delivered by the vector) often produce non-essential proteins that may trigger an immune response, causing such cells to be cleared from the body before they can produce a therapeutic effect. Cells transduced with our Stealth Vectors have not expressed extraneous proteins.

Smart Vectors. We incorporate into the surface of our vectors proteins that are designed to have an affinity for the surface of the cell types intended to be transduced. By including this targeting mechanism, we create in essence smart vectors that preferentially transduce the intended cell type. This may ultimately permit us to develop a genetic antisense product that is administered directly to the patient.

Safety components. Certain retroviral vectors have been shown to insert within the cell in regions of the cellular DNA that could activate genes that cause cells to grow or multiply. This insertional gene activation may cause uncontrolled cell division resulting in a cancer. Our vector has been designed to prevent insertional gene activation by inactivation of the viral promoters.

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

the viral promoters are inactivated;

insertional gene activation is prevented a major safety factor;

chromosomal integration; and

nuclear localization.

In summary, we have developed proprietary technologies in the areas of cell signaling, immune modulation and gene regulation (genetic antisense or antisense RNA) that we are using as platforms for a portfolio of novel therapeutics. There can be no assurance that we will be able to secure patents or that these programs will be successful. The potential therapeutics we are developing could be used, if successful, for the treatment of a variety of diseases, including osteoporosis, osteonecrosis and other bone pathologies, diabetes, autoimmune uveitis, and inflammatory bowel disease, including Crohn s Disease and ulcerative colitis, among others.

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

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

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Products and Services

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

Research Products

We are organized to lead in the development, production, marketing and sales of innovative life science research reagents worldwide based on over 30 years of experience in building strong international market recognition, implementing outstanding operational capabilities, and establishing a state of the art electronic information and ordering marketplace. We in-license and manufacture over 8,000 products, and distribute an additional 20,000 products, that may be sold individually or combined in a kit to meet the specific needs of researchers. We market these products to biomedical and pharmaceutical firms as well as academic and government research institutions worldwide. Our comprehensive portfolio of high quality reagents and kits in key research areas are sold to scientific experts in the following fields:

Adipokines
Antibiotics
Apotosis/Cell Death
Biologically Active Peptides
Bone Metabolism
Cancer Research
Cell Death
Cell Cycle
Chemokines/Cytokines
Cytoskeletal Research
Dependence Receptors
DNA Fragmentation/Damage/Repair
DNA Regulation
Epigenetics
FISH
Growth Factors/Cytokines
Hypoxia
Immunology
Inflammation/Innate Immunity
Interferons
Kinases/Inhibitors
Leukotrienes/Prostaglandins/Thromboxanes
Microarray Labeling
Multidrug Resistance
Natural Products/Antibiotics
Neuroscience
Nitric Oxide Pathway
Nuclear Receptors
Oxidative Stress
Proteosome/Ubiqutin
Receptors
Signal Transduction
Stem Cell/Cell Differentiation
Stress Proteins/Heat Shock Proteins
TNF/TNF Receptor Superfamily
Transcription Factors
Viral Signaling

Enzo Life Sciences is organized to promote and market its product through its five brands.

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

Alexis The Alexis brand is internationally recognized as a leader in producing and commercializing innovative high quality reagents and as an established source for a comprehensive panel of products in many of the fields listed above.

Apotech The Apotech branded product portfolio focuses on the fields of apoptosis and inflammation. These products include high quality recombinant proteins, antibodies and research kits.

Axxora The Axxora brand provides an electronic one-stop information, service and purchasing location for innovative high quality life science research reagents and research kits from the three product brands listed above as well as products from original manufacturers.

Biomol The Biomol branded product portfolio is targeted towards the cellular biochemistry segment with an emphasis on areas related to protein post-translational modification, be it by ubiquitin or the ubiquiting-like proteins, acetylation, methylation, phosphorylation, sulphation, or glycolsylation.

