EZ EM INC
Form 10-K
August 11, 2005

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended **May 28, 2005**

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 **1-11479**

E-Z-EM, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**11-1999504**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1111 Marcus Avenue, Lake Success, New York	**11042**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code **(516) 333-8230**

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

None

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

Common stock, par value $.10

(Title of class)

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 an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes x No o

The aggregate market value of the registrant s common stock held by non-affiliates on November 26, 2004, the last business day of the registrant s most recently completed second fiscal quarter, was approximately $115,470,000. Such aggregate market value is computed by reference to the closing sale price of the registrant s common stock as reported on the American Stock Exchange on such date.

As of August 1, 2005, there were 10,842,622 shares of the registrant s common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the registrant s 2005 Annual Meeting of Stockholders to be held October 19, 2005 are incorporated by reference in Part III of this Form 10-K Report.

E-Z-EM, Inc. and Subsidiaries

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Part I

Item 1. **Business**

(a) **General Development of Business**

Overview

E-Z-EM is a leading provider of medical products used by radiologists, gastroenterologists and speech language pathologists primarily in screening for and diagnosing diseases and disorders of the gastrointestinal (GI) tract. We develop, manufacture and market medical diagnostic products used for colorectal cancer screening, evaluation of swallowing disorders (dysphagia), and testing for other diseases and disorders of the GI system. We are also a third-party contract manufacturer, which enables us to leverage our quality control, process, automation and manufacturing capabilities.

Prior to our spin-off of AngioDynamics to our shareholders on October 30, 2004, we were also a provider of innovative medical devices used in minimally invasive, image-guided procedures to treat peripheral vascular disease, or PVD. AngioDynamics designed, developed, manufactured and marketed a broad line of therapeutic and diagnostic devices that enabled interventional physicians (interventional radiologists, vascular surgeons and others) to treat PVD and other non-coronary diseases.

We have been in business for more than 43 years. Our global headquarters are located at 1111 Marcus Avenue, Suite LL-26, Lake Success, N.Y. 11042.

Our company web site is www.ezem.com[1]. We make available free of charge through our web site, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC.

History

We were founded in 1961 by Howard Stern and Phillip Meyers, M.D. to develop and market a unit dose product for delivering barium sulfate contrast media to patients for the X-ray visualization of the GI tract and the detection of colorectal cancer and other GI-related diseases. The Stern-Meyers product was considered to be a major innovation that virtually eliminated cross contamination in lower GI examinations. The product also established E-Z-EM s brand among radiologists around the world.

In 1983, we reorganized in Delaware and completed an initial public offering. In 1985, we acquired Therapex, a Canadian manufacturer of barium sulfate, creating enhanced manufacturing capacity and providing a platform for our contract manufacturing operations. In 1988, we founded AngioDynamics to provide medical devices for new procedures being developed by interventional radiologists. AngioDynamics was spun-off in a tax-free distribution to our shareholders on October 30, 2004.

[1] This website address is not intended to function as a hyperlink and information on our website is not part of this annual report on Form 10-K.

Recent Developments

On October 30, 2004, we completed our spin-off of AngioDynamics by means of a tax-free distribution of our remaining 80.4% ownership of AngioDynamics. AngioDynamics had previously completed an initial public offering in June 2004. In February 2004, we received a favorable private letter ruling from the Internal Revenue Service regarding the tax-free treatment of the distribution of our remaining ownership in AngioDynamics. We made a pro rata distribution of our 9,200,000 shares of AngioDynamics on October 30, 2004 to our shareholders of record as of October 11, 2004 (the Record Date). Based on the shares outstanding of each company on the Record Date, our shareholders received .856377 of a share of AngioDynamics stock for each share of E-Z-EM stock they owned on the Record Date. For all periods presented, AngioDynamics is accounted for as a discontinued operation in our financial statements.

For fiscal 2005, our net sales increased 12%, or $12,466,000, to $113,075,000 due to: i) sales growth, of which we estimate from $5,600,000 to $6,300,000 was attributable to the liquid barium product recall by Mallinckrodt, our principal competitor; ii) foreign currency exchange rate fluctuations, which increased the translated amounts of our foreign subsidiaries sales to U.S. dollars for financial reporting purposes by $1,818,000; and iii) price increases, which accounted for less than 1% of net sales for 2005. Price increases have had minimal effect on sales since a significant portion of our domestic products are sold under long-term group purchasing organization contracts. On a product line basis, the net sales increase resulted from increased sales of computed tomography (CT) imaging contrast products, particularly our CT Smoothie lines, and CT injector systems totaling $11,268,000.

On April 7, 2005, we acquired from our strategic partner, O Dell Engineering, all its assets related to Reactive Skin Decontamination Lotion (RSDL). RSDL is a liquid skin decontaminant that breaks down chemical agents such as Sarin or VX in seconds, leaving a non-toxic liquid that can be washed away with water. RSDL is packaged in a tear-open pouch that first-responders and soldiers can use to aid victims of a chemical attack or for personal protection. RSDL was originally developed by the Canadian Defense Research Establishment. The U.S. Department of Defense (DoD) is currently conducting final configuration and compatibility testing on the product, a required process for the replacement of product currently used in this role. RSDL is currently used by several NATO countries as their exclusive product for personal chemical agent decontamination. Under the rights we acquired through this agreement, RSDL can be marketed to military and first-responder organizations worldwide. Prior to the acquisition, we were the exclusive manufacturer of RSDL under an agreement between O Dell Engineering and our wholly owned Canadian subsidiary.