Therapeutic Development Programs

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

Osteoporosis (and certain bone disorders) and Diabetes

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

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

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

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

Autoimmune Uveitis. Autoimmune uveitis, which results from inflammation of a part of the eye known as the uvea, is believed to result from an immune reaction to antigens in the eye, specifically the S-antigen and the interphotoreceptor retinoid-binding protein (IRBP). There is no known cure for uveitis, which in the United States, according to the American Uveitis Society, is newly diagnosed in approximately 38,000 people every year. While there are steps that can be taken to preserve sight and slow the progress of vision loss, individuals with uveitis also are at increased risk of developing cataracts, glaucoma or retinal detachment.

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

Using our immune regulation platform and the recently acquired rights to the candidate drug, Optiquel (B27PD), Enzo is currently developing a protocol for a multi-center, double-blind, placebo-controlled, proof-of-concept clinical trial to be carried out in the United States and possibly ex-US. We have begun collaborations with scientists and physicians in both the US and abroad and have assembled an advisory board of consultants who are experts in the management and treatment of uveitis. In addition, we have held a pre-IND meeting with the U.S. Food and Drug Agency (FDA) in preparation for regulatory approval to initiate clinical studies in the US. We will be filing an IND with the FDA assuming all manufacturing, quality and preclinical studies meet FDA requirements.

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

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

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

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

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

An expanded double-blind, placebo-controlled study to broaden the diversity of the patient population is currently being completed at Hadassah Hospital in Jerusalem. We expect results from this study in Fiscal 2009. If the results are positive, we will request a pre-IND meeting with the US FDA to plan for regulatory approval to initiate studies in the US. We have begun collaborations with scientists and physicians and have assembled an advisory board of consultants who are experts in the management and treatment of inflammatory bowel disease.

Human Immunodeficiency Virus (HIV-1)

HIV-1 is a human pathogenic virus. After infection it runs a slow course in which certain of the cells in the immune system (CD4+ cells) progressively disappear from the body. This results in a state in which the infected individual can no longer mount an immune response. This loss of immune responsiveness is the cause of the complex of diseases known as AIDS and ultimately of death.

According to the World Health Organization, there were more than 60 million individuals worldwide living with HIV infection during 2007. There were over 5 million new infections and 3 million deaths from HIV during that same year. More than 20 million have died since the first cases of AIDS were identified in 1981. At present, several classes of products have received FDA marketing approval for HIV-1 infection: reverse transcriptase inhibitors protease inhibitors, fusion inhibitors and binding inhibitors.

HGTV43 gene medicine. Enzo s proprietary Stealth Vector HGTV43 gene construct is a vehicle designed to carry and deliver anti-HIV-1 antisense RNA genes. These genes produce antisense RNA directed against the genes responsible for viral replication. HGTV43 is designed to deliver the antisense genes to targeted blood cells of subjects infected with HIV-1. These genes are incorporated into the DNA of the blood cells, and subsequent production of the antisense RNA prevents replication of the virus, providing resistance to the virus.

Preclinical *in vitro* studies, performed in conjunction with our academic collaborators, demonstrated resistance to HIV-1 in human immune cells into which the antisense genes had been inserted. Our Phase I clinical trial of the HIV-1 gene medicine is in the long-term safety follow up phase. In this study, white blood cell precursors, known as stem cells, were collected from the subjects. These stem cells were then treated *ex vivo* with our Stealth Vector® HGTV43 transducing vector and infused into the subject. Results of the trial showed that all subjects tolerated the procedure and that:

all subjects tolerated the procedure. There were no treatment-related adverse events during the study and no evidence for expansion of the inserted transgenes in any subjects tested, nor was any evidence of leukemia seen by standard hematology;

CD34+ cells from the bone marrow of all subjects were tested for the presence of anti HIV-1 antisense RNA between 6 months and 20 months after infusion and these cells contained the antisense RNA, indicating engraftment of the engineered cells;

anti HIV-1 antisense RNA-containing immune cells were detected in the circulation of subjects, the longest at 72 months;

cells contained the antisense RNA.

Based on these Phase I trial results demonstrating long-term survival and functioning of antisense RNA in white blood cells, including CD4+ cells, we initiated a Phase I/II study at University of California San Francisco (UCSF), the site of the Phase I study. This study focuses on a strategy designed to increase the percentage of engineered CD4+ cells that contain the anti-HIV-1 antisense genes. The first patient has undergone treatment and we are monitoring the progress.

Non-Alcoholic SteatoHepatitis (NASH)

We are currently conducting a double-blind, placebo-controlled study at Hadassah Hospital in Jerusalem which is designed to investigate the effects of EGS-21, a glycolipid, as an immune modulator for the alleviation of NASH. We expect to have results from this study by the end of fiscal 2009.

Hepatitis B Virus (HBV)

We have developed a HBV therapeutic utilizing our proprietary immune regulation technology. HBV is a viral pathogen that can lead to a condition in which the body destroys its own liver cells through an immune response. This condition is commonly referred to as chronic active hepatitis. According to the latest figures published by the World Health Organization, approximately 2 billion people are infected by HBV, of whom an estimated 350 million are chronically infected and therefore at risk of death from liver disease.

EHT899 immune regulation product. EHT899 is a proprietary formulation of an HBV viral protein designed to eliminate the undesirable immune response elicited by the HBV infection. It may enhance a secondary immune response to clear the viral infection, resulting in reduction in liver damage and decrease in viral load.

Based on both the preclinical and clinical results, the Company began exploring several options for development of the candidate drug. Our current strategy is to seek a commercial partner to continue the drug development. To this end pharmaceutical partnerships are being explored and evaluated, although there can be no assurances that such efforts will be successful

Clinical Laboratory Services

We operate a regional clinical laboratory that offers full diagnostic services to the New York Metropolitan and New Jersey medical community. Our clinical laboratory testing is utilized by physicians as an essential element in the delivery of healthcare services. Physicians use laboratory tests to assist in the detection, diagnoses, evaluation, monitoring and treatment of diseases and other medical conditions. Clinical laboratory testing is generally categorized as clinical testing and anatomic pathology testing. Clinical testing is performed on body fluids, such as blood and urine. Anatomic pathology testing is performed on tissues and other samples, such as human cells. Most clinical laboratory tests are considered routine and can be performed by most commercial clinical laboratories. Tests that are not routine and that require more sophisticated equipment and highly skilled personnel are considered esoteric tests and may be performed less frequently than routine tests. We do not perform certain low-volume esoteric tests in-house; generally many of these tests are referred to an esoteric clinical testing laboratory that specializes in performing these more complex tests.

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

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

Patient specimens are delivered to our laboratory facilities 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. Once this information is entered into the laboratory computer system the tests are performed and the results are entered primarily through an interface from the laboratory testing equipment or in some instances, manually into the laboratory computer system. Most routine testing is completed by early the next morning, and test results are reported to the ordering physician. These test results are either delivered electronically via our proprietary EnzoDirect system or delivered by our logistics department directly to the ordering physicians offices. Physicians who request that they be called with a particular result are so notified.

For fiscal years ended July 31, 2008, 2007, and 2006, respectively, 54%, 76% and 80% of the Company s revenues were derived from the clinical laboratory. At July 31, 2008 and 2007, respectively, approximately 58% and 68% of the Company s net accounts receivable were derived from its clinical laboratory business. The Company believes that the concentration of credit risk with respect to the Clinical Labs accounts receivable is mitigated by the diversity of its numerous third party payers and individual patient accounts, and is limited to certain large payers that insure individuals that utilize the Clinical Labs services. To reduce risk, the Company routinely assesses the financial strength of these payers and, consequently, believes that its accounts receivable credit risk exposure, with respect to these payers, is limited. While the Company also has receivables due from the Federal Medicare program, the Company does not believe that these receivables represent a credit risk since the Medicare program is funded by the federal government and payment is primarily dependent on our submitting the appropriate documentation.