Unless the context requires otherwise, all references herein to a particular year are references to our fiscal year, which concludes on the Saturday nearest to May 31st.

(b) **Financial Information About Industry Segments**

Not Applicable.

(c) **Narrative Description of Business**

General

We are a leading provider of medical products that can be categorized into the following product groupings:

CT Imaging

X-Ray Fluoroscopy

Contract Manufacturing

Accessory Medical Devices

Gastroenterology

Virtual Colonoscopy

Defense Decontaminants

Virtually all of our products are cleared for sale in the U.S. Certain products are cleared for sale in the European Community, Japan and other countries.

The following table sets forth revenues from external customers for the last three fiscal years:

	2005		2004		2003	
	$	%	$	%	$	%
	(dollars in thousands)					
CT Imaging	$ 45,666	40.4	$ 34,398	34.2	$ 29,932	31.3
X-Ray Fluoroscopy	40,649	36.0	40,810	40.6	40,639	42.5
Contract Manufacturing	9,183	8.1	8,054	8.0	8,571	9.0
Accessory Medical Devices	5,328	4.7	5,351	5.3	5,392	5.6
Gastroenterology	4,627	4.1	4,246	4.2	3,877	4.0
Virtual Colonoscopy	3,654	3.2	3,698	3.7	2,610	2.7
Defense Decontaminants	956	.8	1,164	1.1	1,410	1.5
Other	3,012	2.7	2,888	2.9	3,252	3.4
	$ 113,075	100.0	$ 100,609	100.0	$ 95,683	100.0

GI Disease and Colorectal Cancer

The GI system is one of the most complex systems in the human body. It processes food, extracts nutrients and passes wastes and involves all major body parts and organs used in chewing, swallowing, digestion, absorption and defecation. Digestive glands also provide moisture, lubrication, emulsification and enzymes for digestion of proteins, carbohydrates and fats.

Diseases of the GI tract are considered to be the second most prevalent after cardiac diseases. According to the National Institute of Diabetes and Digestive and Kidney Diseases, 60 to 70 million people each year are affected by digestive disease, leading to more than 190,000 deaths, 10 million hospitalizations (equal to 13 percent of all hospitalizations), 6 million diagnostic and therapeutic procedures (equal to 14 percent of all procedures), 50 million physician office visits, 1.4 million people with disabilities, and costs of $107 billion, including $87 billion in direct medical costs and $20 billion in indirect costs (e.g., disability and mortality). Colorectal cancer is the second most common cancer in the U.S., striking 140,000 people annually and causing 56,000 deaths, according to the American Society of Colon and Rectal Surgeons.

We believe there are four major healthcare trends that will continue to cause a significant shift in spending from direct care to screening and early detection and preventative treatment of GI disease:

Early Detection - Research has shown that colorectal cancer and other GI diseases have higher cure rates if caught early. As a result, the American Cancer Society recommends that Americans age 50 or older should be screened

on a regular basis and, in 1998, Medicare began reimbursing for colorectal cancer screening utilizing GI contrast X-ray examinations, as well as other GI-related procedures.

Aging of the Population - The number of Americans affected by GI diseases is expected to increase substantially as the population grows older. While colorectal cancer may occur at any age, more than 90% of the patients are over age 40, at which point the risk doubles every ten years, according to the American Society of Colon and Rectal Surgeons. The American Cancer Society estimates that less than 50% of the people age 50 or over in the United States have had a recent test.

Technological Innovation - Growth of multi-slice CT, magnetic resonance (MR) scanners, three-dimensional and harmonic ultrasound, and innovations in digital imaging software are increasing the ability of radiologists and gastroenterologists to detect GI problems earlier.

Increasing Healthcare Costs - The need to reduce escalating healthcare costs for direct care is leading to increased use of lower cost diagnostic procedures and minimally invasive preventative treatment.

CT Imaging

CT Imaging is an increasingly important technology for the diagnostic imaging of the GI tract. Frost & Sullivan, a leading market research firm, has estimated that CT procedures will grow at an 11.25% compound annual growth rate from 2003 through 2010, and we are focused on finding solutions to capitalize on this trend. During this past year, sales of CT products surpassed those of our X-ray fluoroscopy products for the first time in our history and they now represent our largest product group.

CT scanners take a rapid stream of X-ray photographs from different angles. Through computerization, this block of data is used to create two- and three-dimensional images of bone and hard tissue, and soft tissue when contrast media is introduced inside the body. CT examination is significantly more expensive than X-ray fluoroscopy but, as the cost of CT technology declines and utilization increases, per procedure costs are expected to decline. Radiologists typically employ barium sulfate contrast media for thoracic, abdominal and pelvic studies to mark the GI tract, while water-soluble contrast media are typically used for vascular studies.

We believe we have the most comprehensive line of barium sulfate formulations for thoracic, abdominal and pelvic CT scanning. We market 11 formulations under our Esopho-CAT®, E-Z-CAT® and Readi-CAT® Smoothie lines. Early in fiscal 2005, we introduced VoLumen , the next generation, low-density barium sulfate suspension for use as an oral contrast in Multidetector CT (MDCT) and Positron Emission Tomography (PET)/CT studies. VoLumen is designed to overcome the limitations of water and higher-density positive oral contrasts currently used in these studies, and allows for the simultaneous MDCT investigation of all organs, vasculature, and surrounding structures of the abdominal/pelvic region.The entire CT contrast line consists of formulations that are packaged as a liquid or powder for oral use and in various sizes from unit dose to multi-dose for administration convenience and economy. Each formulation and size is designed to meet the radiologist s need for consistent performance in lumen marking and transit through the GI tract, while maintaining optimal patient comfort and management.

We also address the CT market with our Empower line of electromechanical injectors. Radiologists use injectors to deliver a controlled volume of iodine-based contrast media into patients to visualize the vascular structure

of the circulatory system and organs in the thoracic, abdominal and pelvic regions. Our injectors, EmpowerCT® and EmpowerCTA® with EDA™ technology, aid in the detection of extravasation, an accidental infiltration of contrast media into surrounding tissue. Empower injectors are comprised of an electromechanical injector, and a consumable syringe and EDA detector patch.

Based upon sales, we believe that we are the leading manufacturer of CT barium contrast media and the second largest manufacturer of CT injectors in the U.S. We were recently rated Number 1 in user satisfaction among vendors of CT power injectors by MD Buyline.

X-Ray Fluoroscopy

GI X-ray contrast media has been our principal business for more than 43 years. A standard X-ray takes a photograph of bones (hard tissue). When contrast media is introduced inside the body, the X-ray can also photograph soft tissue details. For more than 85 years, barium sulfate has been the contrast medium of choice for virtually all X-rays of the GI tract and is still one of the most common methods used by radiologists for diagnostic imaging of the GI tract. It permits the visualization of the entire GI tract; has a high absorption coefficient for X-rays; and it is biologically inert, insoluble in water and chemically stable. Compared to endoscopic procedures, X-ray fluoroscopy with barium sulfate contrast can be safer, less expensive and provide increased visualization, depending upon the condition being diagnosed.

We believe we offer the most comprehensive line of barium sulfate formulations. We market approximately 30 fluoroscopy formulations. Formulations focus on five key areas - pharynx, esophagus, stomach and small intestine and large intestine (colon) - and are packaged in different sizes in oral, enema, liquid and powder forms. Each formulation is designed to meet the radiologist s need to optimize visualization of the condition under diagnosis while providing patient comfort and management. Based on sales figures, we believe that we are the leading manufacturer of these contrast media.

We have an ongoing program to develop new formulations, to extend the GI diagnostic power of X-ray fluoroscopy and to enhance the effectiveness of our existing formulations. In recent years, we introduced Varibar®, the first family of barium sulfate contrast for the X-ray diagnosis of dysphagia, or swallowing disorders. Varibar provides a range of viscosity barium suspensions from juice to honey to pudding to evaluate a patient s ability to swallow liquid and solid materials of differing viscosities and volumes, resulting in consistent, repeatable radiographic results. We estimate 10 million Americans have some degree of swallowing disorder.

We also sell accessory medical devices for use in X-ray procedures, such as empty enema administration kits and components.

Contract Manufacturing

Contract manufacturing focuses on three product areas:

Diagnostic Contrast Media - We manufacture an oral iodinated contrast medium for a third party.

Pharmaceuticals - This includes products for dermatology, sunscreen lotions and creams, and cough and cold medicines.

Cosmetics - This includes anti-aging and moisturizer skin care products, as well as topical liquids.

Accessory Medical Devices

We develop, manufacture and market consumable and non-consumable radiological medical devices, such as entry biopsy needles and trays, mammography wipes and related accessories.

Gastroenterology

We are leveraging our core competency in GI imaging to expand on our presence in the gastroenterology market. Our product offerings to this market include the Suction Polyp Trap™, E-Z-Guard™ mouthpieces, Visipace electrogastrogram analyzer, as well as other medical devices. We also market several virtual colonoscopy products, including the LoSo Prep™ bowel cleanser and NutraPrep™ pre-procedure meal plan product lines, to gastroenterologists for use in optical colonoscopy procedures, and distribute a hydrogen breath analyzer under the E-Z-EM trade name H2 Score™ Breath Meter. H2 Score is a convenient hand-held screening tool for lactose malabsorption. We believe we are well positioned to continue building our presence in this market.

Virtual Colonoscopy

Virtual colonoscopy, or CT colonography, employs a CT scanner and three-dimensional imaging software to look inside the body without having to insert a long fiber optic tube (optical colonoscopy) into the colon or having to fill the colon with liquid barium sulfate (barium enema). We support the virtual colonoscopy marketplace with a comprehensive suite of trademarked products:

PROTOCO$_2$L™ is an automated insufflation system that delivers carbon dioxide into the colon to achieve optimal distention for better visualization and greater patient comfort.

Tagitol V™ is a next generation radiopaque marker that blends into stool as it forms. Tagitol V provides immediate, visible identification of retained feces via comparative density analysis, enhancing the accurate detection of pathology and helping to reduce the potential for false positive/negative results.

NutraPrep™ is a pre-packaged, low-residue patient food system that provides a nutritionally sound diet for the day prior to an exam while minimizing the amount of retained fecal material. NutraPrep is covered by U.S. Patent No. 6,866,873 that was issued on March 15, 2005.

LoSo Prep™ is a relatively mild, low sodium, patient colon cleanser. LoSo Prep and other E-Z-EM laxative products are marketed to radiologists and gastroenterologists for the preparation and increased compliance of patients for any medical procedure requiring a clean colon, including X-ray examinations (barium enema), virtual or optical colonoscopy or surgery.