Revenue, net of contractual adjustment, from direct billings under the Federal Medicare program during the years ended July 31, 2008, 2007 and 2006 were approximately 22%, 21% and 23%, respectively, of the clinical laboratory segment s total revenue. We estimate contractual adjustment based on significant assumptions and judgments, such as the interpretation of payer reimbursement policies which bears the risk of change. The estimation process is based on the experience of amounts approved as reimbursable and ultimately settled by payers, versus the corresponding gross amount billed to the respective payers. The contractual adjustment is an estimate that reduces gross revenue, based on gross billing rates, to amounts expected to be approved and reimbursed. Gross billings are based on a standard fee schedule we set for all third party payers, including Medicare, health maintenance organizations (HMO s) and managed care providers. We adjust the contractual adjustment estimate quarterly, based on our evaluation of current and historical settlement experience with payers, industry reimbursement trends, and other relevant factors. The other relevant factors that affect our contractual adjustment include the monthly and quarterly review of: 1) current gross billings and receivables and reimbursement by payer, 2) current changes in third party arrangements. 3) the growth of in-network provider arrangements and managed care plans specific to our Company. The clinical laboratory industry is characterized by a significant amount of uncollectible accounts receivable related to the inability to receive accurate and timely billing information in order to forward it on to the third party payers for reimbursement, and the inaccurate information received from the covered individual patients for unreimbursed unpaid amounts. Our provision for uncollectible accounts receivable is within historical expectations.

Other than the Medicare program, revenues from United Healthcare of New York, Inc. represented 26% and 20% of the Clinical Labs segment s net revenue for the fiscal year ended July 31, 2008 and 2007, respectively. Other than the Medicare program, no other provider exceeded 10% of Clinical Labs service revenue for the fiscal year ended July 31, 2006.

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 New York State, the law prohibits the Company from billing the ordering physician. Compliance with applicable laws and regulations as well as, internal compliance policies and procedures adds further complexity to the billing process. We depend on the ordering physician to provide timely, accurate billing demographic and diagnostic coding information to us. Additional factors complicating the billing process include:

pricing differences between our standard gross fee schedules and the reimbursement rates of the payers;

disputes with payers as to which party is responsible for payment; and

disparity in coverage and information requirements among various payers.

We believe that most of our bad debt expense is primarily the result of missing or incorrect billing information on requisitions received from the ordering physician rather than credit related issues. We perform the requested tests and report test results regardless of whether the billing or diagnostic coding information is incorrect or missing. We subsequently attempt to contact the ordering physician to obtain any missing information and rectify incorrect billing information. Missing or incorrect information on requisition adds complexity to and slows the billing process, creates backlogs of unbilled requisitions, and generally increases the aging of accounts receivable. When all issues relating to the missing or incorrect information are not resolved in a timely manner, the related receivables are fully reserved to the allowance for doubtful accounts or written off.

We incur significant additional costs as a result of our participation in Medicare, as billing and reimbursement for clinical laboratory testing is subject to considerable and complex federal and state regulations. These additional costs include those related to: (1) complexity added to our billing processes; (2) training and education of our employees and customers; (3) compliance and legal costs; and (4) costs related to, among other factors, medical necessity denials and advance beneficiary notices. The Centers for Medicare & Medicaid Services, or CMS (formerly the Health Care Financing Administration), establishes procedures and continuously evaluates and implements changes in the reimbursement process.

The permitted Medicare reimbursement rate for clinical laboratory services has been reduced by the Federal government in a number of instances over the past several years to a present level equal to 74% of the national median of laboratory charges. Clinical Labs have been subjected to a five-year freeze (ending in 2008) on Laboratory fee updates, as required by the Medicare Modernization Act of 2003. A number of proposals for legislation or regulation, such as competitive bidding on laboratory services are under discussion which could have the effect of substantially reducing Medicare reimbursements to clinical laboratories through reduction of the present allowable percentage or through other means. In addition, the structure and nature of Medicare reimbursement for laboratory services is also under discussio