InnerviewGI™ is an application software that processes CT scan data to create two- and three-dimensional views of the GI tract. InnerviewGI was jointly developed with Vital Images, Inc., which develops, markets and supports three-dimensional medical imaging software for use primarily in disease screening, clinical diagnosis and surgical and therapy planning. Vital Images markets InnerviewGI and pays a royalty to us based on sales. We share the cost of InnerviewGI product development with Vital Images.

We are marketing our virtual colonoscopy products as a more patient-friendly procedure to encourage screening. We believe that patients, when given the choice, prefer virtual colonoscopy because it is less invasive than optical

colonoscopy, does not require sedation as with optical colonoscopy (which generally requires missing a day of work) and is more comfortable than both optical colonoscopy and barium enema without compromising visualization. Virtual colonoscopy is gaining academic and clinical acceptance.

Defense Decontaminants

Our principal product offering is Reactive Skin Decontamination Lotion (RSDL), a liquid decontaminant that reacts very rapidly with chemical warfare (CW) agents, including VX nerve agent. RSDL neutralizes these agents within a matter of seconds or minutes, leaving a non-toxic, water-soluble residue. RSDL s efficacy in neutralizing toxic industrial chemicals is also being evaluated under a U.S. Government Cooperative Research and Development Agreement (CRADA). RSDL can potentially be used to decontaminate intact skin surfaces and is being tested for safety in open wounds. RSDL is currently used by all service branches of the Canadian Forces, as well as the armed forces of Australia, Belgium, Ireland, Holland, Sweden and Slovenia. The U.S. Army is currently conducting final testing of RSDL. The U.S. Food and Drug Administration (FDA) issued a 510(k) clearance for RSDL in March 2003. Developed by Defense Research and Development Canada (DRDC) and licensed to us by the Canadian government, on a worldwide basis, for military, first-responders, and first-receivers, RSDL is patented in the U.S., Canada and more than a dozen European countries. We also serve as a contract manufacturer of a non-RSDL decontaminant.

Other

Revenues from our Other product category totaled 2.7%, 2.9% and 3.4% of net sales in 2005, 2004 and 2003, respectively. This category consists primarily of freight charges billed to customers, miscellaneous products distributed through our foreign operations and royalty income.

Research and Development and Engineering

We believe that the success of our business is due to our ability to improve our existing products and develop new diagnostic contrast formulations and devices for different imaging modalities and procedures. To support these activities, we operate a Research and Development (R&D) department with a staff of seven and a product Engineering department with a staff of 11. To take advantage of synergies and efficiencies, and in anticipation of the relocation of our powder manufacturing from our facility in Westbury, N.Y. to our facility in Montreal, Canada, the Westbury R&D laboratory was closed and all formulation R&D activities now occur at our Montreal facility. This reorganization was completed in 2005.

The Montreal R&D laboratory specializes in liquid and powder barium sulfate contrast formulations. Capabilities include the ability to evaluate barium sulfate particle size and concentration for optimal imaging characteristics, suspension stabilization, coating or non-coating properties depending on the application, flavoring modification, and expertise in analytic, organic and physical chemistry, including colloidal suspensions.

The Engineering department (in Westbury, N.Y.) specializes in FDA Class 2 Medical Device development, manufacturing and regulation for hardware and disposables. Capabilities include mechanical, electrical and software design.

We have a product steering committee to review and evaluate all new product ideas. Furthermore, we have a product development project management process that incorporates all disciplines, including sales and marketing, to ensure

that we accurately address our markets needs. This team approach is responsible for developing new projects under all applicable design control validation procedures throughout the various stages of product development. These procedures include bench testing, animal testing, biocompatibility testing, human-use testing conducted by independent physicians, and post-initial test-market surveillance of product performance. The feedback we receive throughout the process, especially from physicians, is used to confirm product functionality, safety and effectiveness before commencing full-scale marketing.

We conduct clinical research studies to support our product development activities and also to evaluate post-market performance, particularly in comparison to competitive products in the market. We manage and monitor the clinical studies performed by investigators and institutions to study the clinical outcome of our products. In addition to offering administrative support and funding, our clinical applications team assists investigators in writing protocols and collecting and analyzing data when necessary.

We are jointly developing with Berlex Laboratories, a U.S. affiliate of Schering AG, the ULTRAVIST® Glass Pre-filled Cartridge (PFC), a pre-filled contrast syringe loaded with ULTRAVIST (iopromide) injection. We will adapt our EmpowerCT® injector system to permit the use of the ULTRAVIST Glass PFC. The program is expected to be completed in fiscal 2006.

Our research and development (R&D) expenditures totaled $5,494,000, $4,467,000, and $4,267,000 in 2005, 2004 and 2003, respectively. R&D expenditures are expected to continue at or exceed current levels.

Sales and Marketing

We also believe that the success of our business is due to the effectiveness of our sales, marketing and distribution infrastructure.

In North America, our products are sold through a 38-person sales force (including three regional managers), some of whom began their careers as X-ray or CT technologists or had other specialized training before joining our company. The sales force calls on the 1,500 major hospitals in North America where approximately 25,000 radiologists and an increasing number of gastroenterologists are located.

We promote our products through exhibits at major medical conventions worldwide. We also advertise in select medical journals and trade publications, conduct direct mail campaigns and sponsor web sites, and sponsor continuing medical education seminars in virtual colonoscopy to reach our target markets. In 2005, we supported 18 such courses, which trained over 430 physicians in virtual colonoscopy. Each course typically lasts for two days and consists of didactic lectures and hands-on training sessions focused on performing and interpreting virtual colonoscopy examinations. We offer a marketing program for virtual colonoscopy, through which customers can receive comprehensive marketing support materials for use in promoting their practices.

We sell our products in the U.S. through a network of approximately 150 distributors.

Outside North America, our products are marketed through a 17-person sales force. We market and distribute directly in the United Kingdom, Benelux and Tokyo, Japan, reaching major hospitals in these markets. Independent distributors, such as GE Medical in Central and Eastern Europe, Bracco in Italy, and Astra in Scandinavia, are used in other markets. Significant sales are made in the United Kingdom, Holland, Japan, Italy, Belgium, Germany,

Sweden, South Africa, Australia and Austria. Foreign distributors are generally granted exclusive distribution rights, where permissible by applicable law, and some hold governmental product registrations in their names. New registrations are filed in our name when permissible under applicable law.

Competition

We believe that our CT and X-ray fluoroscopy contrast products are the most widely used diagnostic imaging products of their kind in the U.S., Canada and certain European countries. We face competition in the domestic contrast systems market primarily from Mallinckrodt, a division of Tyco International Ltd., GE Healthcare, a segment of General Electric Co., and Bracco. Significant competition exists outside of the U.S. We compete primarily on the basis of product quality, customer service, and the availability of a full line of barium sulfate formulations tailored to user needs, while maintaining competitive pricing.

The CT and X-ray fluoroscopy procedures for which we provide products complement, as well as compete with, procedures such as colonoscopy and endoscopy. Such procedures involve direct visual inspection of the GI tract by a gastroenterologist using a flexible fiber optic instrument inserted into the patient. The use of gastroenterology procedures has been growing in both upper and lower GI examinations, as patients have been increasingly referred to gastroenterologists rather than radiologists. Also, the availability of drugs that successfully treat ulcers and other GI disorders has tended to reduce the need for upper GI tract X-ray examinations.

We also compete in the medical device radiology market, which is highly competitive. To our knowledge, no single company, domestic or foreign, competes with us across all of our medical device product lines. In electromechanical injectors and syringes, our main competitors are Medrad, a division of Schering AG, and Liebel-Flarsheim, a division of Mallinckrodt. In needles and trays, we compete with C.R. Bard, Inc., Baxter Healthcare Corporation, Sherwood Medical Co., as well as other competitors. We also encounter competition for our other medical device products.

Significant Customer

Sales to SourceOne Healthcare Technologies, Inc., a distributor of our products, accounted for 30% of our net sales for 2005.

Backlog

At July 31, 2005, we had a backlog of unfilled customer orders of $7,056,000, compared to a backlog of $5,089,000 at July 31, 2004. The backlog figures represent sales less estimated rebates. We expect all backlog at July 31, 2005 will be filled during fiscal 2006. The changes in backlog are not necessarily indicative of comparable variations in sales or earnings.

Raw Materials and Supplies

Most barium sulfate used in our X-ray fluoroscopy and CT imaging products is supplied by several European and U.S. manufacturers. A minor portion of our barium sulfate requirements is supplied by E-Z-EM Canada Inc., our wholly owned subsidiary, which operates a barium sulfate mine and processing facility in Nova Scotia and whose reserves are anticipated to last a minimum of five years at current usage rates. We believe that these sources should be adequate for our foreseeable needs.

We have generally been able to obtain adequate supplies of all raw materials and components for our business in a timely manner from existing sources. However, the inability to develop alternative sources, if required, or a reduction or interruption in supply, or a significant increase in the price of components, could adversely affect operations.

We recently received notice of price increases from several of our single-source processed barium suppliers. While this had no effect on the current year operating results, we estimate it will increase our material cost by approximately $0.8 million in 2006. We currently are evaluating various alternatives to mitigate this cost increase.

Patents and Trademarks

We believe that our success is dependent, in part, on patent protection and the proprietary nature of our technology. We file and prosecute patent applications for our technology in jurisdictions where we believe that patent protection is effective and advisable. Generally, for products that we believe are appropriate for patent protection, we attempt to obtain patents in the U.S., European Union and other appropriate jurisdictions.

Notwithstanding the foregoing, the patent positions of pharmaceutical and medical device companies, including our company, are uncertain and involve complex and evolving legal and factual questions. The coverage sought in a patent application can be denied or significantly reduced either before or after the patent is issued. Consequently, there can be no assurance that any of our pending or future patent applications will result in an issued patent. There is also no assurance that any existing or future patent will provide significant protection or commercial advantage, or whether any existing or future patent will be circumvented by a more basic patent, thus requiring us to obtain a license to produce and sell the product. Generally, patent applications can be maintained in secrecy for at least 18 months after their earliest priority date. In addition, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent the subject matter covered by each of our pending U.S. patent applications or that we were the first to file non-U.S. patent applications for such subject matter.

If a third party files a patent application relating to an invention claimed in our patent application, we may be required to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine who owns the patent. Such proceeding could involve substantial uncertainties and cost, even if the eventual outcome is favorable to us. There can be no assurance that our patents, if issued, would be upheld as valid in court.

Third parties may claim that our products infringe on their patents and other intellectual property rights. The pharmaceutical and medical device industries are highly competitive and companies in these areas may have large patent portfolios. Some companies in the medical device industry have used intellectual property infringement litigation to gain a competitive advantage. If a competitor were to challenge our patents, licenses or other intellectual property rights, or assert that our products infringe its patent or other intellectual property rights, we could incur substantial litigation costs, be forced to stop selling our products and/or make expensive changes to our product designs, license rights in order to continue manufacturing and selling our products, or pay substantial damages. Third-party infringement claims, regardless of their outcome, would not only consume our financial resources but also divert our management s time and effort. Such claims could also cause our customers or potential customers to defer or limit their purchase or use of the affected products until resolution of the claim.

We rely on trade secret protection for certain unpatented aspects of other proprietary technology. There can be no assurance that others will not independently develop or otherwise acquire substantially equivalent proprietary information or techniques or gain access to our proprietary technology or disclose such technology, or that we can meaningfully protect our trade secrets. We require key employees and consultants to execute confidentiality agreements upon the commencement of an employment or consulting relationship with us. These agreements also require our employees and, generally, our consultants to assign to us all rights to any inventions made or conceived during their employment with or engagement by us. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for us in the event of unauthorized use, transfer or disclosure of confidential information or inventions.

We believe that a good trademark can help establish brand recognition and awareness for our company and our products. We file and prosecute trademark applications in jurisdictions where we believe that registered trademark protection is effective and advisable. We have registered numerous trademarks in the U.S. and certain foreign jurisdictions. Because the registration of trademarks in the U.S. and foreign countries can be expensive, we also rely on common law protection for certain trademarks.

The laws of foreign countries generally do not protect our proprietary rights to the same extent, as do the laws of the U.S. In addition, we may experience more difficulty enforcing our proprietary rights in certain foreign jurisdictions.

Government Regulation

The products we manufacture and market are subject to regulation by the U.S. Food and Drug Administration, or FDA, and, in some instances, state authorities and foreign governments.

U.S. Regulation

In the U.S., before a pharmaceutical or medical device product can be introduced into the market, a manufacturer must, depending on the product, either register the product with the FDA or obtain clearance or approval from the FDA.

We manufacture and market both pharmaceutical products and medical devices. Our pharmaceutical products, such as contrast agents used in X-ray fluoroscopy and CT imaging procedures, are registered with the FDA. Our medical devices have been cleared and approved by the FDA.

The FDA clearance and approval processes for pharmaceuticals and medical devices are expensive, uncertain and lengthy, and a number of products for which approval or clearance has been sought by other companies have never been approved for marketing. There can be no assurance that we will be able to obtain necessary regulatory clearances or approvals for any future products on a timely basis or at all. Delays in receipt of or failure to receive such clearances or approvals, the loss of previously received clearances or approvals, or the failure to comply with existing or future regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

If and when FDA marketing clearance or approvals are granted for a drug or device, the products and their manufacture are subject to pervasive and continuing regulation by the FDA, including Current Good Manufacturing Practices (CGMP), record keeping requirements and the MedWatch and Medical

Device Reporting regulation, which requires that manufacturers report to the FDA if their drug or device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur. The labeling and promotion activities with respect to products are subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. The FDA actively enforces regulations prohibiting marketing of drugs and devices for unapproved new indications or uses.

The products we manufacture are subject to the FDA s Quality System Regulations. Drug and device manufacturers are required to register and list their facilities with the FDA and certain state agencies. Every phase of production, including raw materials, components and subassemblies, manufacturing, testing, quality control, labeling, traceability after distribution, and follow-up and reporting of complaint information is governed by FDA regulations. The FDA periodically conducts inspections of manufacturing facilities and, if there are alleged violations, the operator of a facility must correct them or satisfactorily demonstrate the absence of the violations or face regulatory action.

In 2005, we had two unrelated product recalls. The first was due to the incomplete or inadequate joint weld on a ceiling mount used with our Empower CT injector. This recall is 95% complete and pending final closure by the FDA.

The second incident involved the recall of Evacupaste. This product is manufactured for us by Mallinckrodt, a division of Tyco International Ltd, and was part of the overall recall of their liquid barium products in December 2004. The Evacupaste recall is about 70% complete with closure expected in the next several months.

We are subject to inspection and marketing surveillance by the FDA to determine our compliance with regulatory requirements. Non-compliance with applicable FDA requirements can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the FDA to grant marketing approvals, withdrawal of marketing approvals, a recommendation by the FDA to disallow us to enter into government contracts, and criminal prosecutions. The FDA also has the authority to request repair, replacement or refund of the cost of any device manufactured or distributed by us.

We believe that we are in compliance, in all material respects, with all applicable FDA regulatory requirements for our products.

Non-U.S. Regulation

Internationally, our products have been registered and approved in each foreign country where such registration and approval is required to market and sell our products. Some of the regulatory requirements in foreign countries are similar to those in the U.S. for product approval and maintenance of such approval. However, the regulatory review process may vary greatly from country to country.

In some cases, we rely on our non-U.S. distributors to obtain registration and approval for our products in a particular foreign jurisdiction.

Non-U.S. sales of pharmaceuticals and medical devices manufactured in the U.S. that are not approved or cleared by the FDA for use in the U.S., or are banned or deviate from lawful performance standards, are subject to FDA export requirements. Before exporting such products to a foreign country, we must first comply with the FDA s regulatory procedures.

We believe that we are in compliance, in all material respects, with all applicable regulatory requirements in those countries where our products are sold.

Other

We are subject to various Federal and state laws governing our relationships with the physicians and others who purchase or make referrals for our products. For instance, Federal law prohibits payments of any form that are intended to induce a referral for any item payable under Medicare, Medicaid or any other Federal healthcare program. Many states have similar laws. There can be no assurance that we will not be required to incur significant costs to comply with such laws and regulations now or in the future or that such laws or regulations will not have a material adverse effect on our ability to do business.

We received International Standards Organization (ISO) 9001 and 13485 certification in January 2005 of our facility in Montreal, Canada. Our facility in Westbury, NY is also certified as compliant with these standards.

Environmental and other Regulations

We and our products are also subject to a variety of state and local laws in those jurisdictions where our products are or will be marketed, and Federal, state and local laws relating to matters such as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. For example, we are registered with the New York State Board of Pharmacy. These include laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emissions, effluent discharge, handling and disposal of certain hazardous and potentially hazardous substances used in connection with our operations. Although we believe that we have complied with these laws and regulations in all material respects and to date have not been required to take any action to correct any noncompliance, there can be no assurance that we will not be required to incur significant costs to comply with environmental regulations in the future.

We operate several facilities within a broad industrial area located in Nassau County, New York, which has been designated by New York State as a Superfund site. This industrial area has been listed as an inactive hazardous waste site due to ground water investigations conducted on Long Island during the 1980 s. Due to the broad area of the designated site, the potential number of responsible parties, and the lack of information concerning the degree of contamination and potential clean-up costs, it is not possible to estimate what, if any, liability we may have. Further, it has not been alleged that we contributed to the contamination, and it is our belief that we have not done so.

Employees

As of May 28, 2005, we employed 553 persons, 153 of whom were covered by various collective bargaining agreements. Collective bargaining agreements covering 26 and 125 employees expire in December 2005 and December 2010, respectively. A third collective bargaining agreement, covering 2 employees, automatically renews every May. We consider employee relations to be satisfactory.

(d) **Financial Information Regarding Foreign and Domestic Operations and Export Sales**

We derived about 35% of our sales for 2005 from customers outside the U.S. Profit margins on export sales are somewhat lower than domestic sales margins. Our domestic operations bill third-party export sales in U.S. dollars and, therefore, do not incur foreign currency transaction gains or losses. Third-party sales to local customers, which are made by our subsidiaries in Canada, the United Kingdom, Holland and Japan, are billed in their local currency.

As of May 28, 2005, 358 of our employees are involved in the developing, manufacturing and marketing of our products outside of the U.S. Of this amount, 268 employees are based at our Canadian subsidiary supporting most of our worldwide manufacturing requirements. Our product lines are marketed through approximately 137 foreign distributors to 87 countries outside of the U.S.

The net sales of each geographic area and the long-lived assets attributable to each geographic area are set forth in Note R to the Consolidated Financial Statements included elsewhere in this annual report on Form 10-K, which information is incorporated by reference into this Item 1 (d).

Item 2. **Properties**

Our global headquarters, located in Lake Success, New York, consist of leased offices aggregating 25,608 square feet. We also occupy two facilities located in Westbury, New York, of which we own one and lease the other, containing an aggregate of 163,800 square feet used for manufacturing, warehousing and administration. We entered into an agreement to sell our Company-owned facility in Westbury, subject to certain conditions to closing. We also occupy manufacturing and warehousing facilities located in Montreal, Canada consisting of two buildings, of which we own one and lease the other, containing an aggregate of 140,544 square feet. We also own a 29,120 square-foot building in Debert, Nova Scotia and both own and lease land encompassing our barium sulfate mining operation in Nova Scotia.

Item 3. **Legal Proceedings**

We were named as a co-defendant in an action entitled Jeffrey Madison d/b/a Maqguide.com vs. Avail Medical Products, Inc. et al., Case No. 05CC03584 filed in Superior Court for the State of California, Orange County, on February 28, 2005. The complaint alleges that in March 2003, we sought a contract manufacturer to manufacture and supply certain medical products and, acting through our agent, Sopheon Corporation, solicited Maqguide to assist in this process. Acting on this information, Maqguide contacted Avail Medical Products, Inc., or Avail, about this opportunity and helped negotiate a final agreement between us and Avail. The complaint alleges that Maqguide had an agreement with Avail that required Avail to pay a commission to Maqguide upon the execution of the agreement with us. The complaint alleges 18 causes of action against all of the defendants, including breach of contract, breach of the covenant of good faith, quantum meruit, fraud and deceit, promissory estoppel, conspiracy and conversion. The complaint seeks compensatory, punitive and other monetary damages in an unspecified amount in excess of $25,000. We have tendered the case to Avail s counsel. We will defend this matter and believe that the allegations against us are without merit and intend to vigorously defend this action.

AngioDynamics and E-Z-EM were named as co-defendants in an action entitled Duhon, et. al vs. Brezoria Kidney Center, Inc. et. al, case no. 27084 filed in the District Court of Brezoria County, Texas, 239th Judicial District on December 29, 2003. The complaint alleged that AngioDynamics and its co-defendants, E-Z-EM and Medical Components, Inc. or Medcomp, designed, manufactured, sold, distributed and marketed a defective catheter that was used in the treatment of, and caused the death of, a hemodialysis patient, as well as committed other negligent acts. The complaint sought compensatory and other monetary damages in unspecified amounts. Under AngioDynamics distribution agreement with Medcomp, Medcomp was required to indemnify AngioDynamics against all its costs and expenses, as well as losses, liabilities and expenses (including reasonable attorneys fees) that relate in any way to products covered by the agreement, and Medcomp has accepted the defense of the action. We have been advised by counsel that the matter was settled on June 30, 2005 and that the action will be dismissed with prejudice. We believe that Medcomp has a sufficient amount of insurance coverage and funds available to fully cover the settlement of this action and, based upon our agreement with Medcomp, we do not expect that either we or AngioDynamics will be required to contribute to the settlement of this matter.

In accordance with the Master Separation and Distribution Agreement between AngioDynamics and E-Z-EM, AngioDynamics has agreed to indemnify us from any claims that arise out of the business operations of AngioDynamics prior to its spin-off (October 30, 2004) in which we are a named defendant solely because we were the sole stockholder of AngioDynamics.

We are party to other claims, legal actions and complaints that arise in the ordinary course of our business. We believe 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 our financial position or results of operations.

Item 4. **Submission of Matters to a Vote of Security Holders**

None.

Part II

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

Effective April 12, 2005, our common stock began trading on the Nasdaq National Market under the symbol EZEM . Previously, our common stock was traded on the American Stock Exchange (AMEX) under the symbol EZM . The following table sets forth, for the periods indicated, the high and low sales prices of the common stock as reported by the AMEX (through April 11, 2005) and the Nasdaq National Market (from April 12, 2005 through May 28, 2005).

	Sales Prices	
	High	**Low**
Fifty-two weeks ended May 28, 2005		
Fourth Quarter	$ 14.84	$ 11.31
Third Quarter	15.58	12.25
Second Quarter (1)	21.45	10.76
First Quarter	19.94	13.50
Fifty-two weeks ended May 29, 2004		
Fourth Quarter	$ 20.65	$ 14.52
Third Quarter	21.50	11.45
Second Quarter	14.95	10.38
First Quarter	11.90	8.11

(1) During the second quarter, we completed the spin-off of our subsidiary, AngioDynamics, Inc., to our shareholders by means of a tax-free distribution.

As of August 1, 2005 there were 385 registered holders of our common stock. This number of registered holders does not represent the actual number of beneficial owners of shares of our common stock because shares are frequently held in street name by securities dealers and others for the benefit of individual owners who have the right to vote their shares.

During the first quarter of fiscal 2004, our Board of Directors declared a cash dividend on our common stock at the rate of $.25 per share. During the first quarter of fiscal 2005, the Board of Directors declared a cash dividend on our common stock at the rate of $.30 per share. We will continue to evaluate our dividend policy on an ongoing basis. Any future dividends are subject to our Board of Directors review of operations and financial and other conditions then prevailing.

Equity Compensation Plan Information

The following table sets forth information, as of May 28, 2005, with respect to compensation plans under which our equity securities are authorized for issuance.

Plan category	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	959,888	$ 10.32	565,570 (1)
Equity compensation plans not approved by security holders	None	None	None
Total	959,888	$ 10.32	565,570

(1) Consists of 460,925 shares reserved for issuance under our 2004 Stock and Incentive Award Plan and 104,645 shares reserved for issuance under our 1985 Employee Stock Purchase Plan.

Issuer Purchases of Equity Securities

The following table presents information regarding repurchases of our common stock during the quarter ended May 28, 2005:

Period	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly announced plans or programs	Maximum number of shares that may yet be purchased under the plans or programs
	(a)	(b)	(c)	(d)
2/27/05 4/2/05				
4/3/05 4/30/05	2,917(1)	$ 12.94		
5/1/05 5/28/05				
Total	2,917	$ 12.94		

(1) Our repurchase of these shares was in settlement of tax withholding obligations of an employee from the exercise of stock options.

In March 2003, our Board of Directors authorized the repurchase of up to 300,000 shares of our common stock at an aggregate purchase price of up to $3,000,000. During the fiscal year ended May 28, 2005, no shares were repurchased under this program. In aggregate, we have repurchased 74,234 shares of common stock for approximately $716,000 under this program.

Item 6. **Selected Financial Data**

You should read the following selected financial data in conjunction with our consolidated financial statements and the related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this report. The consolidated statements of earnings data for the fifty-two weeks ended May 28, 2005, May 29, 2004 and May 31, 2003, and the consolidated balance sheet data as of May 28, 2005 and May 29, 2004, are derived from our audited consolidated financial statements that are included elsewhere in this report. The consolidated statements of earnings data for the fifty-two weeks ended June 1, 2002 and June 2, 2001, and the consolidated balance sheet data as of May 31, 2003, June 1, 2002 and June 2, 2001, are derived from our audited consolidated financial statements not included in the report. Historical results are not necessarily indicative of the results of operations to be expected for future periods. See Note A of Notes to Financial Statements for a description of the method that we used to compute our historical basic and diluted earnings per common share.

	Fifty-two weeks ended				
	May 28, 2005	**May 29, 2004***	**May 31, 2003***	**June 1, 2002***	**June 2, 2001***
	(in thousands, except per share data)				
Income statement data:					
Net sales	$ 113,075	$ 100,609	$ 95,683	$ 92,288	$ 90,610
Gross profit	48,036	40,057	37,887	35,786	34,770
Operating profit (loss)	3,453	2,099	544	(425)	3,865
Earnings from continuing operations before income taxes	6,559	5,542	1,936	919	4,858
Earnings (loss) from continuing operations	5,708	3,598	1,508	(366)	2,993
Net earnings	6,936	6,726	2,741	585	3,286
Earnings (loss) from continuing operations per common share					
Basic	.53	.35	.15	(.04)	.30
Diluted	.52	.34	.14	(.04)	.30
Earnings per common share					
Basic	.64	.65	.27	.06	.33
Diluted	.63	.63	.26	.06	.32
Cash dividends declared per common share	.30	.25	.00	.00	.00
Weighted average common shares					
Basic	10,762	10,344	10,048	9,848	9,881
Diluted	10,951	10,625	10,419	10,160	10,145